Interoperable
Remote Health
Innovation
Brought to Scale

Deliverable 1.1
Mapping of Remote Care Innovation Recommendations to Stakeholders

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Contents

ABBREVIATIONS

AI	Artificial Intelligence
ARCI	Advanced Remote Care Innovations
CE	Conformité Européenne
CIED	Cardiac Implantable Electronic Device
DIH	Digital Innovation Hub
DiGA	Digitale Gesundheitsanwendungen
DMN	Digital Medical Device
DTx	Digital Therapeutics
ECG	Electrocardiogram
EHDS	European Health Data Space
EHR	Electronic Health Record
EPSI	European Platform for Sport Innovation
ERDF	European Regional Development Fund
ESF+	European Social Fund Plus
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
HL7	Health Level 7
ICT	Information and Communication Technology
ICU	Intensive Care Unit
IoT	Internet of Things
IVDR	In Vitro Diagnostic Medical Devices Regulation
I3	Interregional Innovation Investments
LDRs	Less Developed Regions
MDRs	More Developed Regions
MDR	Medical Device Regulation
NHIF	National Health Insurance Fund
NHIS	National Health Information System
PECAN	Prise en Charge Anticipée Numérique
R&D	Research and Development

RIS3	Research and Innovation Smart Specialisation Strategy
RIS4	Research and Innovation Smart Sustainable Specialisation Strategy
RPM	Remote Patient Monitoring
RTO	Research and Technology Organisation
RRF	Resilience and Recovery Facility
QES	Qualified Electronic Signatures
S3	Smart Specialisation Strategy
SME	Small and Medium-sized Enterprise
U.A.E.	United Arab Emirates
U.S.	United States

EXECUTIVE SUMMARY

Remote care technologies, particularly Remote Patient Monitoring (RPM), have demonstrated transformative potential in managing chronic diseases, supporting elderly care, and improving healthcare system efficiency. These solutions leverage wearables, implantable sensors, AI-powered platforms, and teleconsultation tools to ensure continuous, patient-centered care. Their relevance has been amplified in the post-pandemic era, where healthcare systems seek sustainable, digitally enabled models of service delivery.

However, adoption across the European Union (EU) remains uneven. While countries like Germany, France, and Sweden have established robust frameworks for digital health reimbursement and innovation scaling, Less Developed Regions (LDRs) such as in Bulgaria, Greece, Spain, Portugal and Lithuania often face structural, regulatory, and financial barriers. These include fragmented legal frameworks, underdeveloped digital infrastructure, inconsistent interoperability standards, limited public funding for RPM deployment, and a lack of strategic alignment between national health policies and Research and Innovation Smart Specialisation Strategy (S3 / RIS3).

This deliverable presents a **comprehensive mapping of RPM and remote care innovations across Europe, developed under the framework of the IRHIS project**. The report provides a multi-dimensional overview of the current state of remote healthcare delivery, with an emphasis on understanding regional disparities and identifying actionable pathways to scale innovation, especially in LDRs. In addition, it consolidates findings from desk and field research conducted across seven member states. It maps out key actors, accelerators, corporates, research centers, projects, strategic initiatives and networks that are catalyzing innovation in the remote care ecosystem. It identifies enabling and challenging factors for the scaling up of RPM technologies and proposes recommendations for facilitating the penetration of those technologies within the national ecosystems.

Key findings include:

- The RPM innovation ecosystem is more mature in More Developed Regions (MDRs) due to stronger infrastructure, clearer regulatory frameworks, and access to venture capital.
- LDRs show promising innovation potential, but scaling remains limited due to unclear reimbursement pathways, siloed data systems, and low digital health literacy.

- National and EU policy misalignment, especially regarding certification, Artificial Intelligence (AI) regulation, and reimbursement, continues to hinder market access for health tech innovators.

To address these challenges and enable the successful scaling of RPM technologies, the report outlines **strategic recommendations to EU and national stakeholders**:

- **Develop clear and aligned regulatory frameworks**, harmonized with EU legislation, to streamline certification and cross-border scalability of remote care services.
- **Design and implement sustainable reimbursement models** that recognize the clinical and economic value of digital therapeutics, telemonitoring, and AI-assisted diagnostics.
- **Strengthen interoperability, cybersecurity and digital infrastructure**, particularly in underserved regions, by enforcing technical standards such as Fast Healthcare Interoperability Resources by Health Level 7 (HL7 FHIR) and investing in cybersecurity and system connectivity.
- **Invest in digital skills and professional training** to ensure that healthcare professionals are equipped to deploy and manage digital health tools effectively.
- **Support innovation with structured, scalable funding**, spanning from Research and Development (R&D) to commercialization, through blended financial instruments that combine public and private capital.
- **Promote ecosystem collaboration and co-creation** by facilitating partnerships between startups, public health institutions, municipalities, and universities through regional innovation hubs.
- **Embed user-centered design and real-world evidence generation**, ensuring RPM tools are clinically relevant, user-friendly, and supported by real-world data.
- **Monitor implementation and promote continuous improvement** via national observatories and feedback loops to inform adaptive policymaking and innovation management.

1. Introduction

1.1 Purpose of the Deliverable

The present report provides **a structured and in-depth mapping of remote care innovations across the EU**, with a particular emphasis on Transition Regions in the countries of Belgium, and Netherlands, and in LDRs in the countries of Bulgaria, Lithuania, Greece, Spain and Portugal. Developed within the framework of the IRHIS project, this report seeks to support stakeholders and policymakers by offering **clear, evidence-based recommendations for enhancing the adoption, implementation, and scaling of RPM technologies and telehealth solutions**. By compiling data from both desk research and stakeholder interviews, this deliverable identifies key actors in EU, emerging trends, S3 / RIS3, and regulatory conditions that shape the remote care ecosystem.

The overarching objective is to demonstrate the **current levels of effectiveness, acceptability, and accessibility of remote healthcare services across Europe**. In particular, the deliverable highlights innovations in priority areas including musculoskeletal rehabilitation, neurological disorders, and critical care conditions. It aims to inform strategic investments, foster cross-regional learning, improve the acceptability and deployment efficiency for the sustainable growth of remote care services and innovations.

1.2 The IRHIS project

The three-year EU project **"IRHIS – Interoperable Remote Health Innovation brought to Scale"** (Grant Agreement No. 101160941), funded under the Interregional Innovation Investments (I3) Instrument, brings together 21 partners from 13 European regions with the shared objective of accelerating the scale-up of advanced remote care technologies, particularly in LDRs. The central objective of IRHIS is to establish the first EU-wide **Advanced Remote Care Demonstration Chain**. The project supports the demonstration and commercialization of eight AI-powered medical technologies developed by EU-based MedTech Small and Medium-sized Enterprises (SMEs), focusing on three critical areas of remote care: **musculoskeletal rehabilitation**, **neurological disorder treatment**, and **critical patient care in intensive care unit (ICU) settings**. These solutions include wearable monitoring devices, sensor-integrated platforms, and decision-support systems underpinned by AI and machine learning.

To achieve this, IRHIS designs and implements three **Interregional DemoScale Labs**. These labs will provide a structured environment for iterative, real-world validation of emerging

technologies, engaging over 1,000 patients in continuous testing over a two-year period. This multi-regional approach aims to ensure clinical relevance, cross-border applicability, and a faster path to market adoption for innovative remote care tools.

Beyond technology validation, IRHIS places strong emphasis on **strengthening the broader remote health innovation ecosystem**. The project facilitates alignment with national and regional S3 / RIS3, supports regulatory harmonization, and fosters collaboration between startups, healthcare providers, research institutions, and policymakers. It will also establish the Remote Care Investment Club to attract funding, improve market access, and create cross-border synergies for MedTech innovators.

1.3 Remote Care and RPM Solutions in EU Regions

The increasing digitalization of healthcare across the EU has opened new frontiers for care delivery, particularly through RPM and broader remote care innovations. RPM refers to the **use of digital technologies that allow healthcare providers to monitor patients' health conditions, physiological data, and treatment adherence remotely**. These systems integrate wearable and implantable devices, cloud-based platforms, and teleconsultation tools to enable proactive, continuous, and patient-centered care beyond traditional clinical environments.

As part of the broader eHealth ecosystem, RPM combines **telemonitoring with teleconsultation**, facilitating a seamless flow of health information between patients and providers. This approach allows for more timely interventions, promotes self-management, and reduces unnecessary clinical visits, thereby improving health outcomes and optimizing system efficiency. The COVID-19 pandemic underscored the critical importance of remote care by accelerating adoption and demonstrating the potential of RPM in ensuring continuity of care under constrained conditions. According to MedTech Europe [1], RPM technologies significantly **improve access to care, treatment adherence, and health outcomes**, particularly for chronic conditions such as cardiovascular disease, diabetes, chronic kidney disease, and musculoskeletal disorders. By enabling earlier clinical intervention and reducing hospital admissions, RPM contributes to healthcare system sustainability, especially when implemented in aging populations and remote or underserved areas.

Technological innovation used in RPM

RPM solutions encompass a **broad range of digital interconnected tools that collect and transmit data from patients** [1], including:

- **Stand-alone medical measuring devices** such as wearable patches, smartwatches, and textiles that monitor sleep patterns, body temperature, electrocardiogram (ECG), glucose levels, or posture.
- **External monitoring tools** like pulse oximeters and heart rate monitors also fall under this category.
- **Implantable devices**, such as Cardiac Implantable Electronic Devices (CIEDs) and continuous glucose monitoring systems, offer continuous physiological data to support the management of complex chronic conditions like arrhythmias and diabetes. These data streams are typically integrated into digital platforms or health apps that allow for 24/7 structured consultations and remote diagnostics, enhancing real-time clinical decision-making and patient engagement.

EU regulatory framework relevant to RPM

The manufacturers of RPM solutions need to comply with several EU regulatory frameworks governing e.g. the medical devices and health data processing procedures [2]. They also must follow the relevant national legislation (e.g. on organisation and delivery of health services). Some of the most relevant EU regulations concerning product harmonisation, data governance and cybersecurity are the following:

- Regulation (EU) 2017/745 on medical devices - Medical Device Regulation (MDR) [3]
- Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) [4]
- Regulation (EU) 2024/1689 on AI (AI Act) [5]
- Regulation (EU) 2016/679 on General Data Protection Regulation (GDPR) [6]
- Regulation (EU) 2022/868 on Data Governance Act (DGA) [7]
- Regulation (EU) 2023/2854 on Data Act [8]
- Regulation (EU) 2025/327 on European Health Data Space (EHDS) [9]
- Regulation (EU) 2019/881 on Cybersecurity Act [10]

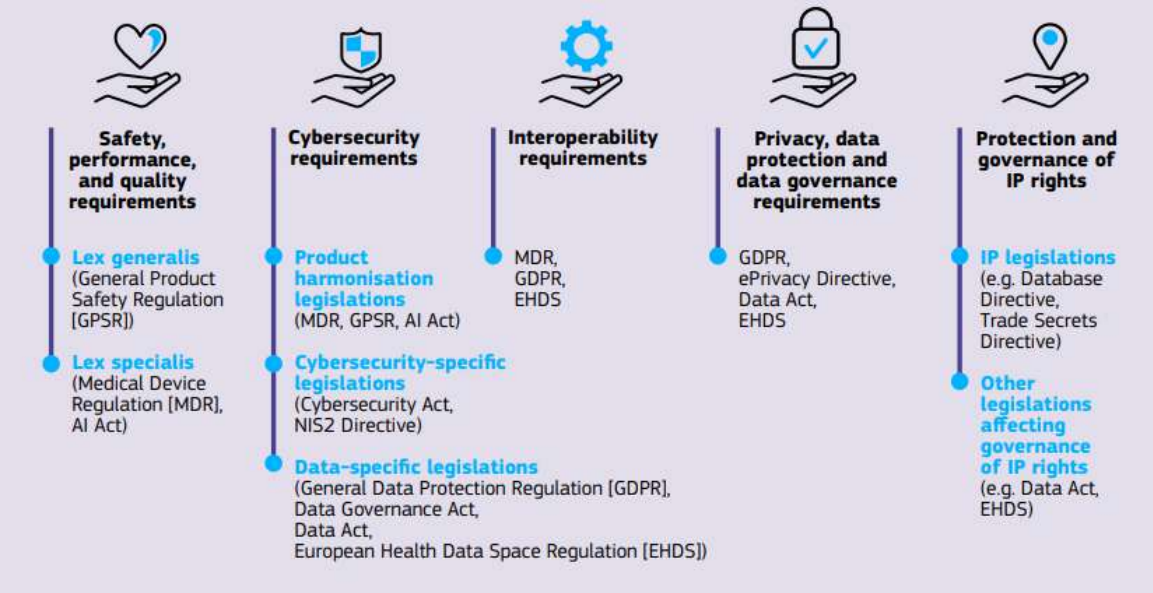

Figure 1. EU regulatory framework applicable to wearable medical devices [2]

Regional implementation of RPM

Despite the promise of RPM, its implementation across Europe remains uneven. **Substantial disparities exist** between MDRs, Transition and LDRs. Under the EU Cohesion Policy framework for 2021–2027, LDRs are eligible for targeted support via the European Regional Development Fund (ERDF) and the European Social Fund Plus (ESF+) [11]. These instruments aim to reduce gaps in digital infrastructure, innovation capacity, and healthcare system resilience. The resources from the ERDF and ESF+ are allocated among the following three categories of NUTS level 2 regions [12]:

a. LDRs, whose Gross Domestic Product (GDP) per capita is less than 75 % of the average GDP per capita of the EU-27;
b. Transition Regions, whose GDP per capita is between 75 % and 100 % of the average GDP per capita of the EU-27;
c. MDRs, whose GDP per capita is above 100 % of the average GDP per capita of the EU-27.

LDRs face a range of **structural barriers** that limit their ability to deploy and scale RPM technologies. These include limited broadband coverage, fragmented or underdeveloped Electronic Health Record (EHR) systems, low digital literacy among healthcare providers and patients, and a general lack of clear reimbursement mechanisms for digital health services.

Consequently, while RPM can enhance equity and efficiency in healthcare delivery, these regions are not yet fully equipped to realize its benefits at scale.

To address this gap, European strategies increasingly emphasize the need to scale and adapt proven RPM models within LDR contexts. The European Commission's initiatives such as EU4Health, Digital Europe, and the RRF aim to build robust digital health infrastructures, upskill healthcare professionals, and create innovation-friendly ecosystems across all Member States.

2. Methodology

2.1 Objectives

This document compiles the results of desk and field research conducted across various EU regions, encompassing both MDRs and Transition Regions such as Belgium and the Netherlands, as well as LDRs in Bulgaria, Greece, Lithuania, Spain, and Portugal. The goal was to provide a clear and comprehensive overview of the state of advanced remote care innovations across these areas, with particular attention to current trends, key actors, and barriers to implementation.

The **specific objectives** of this study were as follows:

a) To create a **consolidated mapping of the existing landscape of advanced remote care innovations across the EU**. This includes identifying key initiatives and stakeholders including EU Leading Initiatives, Key Projects, Entities and Accelerators; Start-Ups; Research Centres and Research and Technology Organisations (RTOs); EU Networks, Clusters and Digital Innovation Hubs (DIHs); Policy Makers and Venture Funds.

b) To identify the **relevant S3 / RIS3** and examine the existing regulatory and legislative frameworks influencing remote care innovations. The study also aims to assess the current limitations and challenges posed by these frameworks across the targeted EU regions.

c) To map **key projects and** initiatives in LDRs and to present a detailed roadmap of major innovations. This includes an assessment of their current development stage, their level of acceptability among national healthcare systems (both from patients and professionals), and their specific domain or area of specialisation.

d) To highlight **the capacities, opportunities, challenges, and barriers** associated with the development and implementation of advanced remote care technologies across the EU. This encompasses both technical and systemic aspects that affect the scalability and integration of such solutions.

e) To provide **actionable recommendations** to stakeholders and policymakers. These suggestions aim to improve the acceptance and deployment efficiency of remote care innovations and to foster a more supportive environment for their growth.

Although the mapping broadly addresses remote care innovations, the research paid particular attention to the **priority care areas** defined within the IRHIS DemoScale Lab Conditions - **musculoskeletal rehabilitation, neurological disorder treatment and ICU**. Where relevant, it also considered condition-specific innovations in areas such as heart failure, sleep apnoea, musculoskeletal disorders, chronic respiratory diseases, chronic kidney disease, and diabetes.

2.2 Analytical Approach

The process to explore the emerging ecosystem of advanced remote care across EU regions combined **desk and field research**. The desk research included a mapping of EU Leading Initiatives, Key Projects, Entities and Accelerators; Start-Ups; Research Centres and RTOs; EU Networks, Clusters and DIHs; Policy Makers and Venture Funds (See Annex A). A common template was created for the overview of the S3 / RIS3.

To explore the capacities, opportunities, challenges, and barriers associated with the development and implementation of advanced remote care technologies across the EU, we conducted stakeholder interviews. For the interviews, the consortium followed a common **data collection instrument** (See Annex B), which was included in the stakeholders' interview guidelines. The interviews questionnaire was based on 15 questions split on the following 4 thematic axes to gain a comprehensive understanding of the i) current landscape, ii) challenges, iii) opportunities in RPM solutions and iv) recommendations for stakeholders.

Based on the data collection, this document includes an **overview of the RPM Landscape in EU** and **consolidated Country Profiles of Belgium, Netherlands, Bulgaria, Greece, Lithuania, Spain, and Portugal**. Each Country Profile includes a RPM Ecosystem Canvas, a National S3 / RIS3 Overview, Insights from Key Stakeholders about National Regulation & Legislation Framing of Remote Care, the pathway to the market of Advanced Remote Care Innovations, the barriers, challenges and limitations in the RPM landscape and

Recommendations at National and EU level. The consortium followed the Delphi method using expert panel's interactive discussion and collective judgments to conclude to this structure of the content.

2.3 Research Participants' Selection

The research focused on stakeholders who are either shaping, delivering, or regulating remote care and telemonitoring services in their respective regions. The criteria to participate at the interview was their **knowledge of local RPM and health innovation systems**. Particular attention was paid to ensuring diversity in institutional representation and regional contexts. The interviews were conducted from February to March 2025, virtually, depending on interviewees' availability. All interviews followed ethical research standards, including informed consent and the anonymization of responses.

Twenty-two (22) interviews were conducted with representatives of the national and EU industry sector including R&D entities, SMEs, Medtech and healthcare clusters; representatives of public and private healthcare providers including hospitals, clinics and departments; representatives of Academia and RTOs; representatives of governmental organisations and EU or National-Level Networks. See Table 1 for the full participant's profile[1].

Table 1. Participants Characteristics (N=22)

Characteristics	**N=22**
Gender	
Male	12
Female	10
Other	0
Place of Operation	
Belgium	3
Bulgaria	4
Denmark	1
Greece	3
Lithuania	5
Portugal	1
Spain	3
Netherlands	1
EU	1

[1] **Note:** All interviewees provided informed consent prior to participation. In accordance with ethical guidelines and data protection regulations, all personally identifiable information—including names, organizations, and other sensitive data—remains confidential and is securely managed under the exclusive control of the IRHIS consortium. Only aggregated, anonymized data is presented in this deliverable.

Years of experience	
1–10 years	4
10–20 years	11
20 + years	7
Type of Organisation	
Healthcare Providers including hospitals, public health departments	3
Industry including R&D entities, SMEs, Medtech/healthcare clusters	11
Academia including academics and researchers	4
Governmental organisations	4
Occupation	
CEO	7
Head of Department/ Director	6
Digital Health Facilitator/Advisor	5
Academic	4

3. Remote Care Innovation Landscape in EU

Remote care innovation across European regions varies considerably, shaped by national healthcare strategies, funding mechanisms, regulatory maturity, and digital readiness. The mapping demonstrates key initiatives and stakeholders including EU Leading Initiatives, Key Projects, Entities and Accelerators, Start-Ups, Research Centres and RTOs, EU Networks, Clusters and DIHs, Policy Makers and Venture Funds. Notably, significant disparities exist among MDRs, Transition Regions, and LDRs, reflecting differing levels of infrastructure, investment, and policy support.

3.1 Good practices in EU Level

European countries follow diverse paths regarding remote care innovation and adoption of digital health care solutions within health systems. Multiple factors determine these paths, including pricing, reimbursement and innovation ecosystems [13]. The cases of three European countries that can be considered as good practices are presented below:

Germany

Germany stands out as a **pioneering example in the digital health applications reimbursement action in Europe**. Digital health apps that have undergone a formalised process of post market evaluation are added to the benefit catalogue of the German statutory health insurance.

In 2019, the German Digital Healthcare Act introduced a new approach to market access for reliable and safe digital health applications. The legislation aimed to **approve digital solutions (Digitale Gesundheitsanwendungen, DiGA) with significant clinical benefits** [14]. The applications that meet the requirements related to safety, functionality, quality, data protection, data security and interoperability, are eligible for regulatory review and entry into a DiGA Directory maintained by the German Federal Agency for Drugs and Medical Devices (BfArM). Since then, digital therapies have become a new form of medicine called digital therapeutics (DTx). DTx can now be prescribed by German doctors and reimbursed by public payers, similarly to traditional medications and treatments.

Moreover, the German state offers **tax-based incentives** in order to support R&D efforts. For instance, since 2020 the research tax allowance (steuerliche Forschungszulage) is available to companies of all sizes in Germany. Under the Research Allowance Act (Forschungszulagengesetz, FZulG), companies can receive tax breaks of up to €3.5 million if

they invest in research and development – regardless of whether the company is currently making a profit or not.

France

France is one of the most advanced countries in Europe for med tech and digital health products reimbursement. Moreover, its **national investment plans** [15] aim at boosting eHealth innovation, including financial incentives and regulatory support for startups and SMEs.

PECAN (Prise en Charge Anticipée Numérique) is a French equivalent to the German DiGA Fast Track, launched in April 2023 [16]. Pecan aims to facilitate rapid patient access to innovative solutions, while maintaining high standards of evidence and safety. Unlike the German DiGA, which is limited to lower risk classes, the French system is **open to all classes of medical devices** (I, IIa, IIb, III). In addition to **DTx,** Pecan also allows for accelerated reimbursement of telemedicine solutions such as digital medical devices (DMNs) for remote monitoring systems. The PECAN reimbursement scheme aims to **reimburse DTx and DMNs in a fast-track model**. The developers of applicable DTx should submit evidence on interoperability and safety. Solutions are first examined by the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) and Digital Health Agency (ANS), and after validation by them, the French Ministry of Health makes the final decision. Early access to reimbursement for digital devices covers up to 12 months. After the initial 12-month period, the provider must deliver evidence of clinical benefit for the solution to enter the reimbursement scheme permanently. Under PECAN, financial compensation for digital therapy (DTx) can reach up to €780/patient/year [17].

Additionally, the French experimental program **ETAPES** was launched in 2014 which focused on the development of telemonitoring approaches in 5 health specialties: heart failure, kidney failure, respiratory failure, diabetes, and implantable cardiac devices. The telemonitoring experiments for five pathologies continued under the ETAPES program until August 1, 2022.

Sweden

Sweden represents a leading model in Europe for integrating digital health, precision medicine, and data-driven innovation into its regional development strategies. Regarding the remuneration of digital health care, the Swedish Association of Local Authorities and Regions (SALAR) provides recommendations to the regions on common reimbursement levels for digital healthcare services [18]. Regions or local authorities should be reimbursed for if a

citizen from another region seeks digital health care within their region and the reimbursement to the provider is decided by the respective region (contracting region).

Through its S3, Sweden has prioritized health-related innovation areas such as digital health, personalized medicine, precision health, and advanced medical technologies. This strategic focus is particularly evident in life science hubs like Stockholm-Uppland, Västra Götaland, and Skåne, where collaborative ecosystems bring together world-class universities, hospitals, science parks, and health tech companies.

Sweden's health innovation landscape is anchored by a robust network of stakeholders. Key actors include the **Karolinska Institutet**, **Uppsala University**, and **Sahlgrenska Science Park**, supported by clusters like **SwedenBIO** and **Medicon Village**. These actors collaborate across academia, industry, and public healthcare to develop, validate, and implement novel remote care and medical technology solutions. Sweden also coordinates national testbed environments through initiatives such as **Testbed Sweden**, allowing companies to pilot digital therapeutics and monitoring solutions in real-world healthcare settings

In terms of funding, Sweden leverages multiple sources. The **ERDF** supports regional innovation infrastructure aligned with health-focused S3 priorities [11]. At the national level, **Vinnova**, Sweden's Innovation Agency, funds collaborative R&D projects in digital health, precision medicine, and AI-driven care. Additional support comes from **Tillväxtverket** for business development and innovation, and the **Swedish Research Council** for foundational medical research. Sweden is also an active participant in **Horizon Europe**, particularly under Cluster 1: Health.

Sweden promotes innovation through mechanisms such as **strategic public procurement**, which enables health regions to stimulate the development of remote care technologies by acting as early adopters. Furthermore, initiatives like **Swelife**, a strategic innovation program co-funded by Vinnova, provide a national framework for collaboration in life sciences, from early research to healthcare implementation.

However, Sweden's advanced innovation capabilities and coordinated stakeholder landscape stand in contrast to persistent systemic bottlenecks that hinder the seamless scaling of remote care technologies. This paradox reveals a critical distinction between technological readiness and implementation maturity.

Despite its strong performance, Sweden continues to address key challenges, including regulatory complexity, regional fragmentation in healthcare procurement, and the need for

improved data interoperability and privacy frameworks. Like many Member States, Sweden is working to align its national systems with the emerging **EHDS** to enable cross-border health data sharing and research [9]. These challenges do not undermine Sweden's leadership in digital health but reflect the complexities of transitioning from pilot-driven innovation to full-scale, interoperable, and equitable deployment across diverse regional systems.

Sweden's ecosystem-oriented approach, supported by high digital literacy, a commitment to public health, and alignment with EU-level strategies such as Horizon Europe and Digital Europe, positions the country as a good practice case for remote care innovation in Europe. Sweden's success illustrates that even frontrunners in digital health must continually evolve governance, procurement, and data systems to translate innovation capacity into national-scale impact. As the country aligns more closely with the European Health Data Space and streamlines public procurement models, it is poised to fully realize its vision for integrated remote care delivery.

3.2 Leading initiatives and key projects

Across the EU, diverse innovation-driven initiatives contribute to the advancement of remote care solutions, as indicated by the conducted mapping. Several R&D and innovation projects funded under national S3, Horizon Europe, INTERREG, and EIT Health are shaping the landscape. For example, in Belgium, projects such as **Frite@home**, **eLISA**, and **Neuro Insights** are emblematic of regional excellence in Wallonia, supported through the BioWin cluster under the S3 framework. These initiatives focus on home-based care, sensor innovation, and neurological disorder monitoring. Similarly, **DIAMOND – The Smart Bandage**, funded by INTERREG France-Wallonie-Vlaanderen, demonstrates cross-border collaboration in creating next-generation wound care technologies.

The **EIT Health programme** has been instrumental in launching a number of high-impact initiatives like **MERLIN**, **Better@Home**, **HARMONICS**, **RAMSES**, and **SMARTDIABETES**, all of which address various aspects of RPM and chronic disease management. These projects leverage European cooperation to support the deployment of validated digital health solutions in real-life healthcare environments. The **Digital Health Uptake** initiative played a pivotal coordination role by aggregating and disseminating insights from digital health implementation across Europe, with the aim of supporting scalability and stakeholder engagement.

Additional initiatives include **Digi4Care**, which focuses on digitally assisted elder care, and the **European Virtual Human Twins**, a forward-looking research programme aiming to simulate patient physiology digitally for personalized treatment. Horizon-funded projects like

ComfortAGE, **VELES Excellence Hub**, and **AIPROGNOSIS** further highlight EU investments in smart ageing, AI diagnostics, and regional health innovation ecosystems. Meanwhile, **StorAIge** and **H2TRAIN**, under Chips JU and Horizon Europe respectively, target next-generation semiconductor and AI training infrastructure to underpin the future of digital health technologies.

3.3 Networks and Accelerators

A growing number of **networks and innovation accelerators** are catalysing collaboration, knowledge transfer, and startup development in the fields of remote care and digital health. These initiatives play a pivotal role in advancing RPMs and telemedicine across Europe. Among EU-level networks, **S3martMed** is a notable platform bringing together smart specialisation actors in medical technologies to foster interregional cooperation and innovation alignment. Similarly, the **European Platform for Sport Innovation (EPSI)** supports digital health applications in active and healthy living, bridging the sport, wellness, and healthcare sectors. Other key coordination mechanisms include **United4Health**, which promotes digital health deployment across Member States with specific pilots in telemonitoring and teleconsultation., and **ECHoS**, a European network supporting the uptake of digital solutions through stakeholder engagement and ecosystem development.

In the accelerator space, initiatives such as the **Beyond pre-accelerator**, **Eleven Ventures**, and the **Able Activator** provide early-stage mentoring, market access support, and investment readiness services to startups working on remote care and telehealth solutions. The **Founder Institute**, a globally active pre-seed accelerator, also supports entrepreneurs developing scalable digital health ventures, many of which contribute to Europe's remote care innovation landscape.

3.4 Corporates

A diverse range of major corporates and technology providers are actively shaping the remote care innovation landscape across Europe through both cutting-edge product development and strategic collaborations. Recent mapping efforts reveal a vibrant ecosystem of innovative companies, a selection of which is outlined below:

- **Philips**, **Siemens Healthineers**, and **Tunstall** are internationally recognized leaders in health technology, delivering sophisticated remote monitoring platforms, comprehensive telehealth systems, and hospital-at-home solutions.

- **FibriCheck** (Belgium) has developed a CE-marked medical device that allows users to measure heart rhythms using a smartphone app, providing an accessible and user-friendly cardiac monitoring tool.
- **Biotronik** (Germany) specializes in telemonitoring for cardiac rhythm management, offering healthcare professionals real-time updates on patients with implanted devices.
- **Roche** (Switzerland) is a key player in digital diabetes care, offering connected solutions such as the mySugr app and Accu-Chek devices to support continuous remote monitoring and personalized disease management.
- **MATCH Biosystems** (Spain) focuses on the development of next-generation in vitro diagnostic (IVD) devices. Their ready-to-use (RTU) portfolio aims to deliver faster, more reliable, and user-friendly diagnostic kits compared to existing solutions.
- **Sentante** (Lithuania) is pioneering robotic teleoperated systems designed for endovascular procedures, contributing to the advancement of remote surgical capabilities.
- **Telematic Medical Applications - TMA** (Greece) is a health technology company specializing in integrated telemedicine and remote patient monitoring solutions, offering a comprehensive digital platform that connects patients with healthcare providers through real-time data, video consultations, and chronic disease management tools.
- **Tonic App** (France, Spain, Italy, and Portugal) offers a CE-marked digital platform tailored for physicians. It integrates functionalities such as video consultations, e-prescriptions, and clinical case discussion tools, and is currently used by over 200,000 medical professionals across specialties.

4. RPM in More Developed & Transition Regions

4.1 Belgium Country Profile

a. Ecosystem Summary

Belgium's telemonitoring landscape in healthcare is rapidly evolving, underpinned by robust academic research and a burgeoning digital health startup ecosystem. The country's commitment to digital health is reflected in its strategic initiatives, regulatory frameworks, and the dynamic growth of health tech ventures. Belgium is home to a vibrant ecosystem of over 40 digital health startups, exhibiting a 4.6% annual growth rate from 2020 to 2025.

b. RPM Ecosystem Canvas

KEY FINANCIAL PLAYERS	KEY INDUSTRY TRENDS	DIGITAL INNOVATION SERVICES SUPPORT
▪ RIZIV/INAMI ▪ VLAIO ▪ Digital Wallonia / SPW Économie ▪ HealthTech.Belgium ▪ PMV ▪ Capricorn Partners – investing in health and medical technologies. ▪ Volta Ventures – supports digital health startups. ▪ Qbic Fund – university-linked VC, funding academic spin-offs in digital health. ▪ BlueHealth Innovation Fund	▪ App-Based RPM ▪ AI-Powered Clinical Decision Support ▪ Interoperability & Integration with EHRs	▪ HEALTHTECH BELGIUM ▪ Living Labs (Flanders & Wallonia) ▪ Belgian eHealth Platform
ESTABLISHED COMPANIES	**KEY START-UPS/SPIN OFFS / SPIN OUTS**	**TOP ACCELERATORS**
▪ BARCO ▪ FibriCheck ▪ Byteflies ▪ Ayes ▪ Epilog ▪ Icometrix ▪ Televitas ▪ Andaman 7 ▪ Ontoforce ▪ IDRO	▪ FibriCheck ▪ Byteflies ▪ Neuroventis ▪ Moveup ▪ Ayes ▪ Sentiance ▪ Lynxcare ▪ Bloomlife ▪ QbD Group – Digital Health Unit	▪ Imec.istart ▪ BlueHealth Innovation Center (BHIC) ▪ Start it @KBC ▪ Medtech Flanders ▪ W.IN.G ▪ EIT Health Belgium-Hub
HEALTHCARE PROVIDERS	**KEY STAKEHOLDERS**	**RESEARCH CENTRES**

▪ MOVE UP ▪ Fibricheck ▪ Neuroventis ▪ Doktr ▪ Qare	▪ Healthcare providers such as UZ Leuven, Cliniques Universitaires Saint-Luc, UZA etc ▪ Federal Public Service (FPS) Health, Food Chain Safety and Environment: ▪ Health Insurers & Payers, like Partenamut, CM, Helan, etc ▪ Proximus, Telenet ea ▪ RIZIV/INAMI: The National Institute for Health and Disability Insurance, responsible for setting reimbursement policies for digital health tools.	▪ UZ Leuven ▪ UZ Ghent ▪ UZ Brussels
STOCK EXCHANGE MARKET	**VENTURE CAPITALS**	**SEED FUNDING**
▪ Euronext Brussels	▪ Sofinova partners ▪ Xange ▪ Ventech ▪ Korys ▪ Qbic ▪ Elysium venture partners	▪ Imec.istart ▪ Xange ▪ Volta Ventures ▪ Sciensano ▪ IHV ▪ Soffinova Partners ▪ Ventec ▪ Prime Ventures

c. National S3 / RIS3 Overview

In Belgium, the RIS3 framework is tailored to address regional needs and challenges while fostering innovation and economic growth. The country's healthcare sector is a key area of focus across its three regions - Brussels [BE1], Flanders [BE2], and Wallonia [BE3], each of which has developed specific strategies aligned with national and EU objectives, including the European Health Data Space, Horizon Europe, and the EU's Green Deal.

1. Brussels Regional Innovation Plan 2021-2027

The Brussels Regional Innovation Plan [19] aligns with Belgium's RIS3 objectives by emphasizing innovation in the healthcare sector. The region's strategy addresses several health-related challenges, including the need for improved health and well-being, health security, and pandemic preparedness. The plan also focuses on social innovation, personalized medicine, and e-healthcare to enhance the accessibility and inclusivity of the healthcare system.

Key healthcare priorities in Brussels include:

- Personalized Medicine: This involves using digital health tools and advanced diagnostics to tailor treatments to individual patients, thus improving outcomes and patient experiences.
- E-Health: The implementation of digital applications for managing and sharing patient data, including electronic medical records, is essential for enhancing healthcare efficiency and accessibility.
- Social Innovation: Addressing mental health, psychosocial health, and ensuring that the healthcare system is inclusive for vulnerable populations such as the elderly, isolated individuals, and people with disabilities.
- Preventive and Predictive Medicine: Innovation in healthcare models that focus on prevention and prediction, rather than just treatment, which aims to reduce the long-term burden on the healthcare system.

Brussels' plan also places a strong emphasis on agile and resilient management of health crises, which was brought into sharper focus by the COVID-19 pandemic. The region aims to create an integrated healthcare ecosystem by developing technologies that can support both professionals and patients, promoting a holistic, patient-centered approach to care.

The region's innovation ecosystem is supported by various stakeholders including research centers, healthcare providers (hospitals, clinics), and startups, such as those in the health-tech sector. Platforms like lifetech.brussels and Medtech play a crucial role in fostering collaboration and advancing digital healthcare solutions.

2. Flanders Strategy for Smart Specialisation 2.0 2021-2027

Flanders' RIS3 strategy [20] places a strong emphasis on biotech and life sciences, positioning these sectors as core areas for innovation. Flanders has long been a leader in the healthcare innovation ecosystem, with its VIB (Flemish Institute for Biotechnology) and SPC MEDVIA (a public-private partnership supporting healthcare innovations) driving progress in medical biotechnology, medical technology, and digital health.

Key healthcare priorities include:

- Biotechnology and Medical Technology: Flanders has a history of success in sectors like oncology, neuro-genetics, and microbiology, with institutions such as VIB conducting research in cutting-edge areas like cancer, brain diseases, and medical

biotechnology. The goal is to develop innovative products and treatments, including personalized bio-/nanopharmaceutical products and precision medicine.

- Digital Health and e-Health: The region is focusing on digital transformation in healthcare, encouraging the adoption of AI, 5G, and IoT to improve healthcare delivery and outcomes. Collaboration through innovation clusters and DIHs enhances the region's ability to scale these digital technologies in healthcare settings.
- Public-Private Partnerships (PPPs): By facilitating joint research and co-created projects, Flanders leverages the expertise of both the public and private sectors to accelerate healthcare innovation. These collaborations are vital for overcoming challenges such as regulatory hurdles and securing funding.

Flanders also participates in EU-wide initiatives, contributing to research programs under Horizon Europe and Interreg, which provide opportunities for cross-border collaboration on healthcare innovations.

3. Wallonia's Smart Specialisation Strategy (S3) 2021-2027

Wallonia's healthcare strategy within the RIS3 framework [21, 22] is designed to foster a technologically advanced and inclusive health system. The region focuses on biotechnology, medtech, and digital health as critical areas for innovation. Wallonia aims to integrate big data, AI, and mobile health solutions into its healthcare ecosystem.

Key healthcare priorities include:

- Biopharmaceuticals and MedTech: Wallonia is recognized as a leader in the production of biopharmaceuticals, with companies like GSK and UCB making significant contributions to medical research. The region's strengths in medtech include innovations in radiotherapy, medical devices, and in-vitro diagnostics.
- E-Health and m-Health: Wallonia is investing in electronic health (e-health) and mobile health (m-health) solutions to improve access to healthcare services, particularly in underserved areas. These technologies help address challenges such as the increasing demand for care due to the aging population.
- Patient-Centered Care: Wallonia is focused on creating solutions that prioritize the needs of the patient, such as personalized treatments, and is leveraging big data to tailor healthcare interventions more effectively.
- Preventive Healthcare: Wallonia aims to develop new products and solutions for preventive care, tackling major public health issues such as chronic diseases and

pandemics. The region also addresses social determinants of health, such as poverty and environmental factors.

The region is also focusing on data interoperability across healthcare systems, improving communication between healthcare providers, insurers, and patients. This is crucial to achieving the goals of integrated healthcare and personalized care.

Wallonia's innovation ecosystem includes stakeholders such as BioWin, Medtech Wallonia, and several research centers, and is bolstered by European funding programs such as Horizon Europe and EU4Health.

4. Cross-Regional Collaboration and Alignment with EU Strategies

The RIS3 strategies of Brussels, Flanders, and Wallonia align closely with several EU-level frameworks, such as Horizon Europe, the European Health Data Space, and the Green Deal. These regional strategies emphasize collaboration between academia, industry, and government, following the Triple Helix model.

At the EU level, initiatives like the Health Innovation Community and the Smart Health value chain under Horizon Europe provide a framework for regional stakeholders to engage in transnational projects and foster cross-border collaboration. The regions' active participation in these EU programs ensures that Belgium remains at the forefront of healthcare innovation, particularly in areas like personalized medicine, digital health, and biotechnology.

d. Insights from Key Stakeholders

i. National Regulation & Legislation Framing of Remote Care

The regulatory framework for remote care and RPM in Belgium is characterized by complexity, fragmentation, and limited harmonization, both at the national and regional levels. While Belgium is actively fostering innovation in healthcare through regional S3, explicit national legislation specifically framing remote care is not clearly defined in either policy documents or stakeholder interviews.

Regulatory Challenges Identified by Stakeholders

According to experts interviewed, one of the major barriers to the adoption of RPM solutions in Belgium is the lack of streamlined regulatory processes and universal standards. The Belgian reimbursement system (RIZIV) is seen as a particularly difficult path for innovators, with only a few digital health tools, like the MOVEUP app, successfully integrated into the

system. This makes the development of viable business models challenging, especially for startups.

Stakeholders also emphasized the complexity of the national regulatory landscape, which makes Belgium a relevant but difficult test case for broader European harmonization. Data privacy regulations, such as GDPR, are considered essential but burdensome, and developers often face uncertainty in ensuring compliance while also achieving interoperability between hospital systems and digital tools.

Furthermore, fragmentation across healthcare institutions and regions causes technical issues related to data exchange and system compatibility. There are no mandatory data standards for RPM integration, and initiatives to improve interoperability, such as middleware solutions, are still under development.

Insights from the S3 Strategies (2021–2027)

Belgium's regional strategies (Brussels, Flanders, and Wallonia) strongly prioritize digital health, personalized medicine, and e-health applications. These strategies reflect policy intentions to foster remote care solutions, for example through integrated care models, home-based monitoring, and support for health innovation pathways (e.g., prototyping, clinical validation, certification).

However, no specific national or regional laws or regulations are mentioned in these documents. The strategies instead highlight systemic and structural goals, such as:

- Developing patient-centered care through digital tools.
- Improving interoperability of health data systems.
- Supporting innovation through public-private partnerships and EU funding (e.g., Horizon Europe, IMI).
- In Wallonia, the issue of data interoperability is noted as a major regulatory and organizational challenge, exacerbated by the division of competencies between federal and regional governments. Similarly, in Flanders, the strategy acknowledges slow regulatory processes and ethical/legal bottlenecks as hurdles for healthcare innovation.

Additional information based on desktop research

Belgium is progressively developing its regulatory framework for remote healthcare, integrating digital health technologies into its healthcare system. While a comprehensive

telemedicine law is still lacking, significant strides have been made to accommodate and regulate remote healthcare services.

Telemedicine and Virtual Care: Historically, the National Council of the Order of Physicians in Belgium was cautious about remote consultations. However, since 2022, teleconsultations are permitted under specific conditions, such as ensuring adequate consultation duration, verifying patient consent, maintaining continuity of care through electronic health records, and using the official electronic prescription system, Recip-e.

Reimbursement Policies: The National Institute for Health and Disability Insurance (NIHDI) has introduced reimbursement schemes for teleconsultations and certain mobile health applications (mHealth apps). These apps must be CE-marked, interoperable with the Belgian eHealth platform, and demonstrate socio-economic value to qualify for reimbursement. RIZIV is also an important player for reimbursements.

Data Protection and Cybersecurity: Belgium has implemented the EU's NIS2 Directive through the NIS2 Act, enhancing cybersecurity measures across healthcare providers. Additionally, the eHealth platform facilitates secure sharing of electronic health records among healthcare professionals, with recent amendments allowing data upload without prior patient consent, provided patients have an opt-out option. Also, GDPR is in place.

Legislative Developments: The Belgian Parliament has called for a comprehensive legal framework to govern digital health applications, emphasizing data processing, security, and reimbursement mechanisms. This includes proposals for a fast-track approval system for digital health applications, inspired by Germany's model, to expedite their integration into the healthcare system.

In summary, Belgium is actively shaping its remote healthcare landscape through regulatory adaptations, reimbursement strategies, and data governance initiatives, aiming to enhance the accessibility and quality of digital health services.

ii. Pathway to the market of Advanced Remote Care Innovations

Belgium’s pathway to the market for advanced remote care innovations is shaped by a unique blend of innovation, policy, and healthcare infrastructure. The ecosystem is rich with cutting-edge solutions ranging from Byteflies' wearable EEG sensors to smartphone applications like FibriCheck and rehabilitation tools such as MOVEUP MSK. These innovations target a broad spectrum of medical domains, including neurology, cardiology, oncology, and musculoskeletal rehabilitation, and are increasingly applied in general health, sports, post-COVID recovery.

The value proposition of these technologies is compelling: they enhance patient comfort, reduce hospital visits, and enable real-time, personalized care. For providers and systems, RPM offers data-driven decision-making and cost-efficiency. However, successful market entry depends not only on technological maturity but also on navigating Belgium's complex regulatory and reimbursement environment, particularly under the RIZIV system, which remains a bottleneck for many startups.

Key challenges include the lack of standardized data exchange formats, privacy concerns under GDPR, and limited digital literacy among certain populations. Fragmentation across healthcare IT systems complicates interoperability, though efforts like middleware solutions and EHDS initiatives aim to mitigate this.

Stakeholder engagement is vital. Patients, clinicians, developers, policymakers, and insurers all play critical roles in co-creating effective solutions. Incubators like IMEC iStart and networks like EPSI help bridge gaps between innovators and funding sources, offering both strategic guidance and practical tools for scaling.

Belgium's **decentralized healthcare system** supports equitable access for patients, yet regional disparities in digital infrastructure and user readiness persist. Despite these, the country's strong R&D ecosystem, public-private partnerships, and focus on cross-border collaboration (e.g., via Horizon Europe) position it well to lead in RPM innovation, provided regulatory streamlining and infrastructure investments continue.

To move forward, Belgium must balance innovation freedom with necessary standardization, promote user-centered design, and build trust through education and transparency. A coordinated roadmap, driven by collaborative leadership and guided by successful pilot projects, will be key to unlocking the full potential of remote care.

iii. Barriers, challenges and limitations in the RPM landscape

The implementation and RPM innovations in Belgium face a range of barriers, technical, regulatory, operational, and social. While technological solutions are advancing rapidly, their integration into the healthcare system is hindered by several systemic and practical challenges.

One of the most critical issues is the **lack of universal data standards and interoperability**. RPM solutions generate diverse data formats that are difficult to integrate into existing hospital systems. Middleware solutions are being developed to bridge these gaps, but fragmented IT

infrastructures and the absence of centralized standards slow down real-time data exchange and clinical application.

Regulatory complexity is another significant barrier. At the European level, frameworks like the MDR are seen as overly complex, prompting some companies to seek faster market access in countries like the U.S. or Hungary. Nationally, Belgium's reimbursement system (e.g., RIZIV) presents obstacles due to strict criteria and limited financial incentives, especially for startups attempting to scale their innovations.

Funding limitations also present a major hurdle, not in the development phase, but during market entry and business model formation. While public funding is available for technological development, there is a lack of support for implementation strategies and market scaling.

Patient acceptance and trust present socio-behavioral challenges, particularly among the elderly and less digitally literate populations. Many users perceive continuous monitoring as intrusive or stressful. Additionally, digital and health literacy gaps prevent broad adoption, especially in vulnerable or rural communities with limited Wi-Fi access or unfavorable physical conditions (e.g., farming environments).

From a clinical perspective, **accuracy and reliability concerns** persist. Devices like smartwatches may suffer from time zone mismatches (GMT vs. CET) and lack the precision of in-person evaluations. Moreover, delays in data transfer, especially in areas with poor connectivity or during off-hours, reduce the effectiveness of remote interventions.

Finally, **operational readiness is inconsistent**. Healthcare professionals need training to interpret RPM data meaningfully and must trust the digital tools they are expected to use. Without confidence in data quality and usability, clinical adoption remains limited.

iv. Recommendations at National and EU level

To unlock the full potential of RPM, a structured and multi-stakeholder approach is essential. Based on expert insights and observed challenges, several recommendations can guide the effective adoption, implementation, and scaling of RPM technologies.

1. **User-Centered Design and Co-Creation**: Solutions must be co-created with end-users from the earliest stages. Early engagement with patients, healthcare professionals, and caregivers ensures the technology aligns with real needs and expectations. Projects that fail to demonstrate clear user benefits often struggle with adoption. Therefore, involving patient organizations and clinicians in development and testing is crucial.

2. **Strengthen Digital Infrastructure and Interoperability**: A priority is the creation of interoperable digital systems and shared data frameworks. Middleware solutions can bridge current IT gaps, but broader standardization is needed, both nationally and at the EU level. While developers need flexibility, a minimum standard for data exchange is essential for integration across hospitals and platforms.
3. **Regulatory Simplification and Policy Alignment**: The current regulatory landscape is complex and fragmented. Streamlining approval processes and aligning national and European frameworks would ease market access. Countries like Belgium, with strong security frameworks and policy expertise, are well positioned to lead harmonization efforts across Europe.
4. **Scalable Funding and Business Models**: Funding must go beyond technology development and support implementation, training, and scaling. Public programs like VLAIO and EU initiatives (e.g., I3) should be complemented by venture capital and private investments. Clear reimbursement pathways, such as inclusion in the RIZIV system, are vital for sustainability.
5. **Focus on Education and Trust-Building**: Targeted training for healthcare providers and educational campaigns for patients are necessary to build trust and familiarity with RPM tools. Addressing concerns around data security, reliability, and usability, especially among elderly or digitally inexperienced users, is critical for widespread acceptance.
6. **Encourage Collaboration and Knowledge Sharing**: Cross-sector partnerships, between government, healthcare providers, tech developers, and researchers, should be formalized to encourage innovation and avoid duplication. Incubators and networks like IMEC iStart, EPSI, and EIT Health can offer mentorship, funding guidance, and strategic support for growth.
7. **Showcase Impact and Success Stories**: Sharing tangible success stories and proven outcomes fosters confidence in RPM. Demonstrating the practical benefits for patients, providers, and the system at large can accelerate political and financial support for broader implementation.

4.2 Netherlands Country Profile

a. *Ecosystem Summary*

The Netherlands boasts a highly advanced telemonitoring landscape, supported by strong academic research, a robust digital health startup ecosystem, close collaboration with hospitals and medical professionals, and strategic government initiatives. The country is a leader in digital health innovation, with a focus on integrating telemonitoring solutions into its healthcare system to enhance patient care and operational efficiency.

b. *RPM Ecosystem Canvas*

KEY FINANCIAL PLAYERS	KEY INDUSTRY TRENDS	DIGITAL INNOVATION SERVICES SUPPORT
▪ Health~Holland ▪ Dutch Venture Initiative (DVI) ▪ InnovationQuarter ▪ LIOF (Limburg Development and Investment Company) ▪ Oost NL (East Netherlands Development Agency)	▪ Integration of AI in telemonitoring ▪ Expansion of RPM services ▪ Focus on interoperability and data integration with EHRs ▪ Growth in digital health startups and spin-offs	▪ Health~Holland ▪ Dutch Digital Health Coalition ▪ EIT Health Netherlands ▪ Smart Health Amsterdam
ESTABLISHED COMPANIES	**KEY START-UPS/SPIN OFFS / SPIN OUTS**	**TOP ACCELERATORS**
▪ Philips Healthcare ▪ Medtronic Netherlands ▪ Siemens Healthineers Netherlands ▪ Demcon Group	▪ Luscii ▪ FocusCura ▪ Sensara ▪ SkinVision ▪ NightBalance	▪ Rockstart Health ▪ YES!Delft ▪ Health Innovation Park ▪ UtrechtInc
HEALTHCARE PROVIDERS	**KEY STAKEHOLDERS**	**RESEARCH CENTRES**
▪ University Medical Center Utrecht (UMC Utrecht) ▪ Amsterdam UMC ▪ Erasmus MC ▪ Radboud University Medical Center ▪ Maastricht University Medical Center ▪ Groningen University Medical center	▪ Ministry of Health, Welfare and Sport (VWS) ▪ Dutch Health Insurers (e.g., Zilveren Kruis, VGZ) ▪ Dutch Patients Federation ▪ Dutch eHealth Foundation ▪ Healthcare providers	▪ Eindhoven University of Technology (TU/e) ▪ Delft University of Technology (TU Delft) ▪ University of Twente ▪ Netherlands Organisation for Applied Scientific Research (TNO)
VENTURE CAPITALS	**SEED FUNDING**	

▪ Rockstart ▪ EIT InnoEnergy ▪ Prime Ventures ▪ HenQ ▪ Peak Capital	▪ Angel funds and other seed capital schemes via Ministry of Economic Affairs ▪ Dutch Venture Initiative (DVI) ▪ Imec.istart	

c. National S3 / RIS3 Overview

The Netherlands' National RIS3 for 2021–2027 [23, 24] emphasizes innovation in health and life sciences, with a strong focus on digital health and telemonitoring. The strategy aims to leverage the country's strengths in technology and healthcare to develop advanced remote care solutions.

Key Priorities:

- Personalized Medicine: Utilizing digital tools and advanced diagnostics to tailor treatments to individual patients.
- E-Health: Implementing digital applications for managing and sharing patient data, including EHRs.
- Preventive and Predictive Medicine: Focusing on prevention and prediction to reduce the long-term burden on the healthcare system.

Regional Ecosystems & Priorities

North Holland [NL1]:

- Regional Priority: Digital health and AI integration.
- Research Base: University of Amsterdam, VU University Amsterdam.
- Industry Base: High concentration of health tech startups and established companies.

South Holland [NL4]:

- Regional Priority: Medical technology and biotechnology.
- Research Base: Leiden University, Erasmus University Rotterdam.
- Industry Base: Strong presence of biotech companies and research institutions.

North Brabant [NL41]:

- Regional Priority: Telemonitoring and remote care solutions.
- Research Base: Eindhoven University of Technology (TU/e).
- Industry Base: Growing ecosystem of digital health startups and innovation hubs.

d. Insights from Key Stakeholders

i. National Regulation & Legislation Framing of Remote Care

The Netherlands has a well-defined regulatory framework for digital health and telemonitoring. The Dutch government actively supports the integration of telemonitoring solutions into the healthcare system through various initiatives and funding programs.

Key Regulatory Aspects:

- Clear guidelines for telemedicine and remote consultations.
- Reimbursement policies for digital health tools.
- Data protection regulations aligned with GDPR.
- Liability for decisions based on data.

ii. Pathway to the market of Advanced Remote Care Innovations

The Netherlands provides a supportive environment for the development and market entry of advanced remote care innovations. The country's strong R&D ecosystem, public-private partnerships, and focus on cross-border collaboration position it well to lead in RPM innovation.

Key Challenges:

- Transmural and extramural telemonitoring centers involving hospitals, elderly care organizations, and home care organizations to allow elderly patients to live at home longer.
- Ensuring interoperability of health data systems.
- Addressing privacy and data security concerns.
- Overcoming regulatory and reimbursement hurdles.

iii. Barriers, challenges and limitations in the RPM landscape

Despite the advanced state of the telemonitoring landscape, the Netherlands faces several challenges:

- Fragmented IT infrastructures and lack of universal data standards.
- Regulatory complexity and slow approval processes.
- Limited digital literacy among certain populations.

iv. Recommendations at National and EU level

For Adoption, Implementation, and Scaling of RPM Solutions:

- User-Centered Design: Engage end-users early in the development process.
- Strengthen Digital Infrastructure: Create interoperable digital systems and shared data frameworks.
- Regulatory Simplification: Streamline approval processes and align national and EU frameworks.
- Scalable Funding: Support implementation, training, and scaling beyond technological development.
- Education and Trust Building: Provide targeted training and educational campaigns.
- Collaboration and Knowledge Sharing: Foster cross-sector partnerships and share success stories.

5. RPM in Less Developed Regions

5.1 Bulgaria Country Profile

a. Ecosystem Summary

The telemonitoring landscape in Bulgaria is evolving steadily within the broader context of digital transformation and healthcare modernisation. While still in a formative stage compared to leading European counterparts, the sector is gaining momentum through national policy alignment, infrastructure development, and multi-stakeholder engagement.

> *Let's say we have the beginnings of telemedicine systems in Bulgaria. Yes, they exist. But are they being fully implemented? The truth is - NO.*
>
> *CEO of a health-tech start-up*

The telemedicine in Bulgaria is primarily driven by the need to improve healthcare access, chronic disease management, and hospital efficiency, particularly in underserved and ageing rural populations. The national innovation strategy identifies digital *health, personalised medicine, and remote care as priorities under the thematic domain "Industry for a healthy lifestyle, bioeconomy and biotechnologies".* These areas are bolstered by horizontal support for digitalisation and AI, as outlined in both the S3 and the Digital Transformation Strategy of Bulgaria 2020–2030 [25].

At the institutional level, significant infrastructure for digital health has been introduced through the National Health Information System (NHIS), operated by Information Services JSC. This platform serves as the backbone for e-prescriptions, health records, and data exchange between healthcare providers and national authorities. However, while the NHIS provides a foundation for digitisation, its integration with advanced telemonitoring solutions, such as **continuous patient tracking**, **wearable devices**, or **home-based diagnostics, *remains limited and fragmented.***

The RPM landscape is **notably shaped by pilot projects rather than system-wide adoption.** These pilots are often introduced by private providers, research groups, or start-ups in collaboration with hospitals and municipal healthcare actors. Common domains include *cardiology, diabetes management, post-surgical follow-up, and elder care*. Yet, scale-up remains a challenge due to regulatory ambiguity, insufficient reimbursement pathways, and lack of standardised interoperability protocols.

b. RPM Ecosystem Canvas

KEY FINANCIAL PLAYERS	KEY INDUSTRY TRENDS	DIGITAL INNOVATION SERVICES SUPPORT
▪ Ministry of Health ▪ National Health Insurance Fund (NHIF) ▪ European & Donor Programs ▪ Bulgarian Fund of Funds ▪ VC and Private equity investors	▪ Telemedicine Legislation and Standards. ▪ National Health Information System (NHIS) ▪ Post-COVID telehealth Adoption ▪ Public-Private CollaInvestor Interest in Digital Health:boration	▪ Digital Health and Innovation Cluster Bulgaria ▪ Healthcare Lab Accelerator (HealthCare Lab) ▪ Innovation Starter Accelerator ▪ IT Service Providers & Hubs ▪ EIT Health Hub
ESTABLISHED COMPANIES	**KEY START-UPS/SPIN OFFS / SPIN OUTS**	**TOP ACCELERATORS**
▪ Checkpoint Cardio ▪ Sirma Medical Systems ▪ Consento ▪ Hubis ▪ BGO Software ▪ Aionys ▪ Superdoc ▪ SAT Health ▪ Allterco Robotics	▪ Healee ▪ Shemha Health (PrOPA Teleoncology) ▪ FindMeCure ▪ Kardi AI ▪ MindFit ▪ MedGuide ▪ Kelvin Health	▪ HealthCare Lab (Digital Health Accelerator CEE) ▪ Eleven Alpha Program ▪ Innovation Capital Acceleration ▪ Sofia Tech Park Incubator ▪ The EDGE / JA Bulgaria ▪ Plug and Play Health ▪ EIT Health Bootcamps ▪ Bulgarian Innovation Hub (in San Francisco)
HEALTHCARE PROVIDERS	**KEY STAKEHOLDERS**	**RESEARCH CENTRES**
▪ Military Medical Academy ▪ Acibadem City Clinic – Tokuda Hospital ▪ Heart and Brain Hospitals (Bulgarian Cardiac Institute) ▪ General Practitioners (Family Doctors) & Polyclinics ▪ Dr. Shterev Hospital ▪ Nadezhda Women's Health Hospital ▪ National Cardiology Hospital ▪ University Hospitals ▪ Private Clinics	▪ Ministry of Health (MoH) ▪ Bulgarian Medical Association ▪ National Center for Public Health and Analyses (NCPHA) ▪ Patient Organizations ▪ Pharmaceutical and Medtech Companies ▪ Academic Institutions	▪ Center of Competence on Personalized Medicine, 3D and Telemedicine ▪ INSAIT ▪ Institute of Robotics, Bulgarian Academy of Sciences ▪ GATE Institute ▪ Telemedicine Lab – Medical University Varna ▪ SoftUni Digital Health Lab
VENTURE CAPITALS	**SEED FUNDING**	
▪ Eleven Ventures ▪ LAUNCHub Ventures	▪ Innovation Accelerator ▪ Vitosha Venture Partners	

▪ Innovation Capital ▪ Sofia Angels Ventures ▪ BrightCap Ventures ▪ Nina Capital ▪ Calm/Storm ▪ KAYA VC ▪ BGO Ventures ▪ EIC trusted VCs	▪ CEO Angels Club ▪ BVBA (Bulgarian Venture & Business Angel Association) ▪ National Innovation Fund ▪ EU Horizon Europe ▪ America for Bulgaria Foundation ▪ EU COST ▪ NASA Space Apps ▪ Nova TV Hackathon ▪ EIT Health ▪ CEED (Center for Entrepreneurship and Executive Development) ▪ SEE Health Accelerator

c. National S3 / RIS3 Overview

Bulgaria's Innovation S3 for the period 2021–2027 [26] was formally adopted in December 2022, following extensive national consultations and alignment with the EU's cohesion policy and innovation agendas. The overarching goal of the Bulgarian S3 is to accelerate the country's transition toward a smart, sustainable, and inclusive economy through place-based innovation and targeted investment in research and development. This strategic vision focuses on strengthening Bulgaria's scientific and industrial capacity, enhancing regional competitiveness, and positioning the country within key European value chains in both traditional and emerging sectors.

A central pillar of the Bulgarian S3 is the *thematic priority area entitled* ***Industry for a healthy lifestyle, bioeconomy and biotechnologies***. This broad priority encompasses several targeted sub-domains of research and innovation, including personalised medicine, biopharmaceuticals, health-related biotechnology, nutraceuticals, digital health, and telemedicine. It also includes the development of high-tech medical devices, medical 3D printing applications, and biotechnological platforms for public health and agricultural innovation. These focus areas aim to address both individual and societal health needs while simultaneously building up Bulgaria's capacity to participate in EU-wide initiatives related to digital transformation and the European Health Union.

The Bulgarian strategy is explicitly aligned with key EU-level frameworks and funding mechanisms. It promotes active participation in the Horizon Europe programme, particularly in missions related to cancer, climate, and digital health, and encourages integration into the EHDS through digital infrastructure and secure data interoperability initiatives. It also supports the objectives of the European Green Deal by linking health innovation with bio-based and low-carbon technologies, and it reflects the New European Innovation Agenda through its

efforts to **scale up deep-tech start-ups, deploy regulatory sandboxes, and promote inclusive innovation ecosystems.** The strategy's commitment to open science, skills development, and regional specialisation ensures that it not only addresses national challenges but also contributes meaningfully to Europe's shared goals in resilience, sustainability, and competitiveness.

d. Insights from Key Stakeholders

i. National Regulation & Legislation Framing of Remote Care

1. Absence of a legal definition and comprehensive regulatory framework

As of 2024, the term "telemedicine" lacks a unified and legally binding definition in Bulgarian law. While various legislative documents such as the **Health Act**, the **Electronic Governance Act**, and **Ordinance H-6/2022** for the functioning of NHIS make reference to digital healthcare tools, there is no codified definition of "telemedical service" or its subtypes (e.g., teleconsultation, telemonitoring, tele-diagnostics). The legal treatment of such services remains scattered and indirect.

A temporary provision during the COVID-19 pandemic (via amendments to Ordinance No. 10 and other normative texts) permitted remote consultations and the issuance of medical referrals by general practitioners without in-person examination. However, this was a crisis measure and not a structurally embedded legal right.

2. Misclassification and institutional fragmentation

As noted across stakeholder interviews and legal analysis, RPM platforms and services are often misclassified under commercial or ICT service categories, such as online scheduling tools or communication platforms. This prevents their recognition as clinical interventions and exposes providers to liability and ambiguity. Legal responsibility for outcomes delivered via RPM is unclear, especially where the service includes multiple agents, software developers, data hosts, healthcare professionals, and platform providers.

This fragmentation extends to regulatory oversight. No single institution is currently mandated to accredit, monitor, or audit RPM systems. The absence of unified coordination among the **Ministry of Health**, **NHIF**, **cybersecurity regulators**, and **data protection authorities** may lead to stalled adoption and low stakeholder confidence.

3. Gaps in certification, reimbursement, and implementation mandates

A recurring barrier identified in the *legal report* and stakeholder interviews is the **absence of a formal certification pathway** for RPM devices and digital health platforms. Even when systems are aligned with EU and international standards such as **GDPR**, **HL7**, **FHIR**, or **MDR**, there is no national-level mechanism to validate or register them as certified health technologies. This prevents NHIF from reimbursing RPM services, which are entirely absent from the current **National Framework Contract**.

Moreover, no funding incentives currently exist for hospitals or GPs to integrate remote monitoring, and all implementations are either donor-funded, privately financed, or voluntary. This leaves RPM in a legal grey zone, dependent on individual initiatives rather than institutional commitment.

4. NHIS as a dormant infrastructure for RPM integration

Ordinance H-6/2022 on the functioning of the **NHIS** provides a legal opportunity for RPM integration by enabling remote health data to be stored and accessed via an **electronic health record**. However, the current implementation does not support **real-time ingestion from RPM devices**, nor does it provide structured interoperability with third-party systems. RPM systems, like **Check Point Cardio, Shemha Health etc.,** function independently from NHIS and remain isolated.

Moreover, the use of **Qualified Electronic Signatures (QES)** and other access protocols is mandatory for data entry, which creates barriers for patient-generated data and user-friendly mobile platforms, especially in remote areas with limited digital literacy or infrastructure.

5. Protection of sensitive data and cybersecurity

The handling of sensitive health data in telemedicine and RPM falls under the **Personal Data Protection Act**, aligned with the **EU's GDPR**. While the law permits data processing for medical purposes, provided appropriate safeguards exist, Bulgaria lacks specific guidance on **data integrity, digital consent, and cybersecurity standards** for telehealth and RPM applications. The NHIS uses certified mechanisms for internal data governance, segmented databases, dual-authentication QES access, and encrypted exchanges, but these are not extended to patient-facing tools. Most mobile RPM systems store data locally or on cloud platforms without integration into the national infrastructure, raising concerns about legal exposure, patient privacy, and cyberthreats.

6. Legislative proposals and ongoing policy evolution

The most structured attempt to define and regulate telemedicine was the **2022 Draft Law for Amendments to the Health Act**, introduced in Bulgaria's 47th National Assembly. This draft proposed:

- Legal recognition of remote diagnostics, treatment, and rehabilitation.
- Mandatory registration of RPM and telemedicine providers.
- Governance through the **Executive Agency Medical Supervision**.
- Creation of a public registry for authorised providers.
- Binding requirements for informed consent and personal data protection.

Although the draft was not adopted due to parliamentary dissolution, it represents a solid **policy baseline** for future reform. Experts argue for its revival, with refinements to cover platform accreditation, institutional liability, insurance coverage, and ethical AI use in clinical decision-making.

7. Integration into EU frameworks and upcoming directives

At the EU level, Bulgaria is expected to align its national frameworks with:

- **EHDS** [9] – which mandates patient data portability and cross-border interoperability.
- **Digital Services Act (DSA)** [27] and **Data Governance Act (DGA)** [7] – addressing data access, reuse, and control in health contexts.
- **AI Act** [5]– which includes provisions for clinical algorithms and diagnostics.

Currently, Bulgaria has made only partial preparations to meet these targets. There is no roadmap to integrate NHIS with cross-border health data networks or to update national laws to match EU regulations. Stakeholders urge the Ministry of Health to appoint a national coordination body for EHDS compliance and RPM acceleration.

ii. Pathway to the market of Advanced Remote Care Innovations

Advanced Remote Care Innovations (ARCI), particularly those involving RPM, represent one of the most promising yet under-realised opportunities for health system transformation in Bulgaria. While international trends point toward rapid adoption of data-driven, AI-supported, and real-time patient engagement technologies, Bulgaria remains at an early stage in converting prototypes and pilot platforms into integrated, reimbursed, and scalable services.

The **pathway to the market** for ARCI in Bulgaria is not clearly defined. It is hindered by a fragmented legal framework, institutional uncertainty, and misaligned incentives. However, there is evidence of progress, emerging models, and stakeholder consensus on the reforms

required to transition from pilot to practice. This pathway can be understood in five interdependent stages: (1) development and validation, (2) certification and compliance, (3) system integration, (4) reimbursement and funding, and (5) diffusion and adoption.

1. Development and validation

The first stage of market entry is dominated by private actors and start-ups such as Shemha Health, BGO Software, and legacy systems like Check Point Cardio. Development of RPM solutions in Bulgaria typically follows a bottom-up model, in which innovators identify clinical needs, particularly in chronic disease management and post-hospital care, and attempt to build mobile or wearable-supported platforms to meet them. The technical environment often incorporates AI modules, cloud-native architecture, and real-time physiological data transmission.

However, these innovations largely **lack a formal domestic validation process**. There is **no national sandbox for digital health experimentation, no harmonised medical device pathway that includes software as a medical device (SaMD)**, and **no public programme for early-stage clinical piloting of digital care technologies**. Consequently, developers must either validate solutions through international trials or pilot them privately in partner clinics and hospitals. This creates high entry costs, out-of-pocket expenditure for the patient and excludes smaller developers, academic teams, and regional innovators from participating.

2. Certification and compliance

Once developed, ARCI solutions must be certified, both technically and legally, to enter the market. In Bulgaria, this process is **undefined for RPM tools**. 75% of the interviewees reported that RPM platforms are either:

- Misclassified as ICT services, regulated under general e-commerce or software rules;
- Treated as uncertified medical tools, operating in a legal grey zone; or
- Developed for foreign markets, bypassing national systems altogether.

There is **no national body tasked with certifying telemedical / telehealth platforms**, assessing cybersecurity protocols for remote devices, or validating AI-driven clinical decision support. Moreover, integration with the NHIS is neither incentivised nor mandated, and interoperability standards (e.g. HL7, FHIR, DICOM) are not uniformly adopted in the public sector.

This lack of certification clarity has significant consequences: RPM developers cannot market their services as reimbursable medical tools, cannot ensure patient data is covered by national

protection frameworks, and cannot guarantee legal protection for clinicians using their solutions. As a result, most services remain **informal, non-integrated, and commercially stagnated**.

3. System integration

The third stage, connecting ARCI tools to mainstream health workflows, is particularly problematic. Despite the existence of NHIS as a national infrastructure, there is **no formal integration process for third-party RPM platforms**. While NHIS maintains a structured API and centralised health records, it currently does not ingest real-time data from wearable or mobile monitoring devices. Furthermore, external systems must comply with data field specifications and authentication protocols that are not designed with remote or patient-side entry in mind.

However, NHIS is technically capable of supporting future RPM integration, but no policy mandates, incentives, or strategic partnerships exist to actualise this potential. In effect, RPM providers operate in **parallel digital ecosystems** with no shared language, certification protocol or access point into public care coordination mechanisms.

The lack of system integration has downstream effects. RPM data are not visible to treating physicians unless shared informally; patients cannot use their monitoring data for referrals or prescriptions; and digital care pathways remain siloed from national disease registries, surveillance tools, and strategic public health data planning.

4. Reimbursement and funding

In Bulgaria, RPM and other advanced remote care services are **not included in the National Framework Contract** and have **no designated reimbursement codes**. This excludes them from NHIF funding, which remains tethered to physical consultations, procedural codes, and face-to-face service delivery.

In this vacuum, RPM solutions must either:

- Be purchased out-of-pocket by patients (limiting access);
- Be bundled into premium private services (excluding vulnerable groups and rural areas);
- Be funded by external donors or corporate sponsors (unsustainable and often project-bound).

Providers report that **cost recovery is a major barrier to scaling**. Without a tariff model, result or value-based reimbursement schemes, or pay-for-performance frameworks, there is little incentive for clinicians or institutions to adopt digital care models, particularly when these require workflow redesign or additional training.

While there have been EU-funded projects and pilot grants supporting telemedicine, these have not translated into stable financing pathways. Stakeholders advocate for:

- NHIF inclusion of digital care services (e.g. through new procedure codes);
- Dedicated funding streams for RPM technologies in primary care and chronic disease;
- Innovation vouchers or subsidies for health facilities implementing integrated ARCI tools.

5. Diffusion and adoption

Even when a solution is technically ready, certified, and funded, its **adoption depends on awareness, trust, and cultural readiness**. In Bulgaria, ARCI tools face:

- Low digital health literacy among patients, particularly elderly and rural populations;
- Clinician scepticism toward patient-generated data and algorithmic recommendations;
- Institutional resistance from hospital administrators tied to volume-based funding;
- Limited public trust in state-run digital systems, perceived as bureaucratic and opaque.

Interviewees suggest that for ARCI tools to achieve scale, they must be introduced with:

- Structured patient education and onboarding materials;
- Physician training embedded in continuous professional development;
- Role definition for RPM coordinators or digital health nurses;
- Public communication campaigns demystifying remote care;
- Co-creation platforms where patients, developers, and doctors shape service design.

Moreover, pilot projects must be linked to **scaling plans, procurement mechanisms, and outcome evaluation tools**, ensuring that promising innovations do not remain locked in demonstration mode.

iii. Barriers, challenges and limitations in the RPM landscape

RPM is widely recognised as key solution for crafting personalised, continuous, and decentralised care, particularly for patients with chronic conditions, limited mobility, or those in remote, rural or underserved regions. In Bulgaria, however, the landscape of RPM remains significantly underdeveloped.

1. Regulatory and legal barriers

One of the ley impediments that can be marked is the **underdeveloped unified regulatory framework** for telemedicine and RPM. Unfortunately, Bulgaria still does not legally define RPM, teleconsultation, or telemonitoring as formal components of healthcare delivery. Current laws treat remote services as generic ICT services or online commerce platforms, which is both inaccurate and legally inappropriate.

Key regulatory barriers include:

- **No legally binding definition of RPM or telemedicine** in the Health Act or related legislation.
- **Misclassification of RPM platforms** under e-commerce rules, excluding them from health-specific oversight.
- **Absence of certification, licensing, or registration pathways** for RPM tools, devices, and providers.
- **No national registry of accredited RPM services**, leading to a lack of transparency and patient trust.
- **No established liability model** for clinical outcomes in remote care contexts.
- **No legally recognised informed consent protocols** for patient participation in continuous monitoring.

This fragmented regulatory status forces RPM developers and users to operate in legal uncertainty, deterring investment, slowing innovation, and undermining institutional adoption. The lack of alignment with EU frameworks such as the EHDS and AI Act further isolates Bulgaria from continental health data strategies.

2. Technical and interoperability limitations

While NHIS provides a foundational architecture for national e-health infrastructure, its current design is not optimised for real-time data exchange with RPM devices or mobile platforms. There is **no national interoperability strategy**, and key international standards such as **HL7, FHIR, and DICOM** are under implementation across public systems.

Technical bottlenecks include:

- **Lack of structured, real-time API pathways** from RPM devices into the NHIS.
- **Closed architectures and siloed platforms** in both public and private sectors.
- **No certification or technical validation process** for RPM devices and applications.

- **Incompatibility of wearable-generated data** with national patient record formats and field structures.
- **Absence of cloud-native or edge-computing support** in public infrastructure.

From a hardware and connectivity perspective, rural and peripheral regions often lack stable internet access or sufficient digital infrastructure to support continuous data streaming. This creates inequities and undermines one of RPM's central promises: to bridge gaps in care across geographies.

3. Financial and reimbursement challenges

There is **no reimbursement pathway** for RPM in Bulgaria. The National Health Insurance Fund (NHIF) does not recognise RPM procedures, nor does it provide coverage or tariff codes for remote consultations, continuous monitoring, or device-supported interventions.

Key financial limitations

- **No NHIF reimbursement** for RPM-related procedures, services, or technology use.
- **No inclusion of RPM in the National Framework Contract**, excluding it from public-private delivery models.
- **Lack of public procurement mechanisms** for digital health infrastructure.
- **High upfront costs** of device deployment, borne entirely by private providers or patients.
- **No funding or voucher scheme** to support innovation adoption in small clinics or rural GPs.

Private providers, especially in outpatient care, view RPM as an **unrecoverable cost**, limiting its adoption to donor-funded pilots or high-income patient groups. This restricts RPM to narrow urban markets and undermines its systemic value in chronic care and public health surveillance.

4. Institutional and operational inertia

Bulgaria's health system is characterised by **deeply entrenched operational cultures**, where change is often met with scepticism or resistance. Institutions operate under a "volume-over-value" logic, where success is measured by procedure counts and physical consultations, not outcomes.

Institutional barriers:

- **Low digital maturity** among healthcare facilities, especially outside the state capital.
- **Limited administrative capacity** for digital transformation at the hospital and ministry level.
- **Absence of clear roles or staff positions** (e.g. digital nurses, RPM coordinators) for managing remote care.
- **No integration of RPM tools into clinical workflows**, leading to duplication and low uptake.
- **No incentives for doctors or nurses** to adopt RPM in daily care delivery.
- **Fragmented leadership** among public agencies, with unclear mandates or conflicting digital health priorities.

NHIS has the infrastructure potential but lacks a legal and managerial framework for activating RPM data streams or clinical use cases.

5. Socio-cultural and trust-related challenges

Beyond technical and institutional issues, RPM faces **cultural resistance and low health system trust** among both professionals and patients. Many clinicians view RPM tools as additional workload, outside their core duties and unsupported by training or compensation. Others worry that algorithmic monitoring may challenge their clinical authority or expose them to liability.

Key socio-cultural challenges:

- **Low digital health literacy** among elderly populations and rural communities.
- **Scepticism among physicians** toward patient-generated data or AI-driven alerts.
- **No public education campaigns** on RPM's safety, benefits, or evidence base.
- **Limited trust in state-managed digital infrastructure**, often viewed as opaque or inefficient.
- **Lack of patient empowerment tools** to help individuals understand, manage, and control their remote health data.

Patients and providers alike often operate in informal systems (e.g. Viber consultations, WhatsApp messaging), which offer convenience but lack structure, accountability, and clinical integration.

6. Strategic and governance limitations

RPM in Bulgaria suffers from weak to no coordinated strategy. There is **no national roadmap**, action plan, or regulatory white paper outlining how RPM will be incorporated into the health system, funded, governed, or scaled.

Strategic deficits:

- **No national coordinator or digital health authority** dedicated to RPM.
- **No structured stakeholder platform** for developers, clinicians, and policymakers to co-design services.
- **No alignment between Bulgaria's S3 Smart Specialisation priorities, the Recovery and Resilience Facility and the health innovation ecosystems**.
- **Weak connections between national efforts and EU-wide programmes**, including Digital Health Europe and Horizon Europe RPM initiatives.

This absence of a strategic centre means that even promising RPM systems, such as Shemha Health and Check Point Cardio, remain peripheral and disconnected from systemic reforms. It also prevents Bulgaria from fully leveraging EU investments, regulatory alignment, and technical guidance offered through the European Health Data Space and AI Act.

iv. Recommendations at National and EU level

The successful uptake and mainstreaming RPM in Bulgaria will require a synchronised reform agenda spanning legislation, financing, system integration, clinical culture, and citizen engagement. RPM is not a single product or service, it is a complex, systemic enabler of decentralised, proactive, and value-based care. As such, its success depends on **multi-level coordination** and **ecosystem alignment**, anchored in both national strategy and EU-wide standards.

The following recommendations are presented thematically and supported by practical steps for implementation.

1. Establish a dedicated legal and regulatory framework for RPM

A coherent and enforceable regulatory foundation is the precondition for all other steps in RPM adoption. Current legislation in Bulgaria is fragmented, and RPM remains undefined in law.

Recommendations

- Define RPM and telemedicine explicitly in the Health Act, covering services such as remote monitoring, teleconsultation, and digital diagnostics.

- Create a **national registry of certified RPM platforms and providers**, including rules for accreditation and clinical liability.
- Develop **standardised informed consent procedures** for continuous remote data collection.
- Align with EU frameworks such as EHDS, GDPR, AI Act, MDR
- Revive and adapt the **2022 Draft Law on Telemedicine**, incorporating stakeholder feedback and introduce governance models, e.g. the DHI's penta-helix.

2. Develop national reimbursement and financing mechanisms

RPM must be financially viable to scale. Without reimbursement, it remains confined to private payment models and disconnected from system-wide delivery.

Recommendations

- Introduce **NHIF reimbursement codes** for RPM services, based on clinical use cases (e.g. hypertension, diabetes, post-operative care).
- Pilot **value-based care models**, where providers are reimbursed based on patient outcomes rather than volume of activity.
- Create a national [**Digital] Health Innovation Fund** to:
    - Subsidise RPM implementation in public hospitals and GP networks.
    - Support training and infrastructure upgrades.
    - Fund evidence generation on cost-effectiveness and clinical benefit.
    - Integrate RPM into the **National Framework Contract for Medical Services**.

3. Integrate RPM data and services into the NHIS

Integration with NHIS is critical for RPM data to be useful, secure, and clinically actionable.

Recommendations

- Extend the NHIS public API to accept structured real-time data from certified RPM devices.
- Adopt international interoperability standards including **HL7, FHIR, and DICOM**.
- Enable **role-based access control** and **QES-authenticated uploads** for patient-generated health data.
- Certify third-party RPM platforms for integration with NHIS through a transparent validation process.

- Develop **real-time data dashboards** for clinicians to access and interpret RPM data inside their EHR interface.

4. Build capacity within healthcare institutions

Institutional readiness is a major bottleneck for RPM adoption. Facilities must be equipped both technically and organisationally.

Recommendations

- Train healthcare professionals in digital health tools, clinical interpretation of remote monitoring data, digital ethics and patient communication
- Create new professional roles such as RPM coordinators, digital care navigators, telehealth nurses
- Equip GPs and outpatient centres with stable connectivity, device compatibility modules, secure workstations for monitoring dashboards
- Launch pilot RPM integration projects in **regional and municipal hospitals**, prioritising underserved areas.

5. Foster trust, awareness, and patient empowerment

Patients and clinicians must trust and understand RPM before it can become part of care routines.

Recommendations

- Co-create educational campaigns with patient associations to explain What RPM is; How it protects data; How it benefits care quality and safety
- Publish **guidelines on digital consent, rights, and data use** in accessible formats.
- Build **digital literacy tools** tailored to older adults, rural communities, patients with chronic conditions
- Promote success stories, such as Check Point Cardio, Shemha Health etc. through media and professional networks to build acceptance.

6. Create inclusive innovation ecosystems and governance structures

Bulgaria needs an institutional space where stakeholders can jointly design, test, and govern RPM.

Recommendations

- Launch a **National RPM consultancy / expert board** , chaired by the Ministry of Health and involving NHIS administrators, RPM technology developers, medical associations, civil society groups, academia and media
- Establish a **co-creation lab or testbed environment**, supported by EU structural funds, Public-private investment, Smart Specialisation Strategy (S3) priority alignment
- Ensure ethical oversight through collaboration with the Personal Data Protection commission, medical ethics committees, bioethics and AI experts.

7. Align with European initiatives and cross-border frameworks

Bulgaria's RPM strategy must position the country within the evolving European health data ecosystem.

Recommendations

- Nominate a national **EHDS Coordination Office** to align NHIS with EU architecture and health data nodes.
- Participate in Digital Health Europe, TEHDAS (Joint Action Towards EHDS), Horizon Europe RPM clusters etc.
- Harmonise technical requirements with the **EU AI Act** and **DSA/DGA frameworks** for platform governance.
- Use **peer exchange with countries with advanced RPM ecosystem** to model regulatory and technical pathways.

8. Ensure equitable access and regional inclusion

Equity must be built into RPM from the start to avoid reinforcing urban-rural health disparities.

Recommendations

- Prioritise RPM pilots in underserved regions, small towns, and peripheral municipalities.
- Provide infrastructure grants for internet upgrades, local health IT support, patient engagement centres, monitor RPM usage by geography, gender, age, and socioeconomic status.
- Design **RPM for inclusion**, incorporating multilingual interfaces, offline functionality, and support for caregivers.

5.2 Greece Country Profile

a. Ecosystem Summary

Greece's remote care and telemonitoring ecosystem is emerging, driven by a combination of academic excellence, local innovation, and fragmented yet promising public-private initiatives. The landscape is anchored in urban hubs such as Athens and Thessaloniki, with strong participation from research institutions, startups, and healthcare providers. EU-funded research projects, S3, and targeted investments from the RRF are creating momentum, particularly in areas like chronic disease management, elderly care, and AI-supported diagnostics.

Greece's digital health ecosystem is also increasingly supported by innovation hubs and clusters that promote early-stage development and market readiness for telemedicine and RPM solutions. Notably, the Hellenic Digital Health Cluster (HDHC) acts as a facilitator of partnerships between startups, research centers, and healthcare providers, aligned with both national and EU priorities for digital transformation in health. Several Greek technology parks and incubators (e.g., Athens Center for Entrepreneurship and Innovation, ThessINTEC in Thessaloniki, and Heraklion's Science and Technology Park) are supporting health-focused ventures, often leveraging RRF and Horizon Europe grants. These innovation spaces offer mentoring, regulatory support, and access to infrastructure for testing and deploying remote care platforms, particularly those targeting elderly care and chronic disease management.

However, systemic challenges, such as limited regulatory clarity, lack of reimbursement frameworks, and fragmented interoperability infrastructure, constrain national-scale adoption. Despite these barriers, a growing number of modular, device-agnostic RPM platforms are being piloted through municipal programs and EU-funded testbeds. With increasing alignment to EU digital health priorities and promising local expertise, Greece is well positioned towards transforming its remote care ecosystem, provided that structural gaps in policy, financing, and implementation are addressed.

b. RPM Ecosystem Canvas

KEY FINANCIAL PLAYERS	KEY INDUSTRY TRENDS	DIGITAL INNOVATION SERVICES SUPPORT
▪ AXA Doctor at Hand ▪ Telemedicine Service Medion by INTERAMERICAN	▪ Competitive EU funding for R&D ▪ Regional Structural Funding calls for pilot service deployment	▪ SmartHEALTH EDIH ▪ HealthHUB EDIH ▪ digiGOV-innoHUB ▪ Elevate Greece

▪ National Organization for the Provision of Health Services - EOPYY, (only for covid teleconsultations) ▪ Greek Municipalities ▪ Hospital at Home RRF (ΝΟΣΠΙ) Program ▪ Mobile Medical Units (ΚΟΜΥ) RRF program ▪ Vodafone's Telemedicine Programme (VTP)	▪ Out of pocket business model	▪ Hellenic Digital Health Cluster (HDHC) ▪ Science & Technology Parks such as JOIST Innovation Park, STEP-C, PSP etc. ▪ Hellenic Ministry of Digital Governance ▪ General Secretariat for Research and Innovation (GSRI), Ministry of Development ▪ Enterprise Greece ▪ Enterprise Europe Network-Hellas ▪ National Documentation Centre / EIT Health
ESTABLISHED COMPANIES	**KEY START-UPS/SPIN OFFS / SPIN OUTS**	**TOP ACCELERATORS/ SEED FUNDING**
▪ GNOMON INFORMATICS S.A. ▪ TELEMATIC MEDICAL APPLICATIONS LTD (TMA)	▪ CAREPOI ▪ DOCTORANYTIME ▪ TRAQBEAT ▪ DOCANDU ▪ DOCTORNEXT2ME ▪ HiSpin ▪ YPSILON Care Tech ▪ ATRIDE ▪ KINVENT	▪ Archimedes ▪ ACEin ▪ EGG ▪ Orange Grove ▪ NBG BUSSINESS SEED
HEALTHCARE PROVIDERS	**KEY STAKEHOLDERS**	**RESEARCH CENTRES**
▪ 127 Hospitals, 320 Health Centres, more than 1000 Regional Medical Offices of the National Health System ▪ Digital Clinic App, by Hellenic Health Group (HHG) ▪ AFFIDEA Greece – myaffidea Program ▪ National Network of Telemedicine (EDIT)	▪ Hellenic Ministry of Health ▪ Greek Medical Association (PIS) ▪ Hellenic Health Informatics Association of Health (ESPY) ▪ Hellenic Society for Biomedical Technology (ELEBIT) ▪ Greek Patients Association ▪ National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) ▪ Central Union of Municipalities of Greece (KEDE)	▪ Foundation for Research and Technology (FORTH), including Institute of Computer Science (FORTH-ICS) and Center for eHealth Applications and Services (CEHA) ▪ Centre for Research and Technology Hellas (CERTH), including Information Technologies Institute (ITI)

	▪ Hellenic Digital Health Cluster (HDHC)	▪ Universities such as NTUA, AUTH, UOC, etc. ▪ Thess-AHALL Thessaloniki Action for HeAlth & Wellbeing Living Lab
IPO (Alternative Market of Athens Exchange Group)	**VENTURE CAPITALS**	
▪ VIDAVO	▪ Metavallon ▪ Venture Friends ▪ Marathon Venture Capital ▪ Genesis Ventures ▪ UNI.FUND ▪ BigPi	

c. National S3 / RIS3 Overview

Greece's National RIS3 for 2021–2027 was formulated at the national level but builds on regional specialisations that each region proposed [28]. The unified national RIS3 recognizes eight priority areas, **Biosciences, Health, and Pharmaceuticals** being one of them. This priority includes the development and integration of innovative healthcare solutions, with a notable emphasis on remote care such as telemedicine and homecare, particularly for the elderly and patients with chronic conditions.

The Recovery and Resilience Plan (RRP) aligns with RIS3 by supporting investments in digital health technologies, bridging service gaps in remote and rural areas through EHR integration and expanded telemedicine consultations.

Nationally, Greece is classified as a Moderate Innovator according to the European Innovation Scoreboard, comprising 13 regions. Among them:

- Attiki (EL30) is Greece's most innovative region (Moderate Innovator, transition region).
- Kriti (EL43), Kentriki Makedonia (EL52), and Thessalia (EL61) are also Moderate Innovators but are designated as LDRs.

Meanwhile, Greek startups increasingly focus on health-related applications, reinforcing the country's push toward digital health and remote care solutions. The Greek biosciences, health, and pharmaceuticals sector benefits from a highly skilled large number of doctors and researchers, as well as both public and private health services capable of supporting innovative activities such as telemedicine, bioinformatics, and data analytics. However, the sector struggles with limited collaboration between research institutions and industry, frequent regulatory shifts, and a persistent brain drain of talent.

Regional Ecosystems & Priorities:

Attica [EL30]

- Regional Priority: Focus on pharmaceutical innovation.
- Research Base: University of Athens, NTUA (National Technical University of Athens), NCSR "Demokritos."
- Industry Base: High concentration of healthcare infrastructure (major hospitals, digital health spin-offs). Relevant clusters include the Hellenic Digital Health Cluster (HDHC) and the Hellenic Biocluster (HBIO).

Central Macedonia [EL52]

- Regional Priority: Emphasis on elderly care and vulnerable social groups.
- Research Base: Includes major institutions in Thessaloniki (e.g., Aristotle University, CERTH).
- Industry Base: Significant private investments, such as Pfizer (>€100 million for a digital hub) and Deloitte (competence centre).

Crete [EL43]

- Regional Priority: Health–Wellness, with focuses on AI, telemedicine, bioinformatics, data analytics, pharmaceuticals, precision medicine, wearables, and remote monitoring.
- Research Base: Foundation for Research and Technology – Hellas (FORTH) and University of Crete lead nationally in health-related research.
- Industry Base: Growing medtech ecosystem, with cluster/network potential to catalyze advanced digital health solutions.

Thessaly [EL61]

- Research Base: University of Thessaly developing eHealth and telemedicine solutions, especially for rural and mountainous areas.
- Industry Base: Rehabilitation and related medical services were deemed an emerging area (2014–2020). Several rehabilitation centres (e.g. Apokatastasi, Animus) strengthen the region's capability in chronic care and patient recovery.

d. Insights from Key Stakeholders

i. National Regulation & Legislation Framing of Remote Care

The regulatory landscape for remote care in Greece is **progressively evolving** but remains fragmented and often **misaligned with the operational needs** of digital health service providers. While foundational frameworks exist, the scope of regulation is narrow and fails to support broader applications such as remote diagnostics for chronic conditions (e.g., diabetes, sleep apnea, musculoskeletal rehabilitation) or the use of AI-supported monitoring systems.

Although Greece's **Digital Transformation Strategy (2020–2025)** [29] has laid out ambitious goals to digitize public services, it does not explicitly address the **reimbursement, certification, or regulatory handling of RPM and digital health solutions**. This gap in policy direction has left many companies and healthcare institutions operating in a regulatory "grey" area, particularly when trying to scale remote care models.

A key structural advancement has been the establishment of the **National eHealth Interoperability Framework (NeHIF)** in 2021 [30]. Its objective is to dismantle information silos across the healthcare system, promoting standardized and secure data exchange. Despite this, **true interoperability remains limited**, as many healthcare providers still operate isolated systems and there is **no mandatory enforcement mechanism** ensuring full adoption of NeHIF protocols.

Key **national and European regulations** include [31]:

- Privacy and data protection are governed by **GDPR and Law 4624/2019** [32], which provide the general legal framework for handling sensitive health data.
- **Law 4961/2022** [33] mandates the **registration of AI applications** used in public and private sectors and address broader ICT usage.
- **Regulation 2024/1689 (AI Act)** [5] which applies to high-risk AI applications, including those used in digital health.
- **MDR (2017/745)** [2] and **IVDR (2017/746)** [4].
- **Law 4213/2013** [34] governs **cross-border healthcare services**, supporting alignment with Directive 2011/24/EU on patients' rights in the EU.

Despite a growing body of regulation, the current **lack of legal clarity around AI in clinical decision-making**, as well as the **absence of streamlined pathways for CE and ISO certification**, slows down the time-to-market for innovative solutions. The **SWOT analysis in**

Greece's RIS3 strategy also identifies frequent regulatory shifts in healthcare as a **deterrent to long-term investment** in digital health innovation [28].

Still, there are encouraging signs of **policy alignment with EU priorities** such as the **EHDS**, which aims to enable interoperable, secure, and citizen-controlled access to health data across member states. Initiatives like this, alongside the AI Act and Data Act, could anchor Greece's digital health landscape in **common European legal and ethical standards**, encouraging safer, more consistent deployment of remote care services.

ii. Pathway to the market of Advanced Remote Care Innovations

The interviews conducted in Greece reveal a clear pathway to market for Advanced Remote Care Innovations, marked by both technical sophistication and practical barriers. Greek RPM and telehealth companies are advancing highly interoperable, cloud-based platforms that integrate diverse diagnostic devices with electronic medical records through standards like HL7 and DICOM. These platforms combine real-time monitoring, historical patient data, and video consultations, creating comprehensive telemedicine ecosystems that support conditions such as cardiovascular diseases, chronic illnesses, and post-operative care.

These innovations are not condition-specific but modular and device-agnostic, allowing them to adapt across various medical domains. The emphasis is on **practical functionality,** delivering clinical value through continuous data flow, AI-supported diagnostics, and decision-support tools for physicians. For example, decision systems embedded in their platforms not only facilitate remote diagnosis but also propose treatment plans based on live vitals.

The solutions are being piloted primarily in Greece, and **geographic scaling is limited** by regulatory and reimbursement complexities. Most deployments are localized e.g., municipal hubs in remote areas, where they fill critical gaps in care delivery. However, despite technological maturity, broader deployment is held back by the lack of a clear reimbursement framework and the absence of national strategies for remote care integration. The companies are taking gradual steps towards expansion into other markets such as Cyprus, and they are exploring the markets such as the U.A.E. and the U.S.

Concerning funding, Greek companies often resort to **self-funding or EU project grants** (e.g., through RRF, Horizon Europe) to develop and trial their innovations, as domestic venture capital and insurance support are minimal. Companies prioritize data security and compliance through ISO certifications and adherence to GDPR and HIPAA, ensuring readiness for cross-border applications.

It is evident that while Greek remote care innovators have developed robust and clinically relevant platforms, their market pathway depends on resolving structural barriers mainly, sustainable financing, regulation harmonization, and system-level integration into public healthcare infrastructures.

iii. Barriers, challenges and limitations in the RPM landscape

The RPM landscape in Greece is marked by several persistent barriers and challenges that hinder widespread adoption, despite the availability of advanced technologies. One of the most pressing issues is the **resistance to change among healthcare professionals**, driven by heavy workloads, digital illiteracy, and initial scepticism toward new tools. Many clinicians are reluctant to incorporate remote care systems into their routines, viewing them as an additional burden rather than a support mechanism. This hesitation, however, often shifts once they see the time-saving potential and clinical efficiency of these tools in practice.

A critical technical challenge lies in **interoperability and data integration**. RPM platforms often interface with dozens of devices from different manufacturers, each using its own protocol for data encryption and transfer. Ensuring that these systems communicate securely and accurately with each other, and with national electronic health record systems, is both technically demanding and costly. The absence of a standardized, nationwide framework for interoperability deepens this fragmentation, making scaling difficult.

From a policy perspective, **regulatory uncertainty** remains a major obstacle. There is **no consistent or enforceable reimbursement policy** for RPM services in Greece. Public insurance does not cover teleconsultations or remote monitoring, leaving both providers and patients without clear financial support. Additionally, delays in national-level decisions, such as joint ministerial agreements, stall operational readiness and leave municipalities and care providers without the tools to proceed legally or sustainably. Compliance with EU-level standards such as GDPR, MDR, and ISO adds further complexity, particularly for small or early-stage companies that struggle with the financial and administrative burden of certification.

Funding constraints are another key limitation. Venture capital support within Greece is minimal, and local investors often lack the expertise to evaluate and nurture healthtech ventures. As a result, many RPM solutions rely on internal funding or seek partnerships abroad for scaling opportunities. Public funding mechanisms, while available, tend to be project-based and short-term, leading to a cycle of pilot deployments without long-term continuity.

Despite these challenges, some good practices are emerging. Training initiatives aimed at improving digital skills among healthcare providers and older patients are proving effective. Solutions that were pressure-tested during the COVID-19 pandemic offer valuable insights into crisis-driven adoption models. Furthermore, building modular, device-agnostic platforms and involving healthcare professionals early in the design process appear to be successful strategies for increasing engagement and usability.

iv. Recommendations at National and EU level

To support the broader adoption, implementation, and scaling of RPM solutions in Greece and across Europe, a combination of policy, operational, and technological actions is needed. Interview findings reveal that while the foundational technologies exist and are already in use, **systemic enablers, such as reimbursement, training, and strategic coordination,** must be strengthened to ensure long-term success. The interviews highlight both a readiness and a reluctance in the RPM ecosystem: the tools exist, but the structures to support them lag behind. Scaling remote care will require strong leadership from public institutions, funding security beyond pilot projects, and regulatory clarity that gives health providers the confidence to adopt and integrate new systems.

A **comprehensive roadmap** should begin with clear regulatory alignment at both the national and EU levels. Stakeholders emphasized the need for **consistent definitions, recognition of RPM as a reimbursable medical service, and streamlined certification procedures for RPM platforms and devices.** Public institutions, such as ministries of health and digital governance, are best positioned to lead this regulatory framework development, in collaboration with EU health agencies and standards bodies.

Key recommendations for scaling RPM include:

- **Establish a national reimbursement framework**: Define RPM services eligible for public insurance compensation, including nurse-led monitoring, teleconsultation, and AI-supported diagnostics.
- **Support professional training programs**: Invest in continuous education for healthcare providers to improve digital competencies, particularly for older professionals less familiar with new technologies.
- **Promote public-private partnerships**: Encourage collaboration between tech companies, hospitals, and municipalities to co-develop and co-finance solutions.

- **Foster interoperability standards**: Mandate HL7/FHIR and other common standards to ensure that RPM systems can integrate with EHRs and public health databases.
- **Pilot municipal RPM hubs**: Replicate models that have shown success in rural or underserved areas to demonstrate scalability and local value.
- **Additional good practices** suggested include co-designing tools with end-users (clinicians and patients), allowing for iterative feedback and greater ownership; and establishing RPM innovation clusters to share resources and lessons learned across regions.

Ultimately, successful RPM adoption hinges on **three pillars**:

1. **Policy support** to define standards and remove regulatory ambiguity.
2. **Capacity-building** to empower professionals and reduce resistance.
3. **Ecosystem collaboration** to ensure that innovations are not developed in silos but embedded into everyday healthcare delivery.

By addressing these areas in a coordinated manner, Greece can unlock the full potential of remote care to meet rising healthcare demands and close access gaps, especially in remote and aging communities.

5.3 Lithuania Country Profile

a. Ecosystem Summary

Lithuania's healthcare innovation landscape is actively developing, guided by its national S3 for 2021-2027, which prioritizes health technologies, biotechnologies, and safe food. The country shows steady growth in business R&D expenditure in this area and aims to boost its competitiveness through research and innovation. The ecosystem involves universities, research institutes, growing biotech and medtech companies (SMEs, startups, and established players), clusters like iVita, and supportive government agencies. Key remote care innovations focus on connected devices for chronic disease management (like diabetes and hypertension), post-discharge monitoring, telemedicine platforms, and initial explorations into AI-assisted diagnostics. While showing promise and achieving high innovation rankings, the ecosystem faces challenges related to regulatory clarity, funding accessibility, infrastructure gaps, specialist skills shortages, and achieving seamless data interoperability for RPM solutions.

b. RPM Ecosystem Canvas

KEY FINANCIAL PLAYERS	KEY INDUSTRY TRENDS	DIGITAL INNOVATION SERVICES SUPPORT
▪ Ministry of Economy and Innovation (EIMIN) (via funding programs) ▪ Ministry of Education, Science and Sport (ŠMSM) (via funding programs) ▪ National Grants (e.g., InoStartas, Startuolis) ▪ Co-investment / VC Funds (e.g., Koinvesticinis Fondas, Practica Capital, Iron Wolf Capital) ▪ Business Angels (via Lithuanian Business Angels' Network)	▪ Connected devices for chronic disease management (diabetes, hypertension) ▪ Post-discharge monitoring (wearables) ▪ Telemedicine platforms (video/photo consults) ▪ AI-assisted diagnostics (esp. imaging) ▪ Data integration efforts (RPM + EHR) ▪ Growth in HealthTech, MedTech, BioTech R&D	▪ Innovation Agency Lithuania ▪ Science and Technology Parks (e.g. Kaunas Science and Technology Park) ▪ Health technology cluster iVita ▪ Baltic Health Cluster ▪ LithuaniaBio Association ▪ Incubators/Accelerators (e.g., Baltic Sandbox, Startup Wise Guys, 70V, Up2b, Kalista Ventures)
ESTABLISHED COMPANIES	**KEY START-UPS/SPIN OFFS / SPIN OUTS**	**TOP ACCELERATORS**

▪ Teltonika (Telematics/IoT, expanding into health) ▪ Intersurgical (Medical devices) ▪ ThermoFisher Scientific Baltics (Life Sciences/Biotech) ▪ Hollister Lietuva (Medical products) ▪ Sofneta (Health IT solutions)	▪ Ligence (AI Ultrasound) ▪ Oxipit (AI Radiology) ▪ Zive (Wearable ECG) ▪ Manodaktaras.lt (Telemedicine platform) ▪ Pulsetto (Vagus nerve stimulator) ▪ Vilimed (Assistive tech) ▪ MedDream (Medical imaging platform) ▪ Breathcount (Respiratory monitoring) ▪ BrachyDOSE ▪ Voice Screen (Spin-off) ▪ SynHet (Spin-off) ▪ Exolitus Exosome technologies (Spin-off)	▪ Startup Wise Guys ▪ Baltic Sandbox ▪ 70V ▪ Up2b ▪ Kalista Ventures
HEALTHCARE PROVIDERS	**KEY STAKEHOLDERS**	**RESEARCH CENTRES**
▪ Vilnius University Hospital Santaros Klinikos ▪ Hospital of Lithuanian University of Health Sciences (LSMU) Kauno klinikos ▪ Public & Private Clinics using RPM/Telemedicine (general category) ▪ Manodaktaras.lt (Platform connecting providers/patients)	▪ Ministry of Health ▪ Ministry of Economy and Innovation ▪ Ministry of Education, Science and Sport ▪ Patients & Patient Groups ▪ Healthcare Professionals (Doctors, Nurses, Allied Professionals) ▪ Technology Developers & Companies (Startups, SMEs, Large Enterprises) ▪ Universities & Research Institutions ▪ Innovation Agency Lithuania & Invest Lithuania ▪ Clusters (e.g., iVita, Baltic Health) & Associations (e.g., LithuaniaBio) ▪ State Data Agency (VDA) ▪ Regulatory Bodies (e.g., State Drug Control Authority, Accreditation Service) ▪ Public Procurement Specialists ▪ Hospital Management / Innovation Centers	▪ Lithuanian University of Health Sciences (LSMU) & its Institutes (e.g., Institute of Neuroscience) ▪ Vilnius University (VU) & its Institutes (e.g., Faculty of Medicine) ▪ Kaunas University of Technology (KTU) & its Institutes (e.g., Biomedical Engineering Institute) ▪ Vilnius Gediminas Technical University (VILNIUS TECH) (e.g., Faculty of Mechanics - Medical Engineering Research) ▪ Centre for Innovative Medicine ▪ National Cancer Institute ▪ Santaros Klinikos (Research Departments, e.g., Rehabilitation) ▪ Hospital of LUHS Kauno klinikos (Research activities)
VENTURE CAPITALS	**SEED FUNDING**	

▪ Practica Capital ▪ Iron Wolf Capital ▪ Koinvesticinis Fondas (Co-Investment Fund, functions similarly) ▪ Baltic Sandbox (Listed as VC Fund / Accelerator)	▪ National Grants (e.g., Startuolis, InoStartas from EIMIN) ▪ Accelerator Programs (e.g., Baltic Sandbox, Startup Wise Guys, 70V, Up2b, Kalista Ventures) ▪ Business Angels ▪ "Ankstyvos stadijos ir plėtros fondas III" / "Akceleravimo fondas 3" (Early Stage and Development Fund III / Acceleration Fund 3) (EIMIN) ▪ Early-stage components of Venture Capital funds (e.g., Practica Capital, Iron Wolf Capital)	▪ Lithuanian Sports University

c. National S3 / RIS3 Overview

Lithuania's RIS3 for the period 2021-2027 [35] was officially approved in August 2022. The main goal of this strategy is to boost the country's research and innovation capabilities, encourage the development of new technologies, and ultimately make Lithuania more competitive in the global market.

Within this strategy, a key priority area identified for **research, development, and innovation (R&D&I)** is specifically Health technologies, biotechnologies, and safe food. This broad priority is further broken down into more focused thematic fields. These include developing molecular technologies for medicine and biopharmaceuticals, creating advanced technologies for both personal and public health needs, advancing medical engineering for better early diagnosis and treatment methods, and ensuring safe food through sustainable agrobiological resources.

The Lithuanian S3 strategy is designed to align well with broader EU goals and frameworks. It specifically connects with the priorities of the European Health Data Space, the research and innovation funding program Horizon Europe, and the European Green Deal. In practice, this means Lithuania's S3 focuses on promoting sustainability, encouraging innovation, fostering collaboration between researchers and businesses, supporting data sharing initiatives, and developing new solutions within the health sector.

d. Insights from Key Stakeholders

i. National Regulation & Legislation Framing of Remote Care

The regulatory environment for remote care and RPM in Lithuania is currently in a **developmental phase**, presenting a mix of opportunities and challenges. While there isn't a single, comprehensive national law specifically framing all aspects of remote care mentioned in the provided texts, existing and developing regulations significantly impact its adoption.

Stakeholders identify several regulatory barriers. A key issue is the lack of a structured feedback mechanism to identify and address emerging regulatory hurdles in consultation with the industry. SMEs report difficulties accessing specialized legal and regulatory consulting, especially concerning biomedical research permits, clinical trial approvals, and navigating foreign market rules. Regulatory processes are often perceived as complex and lengthy, particularly around clinical trials and the use of biobank data, leading to calls for simplification.

The development of tele-medicine is specifically hindered by inconsistent regulations for remote healthcare services. Current rules mainly focus on tele-radiology and tele-cardiology, lacking frameworks for other areas like tele-ophthalmology or tele-pathology, and crucially, lacking associated compensation or reimbursement mechanisms. There's also a noted absence of mechanisms for electronic consent in clinical trials, requiring physical presence.

On the data front, while the Health Data Usage Act aims to improve accessibility for research and development, its effective implementation, ensuring data quality and system integration, is highlighted as crucial. The need for clear national guidelines for RPM data handling beyond GDPR is apparent, as the current lack contributes to uncertainty. EU regulations like GDPR are seen positively for ensuring data protection and trust, but compliance adds complexity. Similarly, the EU MDR and IVDR ensure device safety but involve complex approval processes that can slow innovation, particularly for smaller companies lacking notified bodies or expert consultants within Lithuania.

Cybersecurity regulations and the role of national security systems are acknowledged as vital for protecting sensitive health data and critical infrastructure, building a trustworthy RPM ecosystem, although they add layers of complexity to implementation. There's also a call from businesses to review tax laws and public procurement regulations to better support R&D activities in the sector.

ii. Pathway to the market of Advanced Remote Care Innovations

The pathway to market for advanced remote care innovations in Lithuania involves several stages, **starting from research and development often originating in universities** (like LSMU, VU, KTU) **and research centres** (like the Centre for Innovative Medicine). These ideas are then frequently nurtured within startups and spin-offs (such as Ligence, Oxipit, Zive, Manodaktaras.lt) or developed by established companies (like Teltonika moving into health).

Support for this journey comes from **various ecosystem players**. Incubators and accelerators (e.g., Startup Wise Guys, Baltic Sandbox) provide early-stage guidance and mentorship. National funding programs managed by entities like the Ministry of Economy and Innovation (EIMIN) offer grants (e.g., InoStartas, InoBranda) to support R&D and initial commercialization. Venture capital funds (e.g., Practica Capital, Iron Wolf Capital) provide later-stage investment. Science and Technology Parks and clusters (like iVita) offer infrastructure and networking opportunities. The Innovation Agency plays a key role in promoting innovation and providing support services.

However, navigating the pathway presents significant hurdles. **Obtaining necessary certifications** (like CE marking for medical devices) is challenging due to a lack of local notified bodies and specialized consultants. Conducting clinical trials faces regulatory complexities and infrastructure limitations within healthcare institutions. Integrating these new solutions into clinical practice within hospitals (like Santaros Klinikos or Kauno klinikos) is hampered by issues of interoperability with existing EHR systems and a lack of standardized data formats, often relying on basic formats like PDF or CSV initially, with a slow transition towards standards like HL7 FHIR. Furthermore, **securing reimbursement for RPM services** is a major obstacle, as clear pathways and funding models are **largely missing**. Public procurement processes can also be complex for innovative solutions.

Therefore, while Lithuania has the foundational elements for bringing remote care innovations to market, such as strong R&D, a growing startup scene, and support structures, the pathway is often slowed by regulatory bottlenecks, funding gaps particularly for scaling, difficulties in clinical integration and validation, and a lack of clear reimbursement strategies. Successful market entry often requires navigating these complexities, frequently leveraging pilot projects and strong collaborations between developers, researchers, and healthcare providers.

iii. Barriers, challenges and limitations in the RPM landscape

Lithuania's journey in adopting RPM faces several significant barriers and challenges, touching upon regulation, funding, infrastructure, skills, and technology integration.

A major hurdle is **the regulatory environment**. Stakeholders point to complex, slow, and sometimes unclear regulations. This includes difficulties in obtaining permits for biomedical research and clinical trials, a lack of specific frameworks for broader tele-medicine applications beyond tele-radiology/tele-cardiology, and insufficient support for medical device certification (like CE marking) within Lithuania. The absence of clear national guidelines for RPM data handling beyond GDPR and, critically, the lack of established reimbursement models for RPM services create significant financial uncertainty and disincentives for providers.

Funding is another key limitation. While grants exist for R&D, there's a perceived lack of consistent funding schemes covering the entire innovation cycle, especially for the 'patient capital' needed for long development and trial phases common in life sciences. Insufficient state funding, in general, impacts infrastructure development and maintenance, as well as the ability to procure and sustain RPM technologies. The high cost of hardware, software, and ongoing maintenance further compounds these financial barriers.

Infrastructure challenges are prominent. There's an underdeveloped infrastructure for practical training and clinical/preclinical research needed for RPM validation. Accessing and effectively using existing RDI infrastructure can be difficult, and maintaining expensive equipment is a struggle for research institutions. Specifically for RPM, interoperability is a major technical problem. Integrating new RPM solutions with existing, often fragmented, HER systems is difficult due to proprietary data formats, lack of standardized APIs, and the slow adoption of standards like HL7 FHIR. Reliable connectivity, especially in more remote areas, can also be a concern for real-time data transmission.

Competency and skills gaps are widespread. There's a shortage of specialists in areas crucial for RPM development and deployment, including clinical trials, medical device regulation, bioinformatics, and health economics. Digital literacy among both patients (especially older individuals) and some healthcare professionals limits effective RPM use. Furthermore, there's a mismatch between the skills taught in academic programs and the specific needs of the industry, particularly concerning startup-specific competencies like commercialization and regulation. Low salaries in the sector compared to other industries or opportunities abroad exacerbate this brain drain.

Finally, **organizational and operational barriers** exist. Resistance to changing established workflows within healthcare institutions can slow adoption. Integrating RPM data meaningfully into daily clinical practice without overburdening clinicians requires careful planning and

workflow redesign. Ensuring data reliability and managing cybersecurity risks associated with connected devices are ongoing concerns.

iv. Recommendations at National and EU level

Based on the challenges and opportunities identified by stakeholders in Lithuania, several recommendations emerge for advancing the adoption, implementation, and scaling of RPM solutions at both national and potentially EU levels:

1. **Develop Clear Regulatory Frameworks and Reimbursement Models**: Nationally, there is a critical need to establish clear, simplified, and consistent regulations specifically for telemedicine and RPM services, going beyond current limitations. This includes creating straightforward processes for approvals (clinical trials, device certification) and developing defined reimbursement pathways to provide financial incentives for healthcare providers to adopt and utilize RPM solutions. Aligning national regulations with EU frameworks like MDR/IVDR while seeking ways to support SMEs through these processes is important.
2. **Ensure Sustainable and Coordinated Funding**: Implement comprehensive funding schemes that support the entire RPM innovation lifecycle, from basic research through R&D, clinical validation, and market scaling. This requires better coordination between funding institutions (like EIMIN, ŠMSM) to avoid gaps or overlaps in calls. Specific mechanisms to encourage long-term 'patient capital' investment and venture capital involvement in high-risk, strategically important projects are needed. Ensure sufficient funding for maintaining RDI infrastructure.
3. **Prioritize Interoperability and Data Standards**: Actively promote and incentivize the adoption of interoperability standards like HL7 FHIR for seamless data exchange between RPM platforms, devices, and national EHR systems. Support the development of necessary digital infrastructure and potentially explore shared platforms or middleware solutions. Continued efforts to implement the Health Data Usage Act effectively, ensuring data quality and accessibility for secondary use (research, innovation), are vital. Learning from successful data exchange models like Estonia's 'X-Road' could be beneficial.
4. **Strengthen Skills and Competencies:** Address the identified skills gaps by fostering closer collaboration between academia and industry to align training programs with market needs (e.g., clinical trials, bioinformatics, regulatory affairs, commercialization). Implement programs to enhance digital literacy for both healthcare professionals and

patients. Create more attractive career pathways and competitive salaries within the life sciences sector to retain talent. Simplify immigration procedures to attract international specialists.

5. **Foster Collaboration and Ecosystem Support:** Strengthen mechanisms for collaboration between research institutions, healthcare providers, industry (startups, SMEs, large companies), and government agencies. Support clusters, associations, and Science and Technology Parks in their role as ecosystem facilitators. Provide better access to specialized consulting (legal, regulatory, IP protection) for SMEs and startups.
6. **Focus on User Needs and Evidence Generation:** Encourage patient-centered design in RPM solutions, ensuring ease of use and accessibility. Systematically evaluate the clinical and economic impact of RPM implementations through pilot projects and ongoing monitoring, generating robust evidence to demonstrate value and guide further adoption and refinement.
7. **Develop a National RPM Roadmap:** Create a strategic national roadmap for RPM adoption, involving all key stakeholders. This roadmap should outline priorities, define clear goals and KPIs, address the barriers identified, and align with the national S3 and relevant EU initiatives like the European Health Data Space.

5.4 Spain Country Profile

a. Ecosystem Summary

Spain's telemonitoring ecosystem is rapidly gaining momentum, characterized by a blend of robust academic innovation and a burgeoning wave of digital health startups. The heart of this dynamic scene lies in major urban centres such as Madrid, Barcelona, and Valencia, where a collaborative effort among public institutions, private companies, and research facilities is driving significant progress [36, 37].

Leading universities and specialized research centres, such as the Universitat Politècnica de València (UPV), are actively engaging in EU-backed projects that address chronic disease management and elderly care, underscoring Spain's proactive strategy to advance its digital healthcare framework [38, 39]. This collaborative ecosystem is further strengthened by the growing presence of innovative startups, which are contributing cutting-edge telemonitoring solutions and digital health services, supported by reports highlighting the expansion of Spain's health tech sector [40, 41].

Together, these actors form a vibrant network that leverages public-private partnerships and European funding to foster innovation, improve patient outcomes, and position Spain as a leader in telemonitoring and digital health transformation [39, 37].

b. RPM Ecosystem Canvas

KEY FINANCIAL PLAYERS	KEY INDUSTRY TRENDS	DIGITAL INNOVATION SERVICES SUPPORT
▪ AEI- Agencia Estatal de Investigación ▪ CDTI- Centro para el Desarrollo Tecnológico Industrial ▪ FUNDACIÓN BBVA ▪ FUNDACIÓN LA CAIXA ▪ BANCO SANTANDER	▪ Integration of AI and predictive analytics ▪ Hybrid care models (in-person care with remote follow-up) ▪ Adoption of wearables biosensors ▪ Co-creation involving end-users	▪ Red.es ▪ Digital Health Strategy of the Spanish NHS ▪ SAS ▪ DIH DATAlife
ESTABLISHED COMPANIES	**KEY START-UPS/SPIN OFFS / SPIN OUTS**	**TOP ACCELERATORS**
▪ HumanITcare ▪ Neuroelectrics ▪ Meditech Capital ▪ Health Circuit ▪ REMEDI ▪ Dedalus Spain	▪ MATCH Biosystem ▪ Neil ▪ mDurance ▪ Eumedical ▪ Medicsen ▪ Dawako Medtech	▪ Beyond pre-accelerator ▪ Eleven Ventures ▪ Founder Institute ▪ Able Activator

	▪ Mediktor	
HEALTHCARE PROVIDERS	**KEY STAKEHOLDERS**	**RESEARCH CENTRES**
▪ SMS	▪ Andalusian Health Cluster	▪ Hospital Universitario La Paz - Neurology Department ▪ Instituto de Salud Carlos III (ISCIII) ▪ Vall d'Hebron Research Institute (VHIR) ▪ CIBERNED (Centro de Investigación Biomédica en Red de Enfermedades Neurodegenerativas) ▪ Biocruces Bizkaia Health Research Institute
	VENTURE CAPITALS ▪ Ysios Capital ▪ Asabys Partners ▪ Inveready	

c. National S3 / RIS3 Overview

The **Spanish Strategy for Science, Technology and Innovation 2021–2027 (EECTI)** [42] serves as the national framework defining the principles, objectives, and priorities to address strategic sectoral challenges through R&D and innovation. As established by Law 14/2011 [43] on Science, Technology and Innovation, the EECTI is coordinated by the stakeholders of the Spanish Science, Technology and Innovation System (SECTI), who seek to align the national strategy with regional R&D&I programming and with broader EU innovation policies, particularly Horizon Europe and the Cohesion Policy 2021–2027. The EECTI 2021–2027 also functions as Spain's national S3. Its participatory approach and thematic investment focus contribute to fulfilling the enabling condition of "Good governance of the national/regional smart specialisation strategy" under Policy Objective 1, "A Smarter Europe", of the current Cohesion Policy.

Mirroring this national framework, the Research and Innovation Smart Sustainable Specialisation Strategy (**RIS4) of the Region of Murcia 2021–2027** [44] places Health & Well-being under the pillar "Quality of Life". RPM and virtual care are explicitly recognised as areas of high potential for both economic diversification and social impact. Governance is structured

through Thematic Working Tables and a dedicated Transformative Pathway on Health & Well-being, in which the Servicio Murciano de Salud (SMS) plays a vital and multifaceted role:

- As a living lab, providing real-world infrastructure for testing and scaling innovation through its 22 public hospitals and over 900 primary care centres.
- As a data provider, contributing health-related data for research projects involving AI, big data, and advanced analytics.
- As an innovation purchaser, engaging in region-level pre-commercial procurement (PCP) schemes to drive the adoption and market integration of novel healthcare technologies.

The RIS4 policy mix includes dedicated calls for health-related public procurement of innovation (CPI), co-creation mechanisms, and DIHs as flagship instruments to accelerate the deployment of RPM solutions and foster smart specialisation aligned with both national and European strategic goals.

d. Insights from Key Stakeholders

i. National Regulation & Legislation Framing of Remote Care

Spain allows the use of telemedicine, although it does not yet have a single, dedicated legal framework regulating remote care. Instead, this practice is supported by **a combination of national and European regulations**. The General Health Law 14/1986 [] lays the foundation of the healthcare system, while the Patient Autonomy Act 41/2002 ensures patients' rights to information and informed consent—both relevant in remote settings. Data privacy is governed by the Spanish Data Protection Act [45], aligned with the EU GDPR [6], ensuring secure handling of sensitive health data.

Further legal references include Royal Decree 81/2014 [46], which transposes the EU directive on cross-border healthcare and enables remote services between Member States, and the Spanish Medical Code of Ethics, which mandates professional identification and confidentiality in all care modalities, including digital. For technologies used in remote care, regulations such as Royal Decree 1591/2009 [47] and EU MDR [3] are directly applicable.

Within this regulatory landscape, the **PHArA-ON project** was implemented in the Region of Murcia as part of the EU's drive to promote digital transformation in healthcare for active and healthy ageing. The project, focused on remote care for chronic heart failure patients, demonstrated how such services could be deployed effectively within existing legal and ethical frameworks in Spain. The pilot respected national and EU legislation on data protection,

patient rights, and medical device certification, highlighting the feasibility of scaling up remote monitoring within public healthcare structures.

Other **relevant instruments** include:

- The Patient Autonomy Act 41/2002 (informed consent) [48].
- The Information-Society & e-Commerce Act 34/2002 (online service obligations) [49].
- The Public-Health Act 33/2011 (confidentiality in population health actions) [50].
- Spain's National Digital-Health Strategy 2021-2026 [51].
- The Royal Decree 957/2020 on observational clinical studies (applicable to remote-monitoring devices) [52].
- The new EU Health-Technology-Assessment Regulation 2021/2282 [53] and the recently adopted EHDS [9], which sets common rules for cross-border telemedicine and EHR interoperability.

ii. Pathway to the market of Advanced Remote Care Innovations

Spain is making progress from invention to market-ready remote care solutions, but it is still a difficult process needing cooperation among clinical, technical, and regulatory players. Particularly from areas like Galicia and Andalusia, the insights provided in the interviews reveal that success relies less on technology itself and more on how well it fits into actual healthcare requirements and processes.

Rather than independent pilots, stakeholders stress the need of creating solutions starting first with healthcare providers and patients. The possibility of acceptance and long-term viability is raised by co-design, early clinical validation, and congruence with local treatment procedures.

Although some areas have been able to go from testing to application, greater market access is still hindered by uneven infrastructure, inadequate funding for scale-up, and broken systems across countries. Still, the increasing alignment of national and EU policies such as digital health action plans and interoperability solutions is helping to define a more obvious course forward.

iii. Barriers, challenges and limitations in the RPM landscape

Despite growing interest across Europe, the RPM landscape continues to face several critical barriers that hinder its wider adoption and integration into routine healthcare. A consistent theme across the interviews is the **reluctance of healthcare professionals** to adopt new digital tools, especially if they are perceived as an additional workload or not clearly aligned

with their clinical routines. While patients often adapt quickly to remote monitoring technologies, professionals may be reluctant to change established workflows without strong institutional support and clear benefits.

In Spain, the **decentralized structure of the healthcare system** is a major obstacle. Each autonomous region operates its own digital infrastructure and procurement processes, creating a fragmented ecosystem where interoperability is limited and scaling solutions nationally becomes a logistical and technical challenge. Even with the use of standards such as HL7, practical integration between systems is often insufficient.

While many RPM projects receive support during early development or pilot phases, there is a well-documented **funding gap** during the implementation and scaling phase, often referred to by stakeholders as the "valley of death". This gap prevents successful pilots from being scaled up into sustainable services.

Several interviewees pointed out that in many regions, roles and responsibilities around telecare are not clearly defined, particularly when it comes to follow-up, data management or cross-sectoral collaboration (e.g. between social care and health services). This lack of clarity hinders coordination and continuity of care.

Although the overall regulatory environment is improving, stakeholders still report **uncertainty around compliance requirements**, particularly in relation to data protection (GDPR), medical device certification and reimbursement eligibility. In some cases, the lack of a CE mark for monitoring tools has delayed their clinical use or prevented them from being covered by public health systems.

Finally, even when RPM tools are well received, there are **concerns about scalability and equitable access**. Some rural or underserved areas may face difficulties due to connectivity issues, lack of digital literacy, or insufficient support structures for patients and caregivers. Without proactive strategies, RPM could inadvertently exacerbate existing health inequalities.

These challenges suggest that advancing RPM solutions requires more than technological innovation. It requires coordinated policies, sustainable funding models, professional commitment and a strong emphasis on equity and user-friendliness.

iv. Recommendations at National and EU level

Based on the interviews conducted with regional and European stakeholders, several clear recommendations emerge to support the successful integration of RPM solutions into

healthcare systems. These recommendations focus on policy design, institutional support, regulatory alignment and long-term sustainability.

Innovations must be developed in close collaboration with healthcare professionals and patients. Co-design processes ensure that RPM tools address real clinical needs and are intuitive for both professionals and end-users. Early involvement of end-users also builds trust and increases the likelihood of adoption.

Innovations must be developed in close collaboration with healthcare professionals and patients. Co-design processes ensure that RPM tools address real clinical needs and are intuitive for both professionals and end-users. To bridge the well-recognized 'valley of death', national and EU-level strategies should include specific funding lines not only for R&D and piloting, but also for implementation and scaling. This includes financial incentives for public health providers to adopt validated RPM tools as part of routine care.

Support for a harmonized digital health infrastructure is essential. The development and enforcement of common interoperability frameworks, including unified data formats and integration standards (e.g. HL7, FHIR), would allow RPM solutions to work seamlessly across regions and countries. Innovations must be developed in close collaboration with healthcare professionals and patients. **Co-design processes** ensure that RPM tools address real clinical needs and are intuitive for both professionals and end-users. Early involvement of end-users also builds trust and increases the likelihood of adoption. To bridge the well-recognized 'valley of death', national and EU-level strategies should include specific funding lines not only for R&D and piloting, but also for implementation and scaling. This includes financial incentives for public health providers to adopt validated RPM tools as part of routine care.

Simplifying and clarifying the regulatory process is key. Stakeholders are calling for faster and more transparent guidance on GDPR compliance, CE marking of digital health tools and reimbursement eligibility. EU bodies could play a leading role in providing cross-country guidance and certifying trusted RPM platforms.

Successful practices - such as Galicia's Telea or Andalusia's patient portal - should be formally documented and shared through interregional cooperation platforms, so that other regions can replicate and adapt proven models. The EU could support this through structured peer learning networks.

Resistance by health professionals is often due to a **lack of awareness or training**. National policies should include **capacity-building programmes and change management strategies** to help professionals understand the benefits and proper use of RPM tools.

Finally, **RPM solutions should not be seen as isolated innovations**. Their success depends on their integration into broader digital health plans, including electronic health records, teleconsultation platforms and population health monitoring.

5.5 Portugal Country Profile

a. Ecosystem Summary

Portugal is emerging as a strong player in remote care innovation, with a specific focus on musculoskeletal rehabilitation through RPM solutions. The country's ecosystem benefits from proactive public initiatives such as the National Strategic Telehealth Plan (PENTS), collaborative health clusters, and the integration of advanced digital tools in clinical practice. Notable deployments include wearable-supported rehabilitation technologies and telemonitoring systems that have significantly reduced emergency episodes and hospital admissions.

b. RPM Ecosystem Canvas

KEY FINANCIAL PLAYERS	KEY INDUSTRY TRENDS	DIGITAL INNOVATION SERVICES SUPPORT
▪ Portugal Ventures ▪ Armilar Venture Partners ▪ Bynd VC ▪ Indico Capital Partners ▪ Caixa Capital ▪ Shilling Capital Partners	▪ Musculoskeletal rehab technologies ▪ Patient-centered telemonitoring ▪ Integration of wearable devices in routine care ▪ Development of digital platforms for patient engagement	▪ EIT Health ▪ Health Cluster Portugal ▪ Citizen Area Platform (RSE Área do Cidadão) ▪ e-Prescriptions System
ESTABLISHED COMPANIES	**KEY START-UPS/SPIN OFFS / SPIN OUTS**	**TOP ACCELERATORS**
▪ Clinks (partnership with public institutions) ▪ Sword Health (wearables for rehabilitation)	▪ Sword Health	▪ Startup Lisboa ▪ Startup Braga ▪ Beta-i ▪ BGI (Building Global Innovators) ▪ UPTEC
HEALTHCARE PROVIDERS	**KEY STAKEHOLDERS**	**RESEARCH CENTRES**
▪ Santa Maria Health School ▪ Centro Hospitalar Lisboa Norte ▪ Centro Hospitalar Universitario de Coimbra ▪ Braga Clinical Centre ▪ Centro Hospitalar Universitário de Lisboa Central ▪ Centro Hospitalar de São João	▪ Ministry of Health ▪ Regional hospitals ▪ Physiotherapy networks ▪ Agência Nacional de Inovação – ANI ▪ Administrações Regionais de Saúde – ARS	▪ University of Lisbon ▪ University of Porto ▪ University of Coimbra

Initial Public Offering (IPO)	VENTURE CAPITALS
Portugal's healthtech sector has seen limited IPO activity to date, with most startups remaining private or seeking international funding rounds.	▪ Portugal Ventures ▪ Indico Capital ▪ Armilar ▪ Bynd VC ▪ Shilling Capital

c. *National S3 / RIS3 Overview*

Portugal's S3 aligns closely with EU frameworks such as Horizon Europe and the European Health Data Space. Health is a recognized priority domain, particularly in relation to digitalization, personalized medicine, and telehealth. The ecosystem integrates research institutions, public hospitals, private companies, and innovation agencies to foster solutions in chronic care management and health data interoperability. Key funding sources include ERDF, Horizon Europe, and Portugal 2020 framework.

d. *Insights from Key Stakeholders*

Stakeholders emphasize the importance of user-friendly RPM technologies, patient empowerment, and active participation of physiotherapists and caregivers. Resistance from patients and limited digital literacy remain challenges, addressed via in-person support and training sessions.

i. National Regulation & Legislation Framing of Remote Care

The PENTS (Plano Estratégico Nacional para a Telessaúde) [54] sets a strategic direction for telehealth deployment across Portugal. While there is strong political will and alignment with EU digital health policies, barriers persist in ensuring uniform infrastructure and incentivizing healthcare professionals. Regulatory gaps include reimbursement schemes and integration of RPM into national health service workflows. The National Strategic Telehealth Plan (PENTS) 2019–2022, developed by the Shared Services of the Ministry of Health (SPMS) through the National TeleHealth Center (CNTS), laid the foundation for telehealth in Portugal. The plan aimed to enhance the use of Information and Communication Technologies (ICT) in healthcare, promoting better articulation, integration, and quality of care.

In alignment with European initiatives, Portugal has been actively participating in the development of the EHDS. SPMS has contributed to establishing guidelines for health data

management, promoting interoperability, and ensuring secure access to health data across borders.

ii. Pathway to the market of Advanced Remote Care Innovations

Portugal's pathway to market is supported by hospital-led pilots, collaborations with high-tech startups, and alignment with national digital health goals. Companies like Sword Health and Clinks have demonstrated successful integration of wearables and telemonitoring tools into public health settings, benefiting particularly chronic musculoskeletal patients. Key to market entry are public-private partnerships and alignment with patient needs through co-design.

Portugal has demonstrated a growing commitment to integrating telemonitoring into its healthcare system. A comprehensive analysis identified 46 TM initiatives across the country, highlighting an increasing adoption by healthcare institutions. This growth has been facilitated by the telehealth governance model and public reimbursement mechanisms, particularly during the COVID-19 pandemic. However, challenges such as low digital literacy among patients and providers, lack of care integration, and resource scarcity continue to hinder the scalability of these initiatives.

iii. Barriers, challenges and limitations in the RPM landscape

The development and implementation of RPM systems face several persistent barriers and limitations that hinder their full potential. One of the primary challenges is **patient acceptance**, particularly among the elderly, where limited digital literacy and reluctance to engage with technology reduce the effectiveness and reach of RPM solutions. Moreover, **interoperability issues** between hospital information systems and external platforms continue to complicate data integration and coordinated care. **Regulatory frameworks remain unclear,** especially concerning **reimbursement policies**, which create uncertainty for healthcare providers and limits broader adoption. Additionally, significant **disparities in infrastructure between urban and rural areas** pose a challenge to ensuring equitable access to RPM services. Finally, **workforce engagement and the availability of dedicated training programs** are still insufficient, underlining the need for continued investment in capacity building and professional development.

iv. Recommendations at National and EU level

To unlock the full potential of RPM in the Portuguese and EU healthcare systems, a multifaceted strategic approach is required. The following **recommendations** are suggested:

- Enhancing digital literacy among patients and caregivers through structured educational programs is essential to ensure meaningful engagement with RPM technologies.
- The establishment of clear and sustainable reimbursement frameworks, fully integrated into public healthcare, will support widespread adoption.
- Aligning national health IT infrastructures with EU interoperability standards will further facilitate data exchange and system integration. Proven models, such as the Sword Health pilot, should be scaled across regions through dedicated structural funding.
- Encouraging co-creation schemes between public hospitals and startups can stimulate innovation, while targeted incentives for professional training in digital physiotherapy and telemonitoring will help build a competent workforce.
- Continuous monitoring and evaluation of RPM implementations will be crucial to guide iterative improvements and inform future policy development.

6. Conclusions & Recommendations

The mapping of remote care innovation ecosystem across seven European countries, Belgium, Netherlands, Bulgaria, Greece, Lithuania, Spain, and Portugal, highlights the **maturity differences, structural gaps, and emerging opportunities in RPM and telehealth solutions**. While advanced economies such as the Netherlands and Belgium show progress in digital integration and reimbursement pathways, LDRs like Bulgaria and Lithuania face critical challenges, particularly in regulation, funding, and infrastructure. Common across all regions, however, is the recognition that **RPM holds transformative potential** for addressing chronic conditions, improving healthcare access, and enabling data-driven health governance, provided that key enabling conditions are met.

Stakeholders emphasized that **systemic issues including interoperability, reimbursement models, digital literacy, regulatory bottlenecks, and workforce preparedness**, continue to hinder wide-scale RPM deployment and adoption. Encouragingly, several pilot programs, academic innovations, and public-private partnerships demonstrate scalable models and good practices across regions.

Derived from stakeholder input across all Country Profiles, the **following priority actions** are recommended to accelerate adoption, implementation, and scaling of RPM technologies:

1. Develop Clear and Aligned Regulatory Frameworks

National regulations for telemedicine and RPM should be simplified and harmonized with overarching EU frameworks such as the MDR, GDPR, and the EHDS Regulation. Fast-track certification and approval processes must be established to accelerate RPM deployment, including mechanisms for mutual recognition across Member States to support EU-wide scalability.

2. Design and Implement Sustainable Reimbursement Models

Reimbursement schemes for telemonitoring, nurse-led services, AI-supported diagnostics, and digital physiotherapy must be institutionalized within national healthcare systems. These models should be grounded in robust health technology assessment, cost-effectiveness analyses and economic impact assessments to guide policy and ensure long-term financial sustainability.

3. Strengthen Interoperability, Cybersecurity and Data Infrastructure

Common technical standards, such as HL7 FHIR, should be enforced for seamless integration of RPM data into EHRs and other health information systems. Ensure cybersecurity-by-design and trust. Investments are needed to upgrade digital infrastructure, particularly in rural and underserved areas, to support real-time data flow and equitable access to care.

4. Invest in Digital Skills and Professional Training

Healthcare professionals require dedicated training programs, supported at both national and EU levels, to build competencies in digital literacy, data analytics, and telemonitoring operations. Academic curricula must also evolve to reflect industry needs in areas like regulatory affairs, clinical trials, and commercialization.

5. Support Innovation through Structured and Scalable Funding

Public and private funding mechanisms should support the full innovation lifecycle, from R&D to market validation and scale-up, addressing both early-stage and long-term capital needs. Blended finance models involving EU structural funds, national grants, and venture capital are essential to de-risk investment and ensure continuity. Encourage the use of public procurement tools such as Pre-Commercial Procurement (PCP) and Public Procurement of Innovative Solutions (PPI) to create demand for RPM technologies.

6. Promote Ecosystem Collaboration and Co-Creation

Collaborative frameworks should bring together startups, hospitals, universities, and municipalities to co-develop RPM solutions tailored to clinical and patient needs. Regional innovation hubs and test-beds can serve as platforms to share practices, validate solutions, and foster cross-sector synergy.

7. Embed User-Centered Design and Real- World Evidence Generation

Patients and healthcare providers should be actively involved throughout the development process to ensure RPM tools are usable, acceptable, and clinically relevant. Longitudinal studies and pilot programs are critical to generating real-world evidence that supports scale-up and policy decisions.

8. Monitor Implementation and Encourage Continuous Adaptation

National observatories or digital health monitoring bodies should be established to track RPM adoption, user feedback, and systemic integration. Continuous data collection and iterative policy updates will help adapt to emerging technologies and ensure that innovation remains aligned with healthcare system needs.

Glossary

Digital health: The field of knowledge and practice associated with the development and use of digital technologies to improve health. Digital health expands the concept of e-health to include digital consumers, with a wider range of smart devices and connected equipment. It also encompasses other uses of digital technologies for health, such as the Internet of Things, AI, big data and robotics [55].

Interoperability: The ability of different applications to access, exchange, integrate and cooperatively use data in a coordinated manner through shared application interfaces and standards, and within and across organizational, regional and national boundaries, to provide seamless portability of information and optimize health outcomes [55].

Internet of things (IoT): A global infrastructure for the information society, enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving interoperable information and communication technologies [56].

Remote Patient Monitoring (RPM): It allows health providers to monitor disease and symptom progression remotely and then engage with patients virtually to modify care plans and to provide education on self-care, based on changes in the patient's condition [57].

Smart Specialisation Strategies (S3): In 2010, the European Commission called on national and regional governments to develop Smart Specialisation Strategies (S3) for research and innovation (R&I) to encourage all European regions to discover their competitive advantage. Participation, prioritisation and localisation, the key pillars of S3, have been fully absorbed in regional development practice [58].

Medical Devices: The physical hardware and interconnected software elements of the device is intended by its manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes defined under Article 2(1) of Regulation (EU) 2017/745 (Medical Device Regulation) to deliver telemedicine (i.e. clinical/medical services at a distance) [3].

Telemedicine: The delivery of health care services where distance is a critical factor by health care professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and the continuing education of health care workers, with the aim of advancing the health of individuals and communities [55].

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ANNEXES

A. EU Mapping Template

For the EU Mapping, the partnership followed a Mapping Template in Excel like the following one to collect information about the nine categories. The actual Mapping Template included more columns for information different for each category, such as contact details, technological aspects etc.

No.	Entity or Inititiative name	Type of Entity	Country	Region	Website URL	Primary Thematic Area (Musculoskeletal, Neurological, ICU, other)	Primary Tech Area	Innovation	Proof of Impact (e.g. funding received, Reimbursement, Certifications (MRD), Interoperability standards adoption)
1.LEADING INITIATIVES & KEY PROJECTS									
2.CORPORATES									
3.NETWORKS									
4.ACCELERATORS									
5.STARTUPS									
6.RESEARCH CENTERS and RTOs									
7.CLUSTERS and INNOVATION HUBS									
8. POLICY MAKERS									
9.VENTURE FUNDS									

B. Interview Questionnaire

Purpose of interview

We will interview representatives of national and EU federations and leading Medtech clusters and R&D entities from our network **to map advanced remote care innovations, data exchange formats and stakeholders, but also good practices informing on best routes for scaling.** The most advanced remote care monitoring innovations will be put forward and analyzed to draw learnings on their pathway to market and key hurdles faced in the process.

Who should answer?

– Representatives of national and EU federations and leading Medtech clusters and R&D entities from our network

Personal data

Name:

Organization:

Position:

Email:

City:

Country:

Federation (National/ European):

Type of organization (R&D entity, Medtech cluster):

Field of expertise:

Years of RPM experience:

THEMATIC AXES

Advanced remote care innovations

1. Could you outline the key innovations in Remote Patient Monitoring (RPM) currently being implemented within your region? Which are their detailed features? Please, specify their value and their impact on stakeholders. (*e.g. new technologies introduced, new legislation, new funding tools, new companies*)

2. In which specific medical domains are these RPM innovations being applied? (*e.g. musculoskeletal, neurological, critical care*)

3. Which geographical regions are benefiting from the implementation of these innovations?

4. What data exchange standards or/and architecture models exist in RPM solutions? Which data exchange formats do they use (concerning both software and hardware etc.)? (*e.g. interoperability framework in the market, HL7, Continua* https://www.pchalliance.org/about-continua)

Stakeholders

5. Which are the target groups to which your RPM solutions are addressed to? *(e.g. patients, healthcare professionals, management department in healthcare settings, insurance companies etc.*

6. Who should collaborate on the effective adoption and implementation of RPM solutions? *(e.g. healthcare professionals, developers, technical staff, regional health authorities, public authorities etc.)*

Challenges, limitations & good practices

7. What are the main challenges you typically encounter when adapting to new therapy with technology, and how do these challenges influence your decision-making or approach to integrating these innovations into your work or daily life?

8. What kind of challenges may arise concerning the connectivity and interoperability of the data collected and exchanged by RPM solutions?

9. What are the main obstacles that may prevent the adoption and implementation of RPM initiatives?

10. Does the existing regulatory framework at national and European level assist or hinders the adoption and implementation of RPM initiatives? / What role does the national security system play in the adoption and implementation of RPM initiatives in the EU (ethics regulatory framework, cybersecurity, protection of critical health infrastructures, safeguarding sensitive medical data etc.)?

11. What factors most strongly influence your work, and where do you typically find the motivation or inspiration to embrace change and innovation?

12. What are the Good Practices or Guidelines that support or are implemented in your RPM solutions? How do they work?

Recommendations informing the adoption, implementation and scaling of RPM solutions

13. What steps could be taken to develop a comprehensive roadmap, concerning the adoption of RPM solutions in Europe in terms of state of development, degree of acceptability by key stakeholders?

14. Who should take the lead in driving these initiatives?

15. Do you recommend any additional good practices or guidelines to support the adoption, implementation, and scaling of RPM solutions?

Interoperable Remote Health Innovation Brought to Scale