



# STRENGTHENING THE SOUTH-EAST EUROPE SMART HEALTH REGIONAL EXCELLENCE AND BOOSTING THE INNOVATION POTENTIAL

HORIZON-WIDERA-2022-ACCESS-04-01, Pr. N.: 101087483

## Deliverable 2.1 State of play and Strategy for innovation ecosystem transition path

WP2 Smart Health Regional ecosystem enablement and  
transformational framework of change

March  
2024

Type of document:	Deliverable - Document, report
Dissemination level:	PU - Public
Lead beneficiary:	Hellenic Digital Health Cluster (HDHC)
Authors & Contributors:	<p>Dimitris Katehakis, Angelina Kouroubali, Eva Salmatani (HDHC)</p> <p>Carmen Mihai (IMAGO-MOL)</p> <p>Ersi Papayianni (AMEN)</p> <p>Aneta Piperkova, Kristina Eskenazi, Yordan Dimitrov, Dimitar Dimitrov (BIOBG)</p> <p>Jordan Kane (CIT)</p> <p>Andreas Panayides, Maria Matsangidou (CYENS)</p> <p>Georgi Petkov, Irena Pavlova</p> <p>Lora Georgieva (GATE)</p> <p>Olga Galanets (IDSA)</p> <p>Miriam Labrado (INNEUROPE)</p> <p>Raluca Ciobotaru, Alina Irimia, Andreea Popa (UEFISCDI)</p> <p>Georgios Gogolos (JOIST)</p> <p>Daniel Hadjittofi, Marios Neophytou (NeHA)</p> <p>Anastasia Arnaudova (TBS)</p> <p>Stavri Vasileiou (3AeHealth)</p>
Version:	Final
Due Date of document:	01/03/2024
Delivery Date of document:	29/03/2024

## Document History

Version	Date	Contributor	Comments
0.1	09/02/2024	HDHC IMAGO-MOL	Development of the deliverable 's draft structure and division of work between the partners
0.2	01/03/2024	All partners (HDHC, IMAGO-MOL, INSO, CIT, GATE, AMEN, UEFISCDI, JOIST, NeHA, 3AeHealth, CYENS, TBS, BIOBG, IDSA)	Development of the Deliverable by all partners. Partners will be responsible for developing short parts of the deliverable.
0.3	15/03/2024	HDHC IMAGO-MOL	Final adjustments and harmonization of the deliverable.
0.4	28/03/2024	CIT & BIOBG	Internal review by CIT & BIOBG
1.0	29/03/2024	HDHC IMAGO-MOL GATE	Final Deliverable 2.1. State of play and Strategy for innovation ecosystem transition path

## Consortium

Logo	Partner	Country
	SOFIA UNIVERSITY ST KLIMENT OHRIDSKI	Bulgaria
	TELELINK BUSINESS SERVICES EAD	Bulgaria
	HELLENIC DIGITAL HEALTH CLUSTER PRIVATE COMPANY	Greece
	INNEUROPE INITIATIVE S.L.	Spain
	JOIST	Greece
	CLUSTERUL REGIONAL INOVATIV DE IMAGISTICA MOLECULARA SI STRUCTURALA NORD-EST (IMAGO-MOL)	Romania
	STIFTELSEN CHALMERS INDUSTRIKTEKNIK	SE
	Health & Life Sciences Cluster Bulgaria	Bulgaria
	UNITATEA EXECUTIVA PENTRU FINANTAREA INVATAMANTULUI SUPERIOR A CERCETARII DEZVOLTARII SI INOVARII	Romania
	CYENS - CENTRE OF EXCELLENCE	Cyprus
	STEGI EVGIAS ARCHAGGELOS MICHAEL KAIMAKLIOY	Cyprus
	National eHealth Authority	Cyprus
	Ministry of Electronic Governance	Bulgaria
	3AE HEALTH LTD	Cyprus
	INTERNATIONAL DATA SPACES EV	Germany

## Table of Contents

<b>1</b>	<b>Introduction.....</b>	<b>5</b>
<b>2</b>	<b>The VELES Excellence Hub project .....</b>	<b>7</b>
<b>3</b>	<b>Methodology for data collection.....</b>	<b>8</b>
3.1	<i>Objectives .....</i>	8
3.2	<i>Analytical Approach.....</i>	8
3.3	<i>Research Participants' Selection.....</i>	9
<b>4</b>	<b>State-of-play .....</b>	<b>10</b>
4.1	<i>Digital health innovation ecosystems .....</i>	10
4.2	<i>Good practices in advanced countries.....</i>	11
4.2.1	Germany .....	11
4.2.2	Spain.....	14
4.2.3	Sweden .....	14
4.3	<i>Widening countries innovation ecosystems dimensions related to health data .....</i>	15
4.3.1	Technical infrastructure for primary and secondary use .....	15
4.3.2	Data infrastructures and readiness .....	18
4.3.3	Governance framework.....	22
4.3.4	Human resources, skills and training.....	24
4.3.5	Legal and regulatory framework regarding health data spaces.....	26
4.3.6	Stakeholders' role in the National, regional, local ecosystems .....	29
4.4	<i>Good Practices in widening countries .....</i>	32
4.4.1	Bulgaria.....	32
4.4.2	Cyprus .....	34
4.4.3	Greece .....	34
4.4.4	Romania.....	36
<b>5</b>	<b>SWOT Analysis.....</b>	<b>37</b>
5.1	<i>SWOT analysis per country.....</i>	38
5.1.1	Bulgaria.....	38
5.1.2	Cyprus .....	39
5.1.3	Greece .....	40
5.1.4	Romania.....	41
5.2	<i>SWOT Critical Analysis .....</i>	42
<b>6</b>	<b>Recommended actions to support the ecosystems transition path .....</b>	<b>44</b>
<b>7</b>	<b>Innovation ecosystem transition path .....</b>	<b>48</b>
7.1	<i>Overall strategy for innovation ecosystem transition path .....</i>	48
7.2	<i>Innovation pathways .....</i>	50
<b>8</b>	<b>Conclusions .....</b>	<b>51</b>
<b>9</b>	<b>References.....</b>	<b>52</b>
	<b>Annex I. Definitions.....</b>	<b>56</b>
	<b>Annex II. Guidelines for T2.1 Data Collection.....</b>	<b>59</b>

## 1 Introduction

Smart Health, recognized as a Strategic Value Chain by the Strategic Forum for Important Projects of Common European Interest, holds significant importance within the framework of fostering a “future-ready EU industry” (Strategic Forum on IPCEI, 2018). At the core of this strategic initiative lies health data and data analytics, acknowledged as the key 'currency' that revolutionizes healthcare delivery. Additionally, the European Commission has prioritized the creation of a European Health Data Space (EU, 2022) to enhance the exchange and accessibility of various health data types. Furthermore, the OECD Council Recommendation on Health Data Governance urges countries to develop and implement national governance frameworks to facilitate greater harmonization and availability of health data (OECD, 2017).

Regionally, the RIS3 strategies and the respective action plans emphasize the pivotal role of Big Data, AI and IoT personalised medicine for better treatment, enabling informed decision-making, improving patient access to treatment, and enhancing disease prediction and risk assessment (Foray et al., 2012). Europe is currently facing important political transformations. The power of innovation within a place-based vision of sustainability, seems to be crucial when it comes to strengthening the integration process of the continent. The European Commission ‘s “Horizon Europe Widening” (EC, 2022) initiative aims at strengthening and widening participation in the programme of countries at a disadvantage in research and innovation (R&I), including lacking infrastructure, funding, and the possibility to create strong networks and retain talents. Focusing on a more inclusive approach in which all can participate, the EU’s R&I system promotes closer links between research and innovation and institutional cooperation to produce high-quality knowledge to bridge the existing disparities between leading and lagging countries. The less advanced countries eligible for widening actions are Bulgaria, Croatia, Cyprus, Czechia, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, and all Associated Countries with equivalent characteristics in terms of R&I performance and the Outermost Regions.

In this context, “VELES Excellence Hub - Strengthening the South-East Europe Smart Health Regional Excellence and Boosting the Innovation Potential” project<sup>1</sup>, implemented under the HORIZON-WIDERA-2022-ACCESS-04 (Excellence Hubs) initiative, advocates for a cross-country coordinated approach among four widening countries – Bulgaria, Cyprus, Greece, Romania. This coordinated effort aims to create an excellent South-East Europe Smart Health Innovation Ecosystem enabled by a Regional Smart Health Data Space (RSHDS). The project aligns with the new RIS3 strategies of the participating widening countries, emphasizing the need for overall digitalization of the society (ICT uptake); the improvement of the essential services provided by public and private stakeholders; the healthcare sector’s further advancement; and the need for increased investment in R&I (Adrnordest, n.d.; Pontikakis, 2020).

This document, **Deliverable 2.1** of the VELES Excellence Hub project, forms part of Work Package 2 “Smart Health Regional ecosystem enablement and transformational framework of change” and focuses on the

---

<sup>1</sup> See more at <https://veleshub.eu/>.

analysis of the current state of play and challenges within the health data ecosystems of the four Widening countries (as per T2.1). Additionally, it presents a strategy to strengthen Smart Health innovation ecosystems for the benefit of all stakeholders (as per T2.2). The analysis is based on desk and field research conducted at the countries with key stakeholders from the local and regional ecosystems.

The structure of this report encompasses a brief overview of the digital health ecosystems and innovation in healthcare, followed by insights into good practices from developed countries within the project consortium: Germany, Spain, and Sweden. Moreover, a methodological note on the research process, an examination of similarities and disparities of the countries at the key topics around health data primary and secondary use, SWOT analyses of the countries' ecosystems, a strategy for innovation transition path, and concluding remarks are also included.

The guidelines and questionnaire prepared are presented in Annex 2.

The full country reports are available in the internal VELES repository, as they will be further used as a baseline for publications:

[https://gateaieu.sharepoint.com/:f/s/VELES/EqtZLIJC93BPgezEDIIT\\_jUBCCLwW7--6\\_IRy-gBoI9OPg?e=sliWWm](https://gateaieu.sharepoint.com/:f/s/VELES/EqtZLIJC93BPgezEDIIT_jUBCCLwW7--6_IRy-gBoI9OPg?e=sliWWm) .

Access to the repository can be provided upon request by VELES coordinator GATE.

## 2 The VELES Excellence Hub project

VELES strengthens the innovation-driven growth and accelerates the innovation excellence in the smart healthcare domain within the participating widening countries Bulgaria, Cyprus, Greece, and Romania. It addresses the RIS3 healthcare priority and combines it with the Smart Health Strategic EU Value Chain to deliver systematic impact and continuous improvement of the smart specialization paths on a multi-country level. All envisaged activities within the hub are reinforced by the Quadruple Helix stakeholder cooperation, coordination, and co-development approach.

VELES comprises of 4 widening countries aiming to reinforce smart health innovations as the main factor towards an excellent place-based innovation ecosystem. The place-based ecosystems build on a strong knowledge base in the healthcare domain which is supported by long-lasting practices, available know-how and important research infrastructures. The role of all quadruple helix stakeholders, Research and Academia, Government, Public organizations, Industry and Civil Society, are considered crucial in shaping the local context of each of the targeted widening countries Bulgaria, Cyprus, Greece and Romania. Each place-based ecosystem is actively supported and facilitated by its university/ academia members (Sofia University, University of Medicine and Pharmacy "Grigore T.Popa" from Iasi and Technical University of Iasi, Foundation for Research and Technology - Hellas, etc.) and regional and city governments (MEG, UEFISCDI, NEHA, e-trikala - Municipality led company). Co-creation with citizens/users is increasingly being cultivated through open innovation methodologies and frameworks, open innovation spaces (JOIST) and other available infrastructure (VR labs, coworking spaces, etc. (AMEN)). Shared activities and large-scale endeavours (including pilot demonstrations) bring together all partners involved in an entrepreneurial discovery process of experimenting, taking responsible research endeavours, and learning in a collaborative way. VELES contributes and further develops the interlink with Horizon 2020, funded projects: "GATE Centre of Excellence" and the "Research Centre on Interactive Media Smart System and Emerging Technologies - CYENS Centre of Excellence" (RISE).

This document reports on the state-of-play on the 4 place-based ecosystems and presents a comprehensive strategy for innovation ecosystem transition - outlining the innovation transition pathways for the HORIZON-WIDERA-2022-ACCESS-04-01 VELES EXCELLENCE HUB - Strengthening the South-East Europe Smart Health Regional Excellence and Boosting the Innovation Potential and constitutes the deliverable D2.1. The project kicked off on June 1st, 2023, and has a duration of 48 months.

## 3 Methodology for data collection

### 3.1 Objectives

This document presents insights derived from the comprehensive desk and field research conducted across four widening countries (Bulgaria, Cyprus, Greece, Romania) aimed at analysing their current state and identifying challenges within their respective innovation ecosystems. The research entailed an examination of pertinent policy documents from both national and EU levels, alongside interviews with key stakeholders. These discussions delved into stakeholders' perspectives on innovation ecosystems, as well as into the primary and secondary use of health data within their national contexts. Based on these findings, the report offers recommendations and a strategy for strengthening Smart Health innovation ecosystems and delineates the necessary steps for a successful transition path.

### 3.2 Analytical Approach

The exploration of each widening country's current landscape, the identification of challenges, alongside the appropriate strategy for innovation ecosystem transition path, relied on targeted interviews with key stakeholder groups. The questionnaire prepared by the VELES T2.1 team (see Annex 2) focused on six key themes related to the primary and secondary use of health data, including:

- 1. Information about the technical infrastructure for primary health data collection and sharing.**
- 2. Data infrastructure features for data quality, data interoperability, security, and consent management.**
- 3. Governance frameworks and bodies for accessing data for secondary use.**
- 4. Information about the existing human resources, skills and training required for establishing health data spaces.**
- 5. The legal and regulatory framework concerning health data spaces.**
- 6. Stakeholders' role and involvement across national, regional, and local ecosystems.**

Thirty-six semi structured interviews were conducted from October to December 2023 in Bulgaria, Cyprus, Greece, and Romania. Participants shared insights into the current state, local challenges, and issues within the specified categories. Moreover, the participants provided input on Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis pertaining to their respective ecosystems. Desk research supplemented these interviews, gathering information on national policies, laws, and strategies related to health data usage. Additionally, insights into national-level health data sharing practices and existing initiatives were incorporated.

This report synthesizes findings across the six key research areas explored during the interviews, providing a comprehensive overview of the innovation ecosystem landscape and challenges related to health data in Bulgaria, Cyprus, Greece, and Romania. Furthermore, the report presents research participants' recommendations for action as part of the overall strategy for innovation ecosystem transition path.

### 3.3 Research Participants' Selection

Key stakeholders were identified from the 4 countries by the T2.1 involved project partners to participate in the research. The stakeholders' selection was guided by the Quadruple Helix approach and interview participants represented diverse sectors, including:

1. Public authorities, encompassing public health policymakers, representatives from Ministries of Health, and Electronic Governance, technical infrastructure providers, hospitals etc.
2. Academia/research, including Higher Education Institutions, public and private research centres etc.
3. Industry, comprising pharmaceutical companies, leading entities in medicine, telemedicine, and digital health, as well as healthcare-related clusters.
4. Citizen/Civil Society, including patient organisations, health professionals' associations etc.

The variety of the stakeholders involved in the research led to bringing in broad knowledge and diverse perspective and to build a comprehensive overview of the current situation in the 4 countries, including performing a comparative gap analysis in Smart Health research, innovation and business uptake capabilities & needs.

## 4 State-of-play

### 4.1 Digital health innovation ecosystems

Recent trends in healthcare innovation explore user participation in the healthcare delivery process. Digital health is an example of healthcare innovation, as it provides a platform in which digital technologies facilitate patients' and practitioners participation in the overall healthcare delivery process. Studies have identified innovative approaches to improve existing healthcare models, for example, incorporating innovation ecosystems into providing digital health services. Although digital health is a trending topic, and digital ecosystems are being discussed in academic literature (Ejehiohen Iyawaa et al., 2016), the term digital health innovation ecosystem is rarely discussed and has not been clearly defined in academic literature. Furthermore, there is limited theoretical research that focuses on the specific components that constitute digital health innovation ecosystems.

Based on the discussions related to digital health, innovation and digital ecosystems, a **digital health innovation ecosystem** can be defined as:

*A network of digital health communities consisting of interconnected, interrelated and interdependent digital health stakeholders, including healthcare institutions, digital healthcare devices situated in a digital health environment, healthcare practitioners, who adopt the best-demonstrated practices proven to be successful, and implementation of those practices through the use of information and communication technologies to monitor and improve the wellbeing and health of patients, to empower patients in the management of their health and that of their families.*

Apart from the above, **innovation in healthcare** as a driver of resilient and sustainable healthcare systems is a concept which deserves the attention of policymakers and other stakeholders. Deployment of innovative technologies, solutions, policies, and funding schemes has accelerated in response to the COVID-19 pandemic, making it essential to understand how these can or should be integrated into our health systems on a long-term basis. Driving innovation and digital transformation in healthcare, and harnessing the benefits for patients, citizens and healthcare systems was already on the EU health agenda, portrayed by initiatives such as its research program, Horizon Europe and its Digital Health policy. Nonetheless, the pandemic highlighted the immediate need for new, transformative innovative technologies and solutions to support public health, while underlining the importance of data to allow collaboration and faster problem solving in a crisis. This has led to a renewed momentum for innovation in health, advancing clinical and regulatory science and health policies that encompass innovation, including medical devices and diagnostics, digital health applications, and the use of FAIR (Findable, Accessible, Interoperable, Reusable) data, to optimise delivery of healthcare, the respective pathways and disease management. Ultimately, these changes aim to ensure that health systems are more agile, and better equipped to handle future crises and long-term needs.

However, the reviews of the pandemic response across the EU and the overall healthcare landscape in the last few years has exposed **key weaknesses** in leveraging opportunities and new solutions. It has highlighted

gaps in existing EU health policy and infrastructure, including fragmented approaches to crisis, a lack of regional coordination, fragile healthcare systems and supply chains, and shortfalls in preparedness and planning and lack of rapid innovation adoption among the health stakeholders.

The main reasons why still too few public procurers in the EU buy innovations and why the adoption of innovation is still hardly used as an innovation support tool are linked to:

- i. The lack of knowledge of public procurers on what new technologies and innovations are available in the internal market or on their capabilities and what could be the medium to long-term benefits and cost savings. This is most critical for the technologies enabling broader utilisation of health data, such as data curation, standardisation, enrichment, analytics and privacy;
- ii. The difficulties for innovative SMEs to become involved in public procurement as direct suppliers, as shown by the EC study on SMEs access to public procurement (Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, 2021). This hampers the access of public authorities to the innovative potential of SMEs, in particular high-tech SMEs who play a key role in creating innovative solutions;
- iii. The lack of strategy linking public procurement with other public policy objectives: for example, the administrations in charge of healthcare services, environment, mobility, energy, housing, waste, and water management do not perceive themselves as having a role to play regarding support for innovative organizations. On the other hand, administrations in charge of research, innovation and business support do not include in their strategies the question of what innovative solutions the public sector would need to procure. In addition, the two sides of the administration do not jointly develop their strategies.

## 4.2 Good practices in advanced countries

Good exemplary practices from across Europe are existing in the digital health innovation ecosystems. Focused on the pioneering efforts of Germany, Spain, and Sweden, this section aims to showcase successful models that have effectively navigated the complexities of digital health. By examining these European good practices, we glean insights into strategies, collaborations, and initiatives that have propelled these countries towards advanced and sustainable digital health innovation.

### 4.2.1 Germany

Germany, being as EU Member State since 1958, is anticipated to adjust its national enactment with the European strategy for data (EU, 2020a) with full regard for the principal rights of people, in line with the GDPR and Member State competences (EU, 2020b). Germany has a complex and decentralized health care system, with governance divided between the federal and state levels, and corporatist bodies of self-governance. Health insurance is compulsory and provided either under the statutory health insurance

(Gesetzliche Krankenversicherung) scheme or through substitutive private health insurance (Private Krankenversicherung).

The European Strategy for Data in Germany is seeing the data as an essential resource for economic growth, competitiveness, innovation, job creation and societal progress in general (EU, 2020a). In the future, the development of data-driven applications would bring various benefits to both citizens and businesses and would improve healthcare. In December 2023, the European Council of Member States agreed on a common position on the European Health Data Space (EHDS) and Germany has submitted a Protocol statement (EU, 2024), which sets out the interpretation of certain provisions. The German Federal Ministry of Health, implementing the EHDS, has proposed to support the digitization of health data within the **Digital Supply Act (Digitale-Versorgung-Gesetz – DVG)** (Bundesgesundheitsministerium, 2019) and the **Health Data Use Act (Gesundheitsdatennutzungsgesetz – GDNG)** (Bundesgesundheitsministerium, 2024a), and the **Hospital Transparency Act (Krankenhaustransparenzgesetz)** (Bundesgesundheitsministerium, 2024b). DVG aims to advance the use of the digital technologies to improve the patients` care, support innovation, and facilitate the integration of digital solutions into healthcare (Bundesgesundheitsministerium, 2023a).

Health records and e-prescriptions will be easily accessible for patients through **healthcare applications (DiGAs)**, as well as for health and care professionals in the field of primary use of health data, increasing the practice of online video consultations. DiGAs are playing the roles of the "digital assistants" in the hands of the patient. They will be also used for more complex treatment processes – e.g. for telemonitoring (Bundesgesundheitsministerium, 2023b). **Electronic Patient Records (ePA)** in the German healthcare system, are the main mechanisms for the secure data exchange (Bundesgesundheitsministerium, 2023c). Since January 2021, all persons with statutory health insurance have been able to submit ePA from their health insurance companies, in which medical findings and information from previous examinations and treatments can be comprehensively shared across practice and hospital boundaries. The DVG clarifies the procedure for the automatic access to health data, stored in the ePA, for most of the professionals with a right of the patient for objection. Also, a separate transfer of data from one health professional to another is not needed, due to the theoretical possibility for all health professionals to access a patient`s ePA.

The DVG aims to regulate the "chronicler programs" - **Disease Management Programmes (DMPs)**, treatment programs for people with chronic diseases. Chronic diseases require long-term and regular treatment, which should be adapted to the patient's life circumstances. DMPs have been offered in Germany since 2002 by the statutory health insurance companies in cooperation with doctors. The DVG will also regulate the procedure for the inclusion of a digital health application in the directory (DIGA Directory) for digital health applications of the Federal Institute for Drugs and Medical Devices pursuant in the supplementary legal regulation, the Digital Health Applications Ordinance - DiGAV (Bundesgesundheitsministerium, 2020a).

**The GDNG** aims to create a decentralized health data infrastructure to coordinate and facilitate the use of data. In the future, the GDNG will be able to better access health data for research and prepare German data-holding bodies for development of innovations and thus contribute to better care (Bundesgesundheitsministerium, 2024a). Among other things, the GDNG facilitates a decentralized health

data infrastructure development within a central data access and coordination point for the data usage. Additionally, the **Hospital Transparency Act** promotes the publication of structural and performance data of hospitals in Germany and prioritizes hospital reform (Bundesgesundheitsministerium, 2024b). Beneath this law, patients will be able to see which hospitals in their region offer which services and how the hospital performs in terms of quality, as well as medical and nursing staffing – referred to as a transparency directory.

This transparency directory is planned to be published by the **German Federal Ministry of Health** in 2024. In accordance with transparency, hospitals are required to provide to the Institute for the Remuneration System in Hospitals (InEK) the following additional information in the future: assignment of services to service groups; location reference for diagnoses and procedures; data on nursing staff and data on medical staff. Respectively, the InEK is obligated to submit the data and evaluations sent by the hospitals to the Institute for Quality Assurance and Transparency in Health Care (IQTIG). The IQTIG accordingly evaluates the data together with the quality data available to it and submits the evaluations to the BMG for publication.

In order to ensure that **data privacy and security measures** are in place to protect sensitive health information, Germany is providing a comprehensive legal and regulatory framework governing health data protection and privacy for patients within **Patient Data Protection Act (Patientendaten-Schutz-Gesetz, PDSG)** (Bundesgesundheitsministerium, 2020b). The PDSG enables regulations concerning the processing of patient data in the healthcare segment. It aims to fortify patients' rights, ensure the security of health data, and promote transparency in the use of such data. With the electronic patient record, the patient alone decides what happens to his or her data. The insured person decides which data is included in the ePA and which ones are deleted. From 2023 onwards, insured persons could use the ePA to voluntarily make the stored data available to research as part of a data donation.

Encouraging **research and innovation** by promoting collaboration between academia, research institutions, and the private sector Germany becomes more attractive for research and production for pharmaceutical companies. At the end of January 2024, the German Federal Health Ministry has presented the draft for a **Medical Research Act (Medizinforschungsgesetz, MFG)** (Bundesgesundheitsministerium, 2024c). The Medical Research Act is part of Germany's new National Pharma Strategy which aims to make Germany more attractive for pharmaceutical R&D and manufacturing (Bundesgesundheitsministerium, 2023d).

On January 2024 European Commission published "The Second staff working document on data spaces" reporting achieved milestones in EHDS implementation (EC, 2024): a. Proposal on the European Health Data Space (EHDS) (May 2022); b. Establishment of European principles for the secondary use of health data (TEHDAS) (July 2023). Additionally, on March 15<sup>th</sup> 2024 agreement has been reached between the European Parliament and the Council on the creation of a European Health Data Space.

To be able to reach raised plan in the next three years Germany will prospectively proceed with the further changes and alignments in the legislation. Further, the Federal Ministry for Economic Affairs and Energy is expecting that the digital health market in Germany will grow up globally to a market share of 12% by 2025 (McKinsey, 2024; BMWK, n.d.; GTAI, n.d.).

## 4.2.2 Spain

Spain is among the top five European countries in health data digitisation and is also a world leader in clinical research. Key strengths that have led to it are the implementation of common standards at a regional level, the ability of regional electronic health record (EHR) systems to export data to a national summaries system, and the comprehensive e-prescribing infrastructure. Spain also has various strategies and programmes at the public level, such as the comprehensive national policy España Digital 2026<sup>2</sup>, as well as funding, that contributes to the digital transformation of the healthcare system.

Despite the segmented structure by region, the physical infrastructure for data storage and processing is already in place in all 17 Spanish Autonomous Communities. This structure has provided fertile ground for many data networking initiatives and secondary uses to flourish over the last decade. As a result, extensive experience and expertise in data standardisation is available throughout the country that can serve as a basis for the technical implementation and quality framework of a federated health data space infrastructure.

Among the good practices and leading initiatives in Spain to achieve the digital transformation of the public and private healthcare system, the "eHealth Future" programme led by INNEUROPE can be highlighted<sup>3</sup>. This initiative aims to connect a large ecosystem of insurers, start-ups, technology companies, hospitals, laboratories, pharmacies, and public health services through open innovation spaces to facilitate technology transfer from research to market application.

## 4.2.3 Sweden

Sweden's readiness for implementing the European Health Data Space has been reported by EIT Health (2023). In Sweden, decentralised public health and care services are managed and run either by the 22 regions, local authority, or sub-regional municipalities, each responsible for its own resource allocation and data governance. Digitalisation of healthcare records is almost universal across settings of care, with only limited examples of paper-based systems still in use. Under specific national legislation, Sweden extracts public health data from these healthcare providers into national Public Health Agency collections and a wide range of disease registries. Implementing broad secondary use use cases, such as myHealth@EU and the European Health Data Space (EHDS) HealthData@EU, will however require legislative changes to the Patient Data Act, the Ethical Review Act, as well as the Public Access to Information and Secrecy Act, and additionally designing a practical governance model for the high number of distributed data governance nodes. Nevertheless, the technical infrastructure for such data sharing and integration is mostly well developed to meet such needs, and consistent political support has been demonstrated by the Swedish government for the EHDS programs. Sweden's digital maturity is reflected in the ubiquitous deployment of digital identification technology (BankID) for most commerce and authorisations across public and private sectors. Swedes score highly in digital literacy, though low in health literacy and health professionals have low awareness and

---

<sup>2</sup> Find out more at <https://espanadigital.gob.es/en/implementation-agenda>.

<sup>3</sup> Find out more at <https://innsomnia.es/en/cont/ehealth-future-the-largest-digital-health-programme-in-spain>

preparedness for implementation of EDHS frameworks, representing important considerations for implementation planning.

Sweden has some of the highest coverage population registries globally, with 14 legally mandated and augmented with national mortality, morbidity, medical and healthcare services data. These registries, some in operation over 70 years, serve academic, health services, government, NGO and industry secondary use cases, with established global clients, access processes and wrap-around study services. A national system is also well established for communication between hospitals, which is being extended with capability for data exchange between regions. Many regions have integrated referrals and patient management systems across different settings of care and rolling out across specialties. A nationwide digital health app (1177)<sup>4</sup> lets patients directly access diagnostic notes and analytic results from their patient records and schedule health care services. Sweden is also working on multiple EU projects examining cross-border sharing of high-quality curated data such as the Genomic Data Infrastructure (GDI)<sup>5</sup> and European Federation for Cancer Images<sup>6</sup> projects. GDI has centralised all Sweden's rare diseases and oncology clinical data in a segregated clinical cloud platform and is exploring curation and both primary and secondary use analytic frameworks that can be overlaid. A local health data space is also established in Stockholm, where all patient records from all settings of healthcare can be ingested, linked and analysed for approved secondary use purposes, though the access process (averaging 18 months in 2023) remains far longer than EHDS 2–3-month targets. A central discussion in focus in the national planning for the EHDS is the need to define the curation and analytics of health data. This includes not just the technology required, but also the skills, workflow processes, funding, process governance and training for the extensive curation and analytics of both the data being generated today, as well as all the existing historical clinical data. With its high digital maturity, high trust in public institutions and 70 years of experience operating nationwide health data secondary use, Sweden is in a privileged position to pursue a reasoned public dialogue to set a vision for a national node of the European Health Data Space.

### 4.3 Widening countries innovation ecosystems dimensions related to health data

The next sections provide an overview of the findings and insights for the state of play of the main elements, of the innovation ecosystems defined above. These are based on the questionnaire and the interviews held, as well as on the desc research performed by the partners within the four widening countries.

#### 4.3.1 Technical infrastructure for primary and secondary use

The analysis of the technical infrastructure for primary and secondary use of health data in the four countries reveals both similarities and disparities, reflecting the current state and the necessary steps toward enhancing health information systems. The presence of public health information systems, operated by Ministries of

---

<sup>4</sup> <https://e-tjanster.1177.se/mvk/login/login.xhtml>

<sup>5</sup> <https://gdi.onemilliongenomes.eu/>

<sup>6</sup> <https://cancerimage.eu/>

Health and health insurance organizations, alongside those deployed in hospitals, marks a significant step towards comprehensive health data management. This dual structure supports both direct healthcare delivery (primary use) and broader applications such as policy making, research, and health system management (secondary use).

### Similarities Across Countries

- **Public Health Information Systems:** A common feature is the implementation of public health information systems by governmental bodies, indicating a centralized effort to manage health data.
- **Hospital Systems:** The IT systems in place within hospitals for managing patient data are another point of similarity, serving the immediate needs of healthcare delivery.
- **Data Collection and Management:** Each country has mechanisms for collecting and managing health data, although the efficiency and comprehensiveness of these systems vary.

### Disparities and Gaps

- **Integration and Interoperability:** A significant gap in most of the countries is the lack of integration and interoperability among different health information systems. This limitation hinders the seamless exchange of data across platforms, affecting patient care and research.
- **Accessibility and Usability:** The disparity in how easily health professionals can access and use these systems impacts the efficiency of healthcare delivery and data analysis for secondary purposes such as for research, policy making etc.

## Bulgaria

The main healthcare related systems in the country are the **National Health Information System (NHIS)**<sup>7</sup>, with the Ministry of Health as its principal, and the **Integrated Information System (IIS)** of the National Health Insurance Fund (NHIF). The **NHIS** creates and maintains the electronic health records of Bulgarian citizens. Essentially, it represents an integrated information infrastructure consisting of system modules, subsystems, integrations, and databases. **IIS** is limited to information and data created only by health-insured individuals and medical professionals, laboratories, and pharmacies that have contracts with the NHIF, according to the Health Insurance Law. The two systems are interconnected and exchange information at the level of the Patient's health record, with the IIS containing more historical data about patients than the NHIS. **NHIS** is a new system and was introduced in 2022. A major challenge for using data from NHIS is the **lack of historical data in citizens' electronic records. In the long term, by 2030, there are plans to expand the functionality and infrastructure of the NHIS for sharing and exchanging data.** This includes additional modules for remote health services and telemedicine; information systems for drug supply, a national digital platform for medical diagnostics (NDPMD), and the creation of functionalities for analyzing the activities and results of the state health policy based on large arrays of health data.

---

<sup>7</sup> <http://www.his.bg>

## Cyprus

The **Electronic Health Records (EHRs)** and **Hospital Information Systems (HIS)** are integrated into Cyprus's healthcare fabric. The Ministry of Health utilizes the MEDICO system across several public facilities, like Nicosia General Hospital and Famagusta General Hospital, while other public institutions and private healthcare establishments feature **diverse HIS or EHR solutions** tailored to their operational needs. The Health Insurance Organization (HIO) serves as Cyprus's nucleus for general healthcare administration, leveraging digital technologies to manage a broad spectrum of patient-centric data, streamlining everything from medical record coordination to billing procedures. **Cyprus is adept at utilizing European Union standards, exemplified by the adoption of the EU Patient Summary in its latest EHR systems.**

## Greece

The National Health System (NHS) in Greece is responsible for the provision of health services in the country. In the period 2000-2010, modern IT systems were introduced in the majority of hospitals in the framework of the implementation of the operational programme for the implementation of the Information Society (IS) strategy. After the end of 2009, many eHealth services started to be introduced in the country, in line with EU recommendations, notably the Electronic Prescribing System<sup>8</sup> and the Individual Electronic Health Record<sup>9</sup> (AHFY) by IDIKA, as well as the Electronic Insurance Record<sup>10</sup> by EOPYY<sup>11</sup> (the National Organization for the Provision of Health Services). Today, the digital services of ministries, agencies, organisations and independent public authorities, including those on health and welfare, provided online, are accessible through the national portal gov.gr<sup>12</sup>, which was launched in 2020. Cross-border eHealth **is supported through e-Governance of Social Security Services - IDIKA S.A.**<sup>13</sup> (currently for **e-prescription and patient summary**) and the **cross-border healthcare services through EOPYY**. In the following years, in the context of the **National Recovery & Resilience Plan "Greece 2.0"**<sup>14</sup> funded by EU's Recovery and Resilience Facility, IDIKA S.A. is expected to implement significant projects including the Management of Oncology Patient Care, the completion of the Individual Electronic Health Record (AHFY), and the modernisation of Hospital Information Systems, amongst others.

## Romania

The Integrated Health Insurance Platform (**PIAS**) is a complex online platform aimed at optimizing access to medical services and the efficient management of the unique National Health Insurance Fund (**FNUASS**). It is managed by the **National Health Insurance House (CNAS)** and integrates several key components such

---

<sup>8</sup> <https://www.e-prescription.gr/>

<sup>9</sup> <https://ehealth.gov.gr/p-rv/p>

<sup>10</sup> <https://eservices.eopyy.gov.gr/eHealthInsuranceRecordInsPerson/login.xhtml>

<sup>11</sup> <https://www.eopyy.gov.gr/>

<sup>12</sup> <https://www.gov.gr/>

<sup>13</sup> <https://www.idika.gr/>

<sup>14</sup> <https://greece20.gov.gr/en/>

as the Single Integrated Information System (SIUI), the National Electronic Prescription System (SIPE), the Electronic Social Health Insurance Card (CEAS), and the Electronic Health Record (DES). The **patient's electronic health record (DES)** has been subject to a lot of controversy since its inception. It worked intermittently between 2013 - 2015, but there were security issues related to patient data which affected its use (CNAS, 2021). Currently, **DES** is not working properly and needs "resuscitation", an interviewee admits. Furthermore, gaining access for patients is challenging, necessitating the use of a username and password generated by their family doctor. At the national level, there is a wide variety of digital systems for the collection of primary data, but their functionality is questionable as the technical infrastructure is fragmented and still under development. Consequently, it is not possible to follow the trajectory of patients after leaving the hospital, so the monitoring process is interrupted. **The National Recovery and Resilience Plan (PNRR)** has launched a call in mid-2023 that seeks to develop a systemic framework for data governance to address data quality and efficient data exchange among various administrative institutions, healthcare units, service providers, and patients (MFE, 2021). In respect to data for secondary use, the universities have their own system for collecting data for secondary use.

### 4.3.2 Data infrastructures and readiness

Across the four widening countries, several common issues emerged regarding data infrastructures features, such as data sets and sources, data quality and integrity, data interoperability standards, security, and consent management (data governance).

#### **Similarities Across Countries:**

Data sets are mainly developed and stored by the Ministries of Health and supervised public and private bodies.

- Fragmentation of data and infrastructure is a pervasive challenge, impeding efficient data exchange and interoperability.
- Data quality assurance lacks standardized approaches across these countries, leading to concerns about the accuracy and reliability of health data.
- There are limitations for the efficient use of interoperability standards. However, efforts are underway to improve interoperability capacities and develop appropriate governance structures.
- Patients are the legal owners of the data and can decide upon the use of the data, through informed consent, including data use for research purposes. The sharing of the data for research purposes can be made upon request, subject to patient consent.
- Additionally, challenges in consent management and patient engagement were evident, with varying degrees of legislative and procedural frameworks governing data ownership and access rights.

## Disparities and Gaps:

- The digitalization of health data is not fully established, since in Cyprus and Romania, the paper formats of health records was mentioned as an obstacle in the data quality assurance and integrity.
- Cloud infrastructure is underdeveloped and not yet fully optimized.

## Bulgaria

Data sets can be found as structured health data in the national systems NHIS and IIS, at the regional level in the systems of the Regional Health Inspectorates (RHI), while also, local collections are maintained in some university databases, private collections, and registries. Structured data, according to the FHIR® standard by HL7, are provided exclusively in NHIS and IIS. The storage of the health data is for 25 years, in accordance with the List of Primary Medical Documentation established by the Ministry of Health in 1987. Data on population morbidity are collected and stored by the National Centre for Public Health and Analysis (NCPHA) and the National Statistical Institute (NSI) for the annual statistical yearbooks. According to the regulatory framework for patients' rights, through filling out an Informed Consent as per the Health Law, allow patients or their authorized representatives to consent to sharing their data with third parties in certain legal cases (e.g. with the Ministry of Health, NHIS, NHIF, Executive Agency 'Medical Surveillance' - EAMS, and other public bodies and institutions). Regarding consent management and patient engagement, the Declaration of Awareness ensures that patients are fully informed about how their personal and health data are collected, processed, and shared, following articles 13-14 of GDPR (EU, 2016).

## Cyprus

Data sources primarily rely on HIS and EHR systems across inpatient and outpatient healthcare settings, biobank facilities (biological material), rare diseases registries, and to a lesser extend research and clinical trials data. There is limited use of data interoperability standards and profiles primarily attributed to (national and/ or EU-funded) research projects and initiatives and, to a significantly lower degree, to a national digital health strategy. Despite the existence of the Cyprus eHealth Law that mandates the use of such profiles and standards, widespread utilization is still weak (Republic of Cyprus, 2014). Medical coding is employed alongside interoperability standards ingrained within HIS and EHR systems. Moreover, data collected through CE accredited medical devices undergoes the established protocols, with assessment mechanisms in place to verify that all healthcare personnel abide by established quality guidelines. However, a significant portion of healthcare providers/ facilities still rely on paper-based health records, with minimal procedures installed to secure data quality and integrity. GDPR compliance and the eHealth Law of Cyprus defines a set of minimum requirements for legal, privacy, and security compliance towards constituting the collection and sharing of clinical data a trusted and robust procedure for future and existing systems. Patient engagement and consent management are presently limited to research projects, studies, and registries that operate under the strict auspices of the Cyprus Bioethics Committee, imposing patient consent for data collection and sharing. Future EHR and HIS systems that adhere to the Cyprus's eHealth Law prerequisites

will witness patient empowerment at the core of health data practices, with transparent information sharing and facilitated consent withdrawal mechanisms.

## Greece

The Hellenic Ministry of Health<sup>15</sup> is the data controller and e-Governance of Social Security Services - IDIKA S.A.<sup>16</sup> is the main data processor of the health data. Data sets exist also, through EOPYY<sup>17</sup> and ELSTAT<sup>18</sup> (Hellenic Statistical Authority), hospitals, private institutions, health registries and European projects<sup>19</sup>, as well as the European research infrastructure BBMRI-ERIC<sup>20</sup> for biobanks. Greece participates in several EU funded projects focusing on establishing a common groundwork for eHealth interoperability for standardizing the sharing of health data for primary and secondary use in line with the European health data space initiative. Also, Greece participates in multiple EU projects examining cross-border sharing of high-quality curated data such as the Genomic Data Infrastructure (GDI) and European Federation for Cancer Images (EUCAIM<sup>21</sup>) projects as well as the OHDSI<sup>22</sup> partnership promoting OMOP CDM.

Although the use of international standards is extensively used as required by public tenders, there is no specific interoperability framework applied at national level to effectively support the use cases under consideration. Interorganizational data sharing and/or national data sharing for research or care delivery is not operating sufficiently at a cross-organizational level (e.g., among hospitals). Not all hospitals are connected to the Business Intelligence System of the National Health System (BI-Health<sup>23</sup>) by the Hellenic Ministry of Health and there is no interface for data exchange with private sector health care providers. The existing issue of fragmentation of data relates to the lack of sufficient communication and cooperation between the different Ministries and stakeholders, including pharmaceutical and technological companies, health professionals/doctors and citizens. Data quality assurance of the primary health data collection has not received the appropriate focus at national or even European level at ensuring common standards about the quality features of the data. Access to health data is regulated through the GDPR legislation (Law 4624/2019), i.e., who has access to them, who can give access to whom and for what reasons. The country is in an early phase concerning secondary data use, with significant projects that will be funded through the Recovery and Resilience Fund (RRF) in the pipeline.

---

<sup>15</sup> <https://www.moh.gov.gr/>

<sup>16</sup> <https://www.idika.gr/>

<sup>17</sup> <https://www.eopyy.gov.gr/>

<sup>18</sup> <https://www.statistics.gr/>

<sup>19</sup> Such as the "[1+ Million Genomes](#)" Initiative (1+MG), which is a complex European data infrastructure for genomic and clinical data.

<sup>20</sup> <https://www.bbmri-eric.eu/>

<sup>21</sup> <https://cancerimage.eu/>

<sup>22</sup> <https://www.ohdsi.org/>

<sup>23</sup> <https://portal.bi.moh.gov.gr/>

## Romania

The digital health systems play an important role in the collection and management of health data. However, these systems were developed at different times in the country, using different architectures, which led to the creation of an indispensable computing platform, but **which has difficulties in performing an integrated analysis of the existing data**. The Integrated Health Insurance Platform (PIAS) is a complex online platform aimed at optimizing access to medical services and the efficient management of the unique National Health Insurance Fund (FNUASS). It is managed by the National Health Insurance House (CNAS) and integrates several key components such as the Single Integrated Information System (SIUI), the National Electronic Prescription System (SIPE), the Electronic Social Health Insurance Card (CEAS), and the Electronic Health Folder (DES). DES is intended to provide an integrated and up-to-date view of patient medical data. An important aspect of the DES is the adoption of the HL7 (Health Level 7) collection standard, a set of international standards for the electronic exchange of medical information. The use of the HL7 standard in DES aims at interoperability and efficiency in the exchange of medical data, contributing to a complete and accurate medical history for each patient. DES is currently inaccessible.

The system is very fragmented due to the existence of parallel information flows that collect the same type of data, often in different formats, the lack of nomenclatures and common standards for data, the exclusivity of data practice, meaning that any health data collected with public funds should automatically be public data (in the aggregated format). Hospitals and clinics are the primary locations where medical data is generated and stored. There is no practice of centralized storage or interoperability. Many medical units (hospitals, clinics, laboratories) integrated their own systems developed by private companies, according to their specific needs, leading to a diversity in systems and standards. Private services do not report data to the DSP (County Public Health Department), so some data of the patients who access private services is lost. They are mandated to transmit only data needed for reimbursement if they have a contract with CNAS. There is also data generated by clinical studies, which are highly regulated. For example, CROs are using a very granulated consent in clinical and treatment's adherence studies. While most health data is digitized, a significant portion remains in text format, reflecting the lack of standardization. In some hospitals, the sharing and communication of data is made on paper, using CDs for medical imaging exams, or via insecure channels like WhatsApp. This lack of secure data transmission poses a significant risk to patient privacy and data security. Despite national efforts, the overall system is in a transition phase, with future infrastructure developments expected. A review of the health information system is expected as part of the initiative to fund the National Data Observatory<sup>24</sup>, dedicated funds from the National Recovery and Resilience Plan - PNRR will most probably lead to infrastructure development and upgrades in the field (MFE, 2021).

---

<sup>24</sup> Find out more at <https://observatoriuledesanatate.ro/home/>.

### 4.3.3 Governance framework

#### Similarities Across Countries:

- **Legal Framework:** All four countries - Bulgaria, Cyprus, Greece, and Romania - have established legal frameworks governing health data management, emphasizing patient privacy, data security, and compliance with EU regulations such as GDPR.
- **National Health Strategies:** Each country has a national health strategy outlining goals and priorities, including aspects related to health data management and digitalization.
- **Evolution of Governance:** The countries lack well-established governance frameworks, and they are still evolving and facing challenges, with ongoing efforts to establish comprehensive frameworks and address gaps.
- **Secondary health data use:** Countries lack structured frameworks that would facilitate sufficiently secondary health data use.
- **Funding and Implementation Challenges:** Countries are facing challenges in financing and integrating health data systems across the healthcare network.
- **Data Protection:** Measures to protect patient data, including encryption, anonymization, and access control, are prioritized across all countries to ensure data security and privacy.

#### Disparities and gaps:

- **Data Access and Sharing Protocols:** Variations in data access and sharing protocols exist across countries, with differing mechanisms for obtaining consent and regulating data sharing for secondary use.
- **Institutional Structures:** Differences in institutional structures for governance are observed, with some countries designating specific authorities for data management and oversight (e.g., Bulgaria), while others rely on committees and agencies (e.g., Cyprus).

#### Bulgaria

Bulgaria is in the process of establishing a legal and strategic framework for data management, with plans for a Data Law and a Digital Transformation Strategy project. The country has designated national competent authorities under the Data Governance Act, appointing the Minister of Electronic Governance for various roles, such as to manage data access, sharing, and intermediary services. Bulgaria is one of the seven EU countries that have already designated such authorities. However, functionalities and management for secondary data use are currently lacking, highlighting a need for further development in this area.

## Cyprus

In Cyprus, ethical oversight of medical data sharing for research purposes is managed by the Cyprus National Bioethics Committee - CBC (Ministry of Health Cyprus, n.d.). Structured application processes ensure compliance with ethical and legal standards, although mechanisms for regular ethics compliance audits are currently lacking. Best practices dictate obtaining approval from the CBC for data collection and sharing initiatives, alongside GDPR compliance and Data Protection Impact Assessments. While such measures demonstrate Cyprus's commitment to patient rights and data privacy, there are many transformative reforms that need to be implemented for the widespread adoption of ethical, private, and secure data sharing, including human capital training and the formation of conformity assessment bodies.

## Greece

Greece lacks a well-defined governance framework for health data management, focused on the collaboration between public authorities, healthcare professionals, and private sector entities. In terms of authorities for the health data, the participants from public authorities tended to propose to have a public authority e.g., the Ministry of Health in the role of the "Health Data Access Body (HDAB)", as it is happening in other countries. While the participants from the private sector believe that an independent authority with sufficient personnel would be more efficient. Moreover, participants mentioned that there should be better central coordination between the existing personnel in the public and private sector and the high scientific expertise that exists in the country to establish adequate governance and legal frameworks. Proper governance requires the establishment of policies, guidelines and tools to ensure conformity with EU regulations and standardization guidelines. Clear governance contributes towards balancing the interests of individuals and organisations involved in the collection and use of health data, enabling citizen centred healthcare while at the same time contributing to progress in research and improved policy making.

## Romania

Romania's governance framework for health data is still evolving, facing challenges in operationalizing key initiatives outlined in the National Health Strategy. Laws establish the legal foundation for data management, but concerns persist regarding fragmented implementations across hospitals and limited financial instruments for interoperability. Stakeholders emphasize the need for legal reforms to define operational standards for healthcare information systems and ensure compliance with patient data protection laws. There is a need for legal reform to define operational standards for healthcare information systems is crucial, particularly on Law 95/2006. Current control of patient data by specific health units contributes to fragmented and potentially insecure data management. Certifying healthcare information systems becomes essential to ensure compliance and prevent unauthorized access or manipulation, preserving patient data integrity and security.

#### 4.3.4 Human resources, skills and training

##### Similarities Across Countries

- General recognition of the need for diverse expertise in the field of data management and sharing (variability in the types of expertise);
- Clear consensus on the involvement of data analysts/scientists and IT personnel, emphasizing the technical nature of data management and security;
- Clear need for competitive advantage when it comes to attracting specialized personnel, i.e., competitive salaries.

##### Disparities and Gaps

- Lack of IT personnel in the healthcare units. Healthcare units and authorities are understaffed in terms of IT personnel, developers, analysts, and project managers;
- Resistance to sharing data due to cultural perceptions: Scepticism or caution towards data sharing driven by concerns over privacy, data control, and transparency;
- Poor cybersecurity policies and overall security practices established for shared data;
- Variability in awareness and involvement among respondents.

##### Bulgaria

There are trained professionals in Bulgaria, but due to non-competitive salary conditions in the public sector, which are far from the levels in the private sector, people with the necessary certificates and professional expertise do not join this unit. Other challenges include limited administrative resources for investing in staff training for acquiring specific knowledge. There are no resources allocated for training staff in internationally recognized programs or certification in international standards, such as IBM Data Science Professional Certificate, CompTIA Certifications, SAS Certifications, Oracle Certifications, etc.

Regarding practical steps to raise public awareness and the importance of data sharing, the interviewees made the following recommendations: 1) Clarify to the public what a data sharing space is, as people confuse the term "open data bases" with "protected data sharing spaces"; 2) Explain how it works and how participants can engage in such a space both as data providers and users; 3) Convince participants in this process – both data providers and users – of the benefits for them. Recommended approaches include workshops, demonstrating good practices for collaboration between business, academic institutions, non-governmental sector, and public sector, popularizing real results for citizens and the organizations themselves.

Currently, the IT department is the main human resource responsible for data management in healthcare facilities and other institutions in the health sector, but it is insufficient. The availability of qualified personnel

in these areas is critical for the effective management of health data, ensuring their security, and using them to improve the quality of healthcare services.

## Cyprus

The responses indicate an awareness of the importance of collaboration agreements focused on real world data practices and blockchain cybersecurity, though there is variability in awareness and involvement among respondents. In terms of human resources, there is a recognized need for a range of expertise including technical, legal, and potentially clinical skills. The predominant emphasis on data analysts, cybersecurity experts, and IT personnel highlights the technical challenges of data management, while the inclusion of legal/governance experts reflects the importance of compliance and ethical considerations in data sharing. The variability in responses suggests differing levels of resources and expertise across various organizations.

The responses indicate a clear understanding that a comprehensive set of skills and training is required to establish effective health data spaces. Core competencies include data management, security, privacy, governance, and analytics, with interoperability also being a key focus. This suggests a recognition of the complex and multidisciplinary nature of health data space initiatives, necessitating a combination of technical, legal, and collaborative skills to successfully manage and utilize health data. The inclusion of clinical and research-related skills further highlights the diverse applications and stakeholders involved in health data spaces.

## Greece

Most of the interviewees mentioned that a major issue is the lack of IT personnel in healthcare units. Healthcare units and authorities are understaffed in terms of IT personnel, developers, analysts, and project managers. This creates problems at the implementation of the ambitious projects under development and implementation in Greece. Additionally, participants highlighted that there should be benefits to attract specialized personnel, such as competitive salaries, to also avoid the problem of “brain drain” that the country has already suffered from, during the recent financial crises and big recession.

There is a great need for specialized skilling and upskilling for all stakeholders within the health data space ecosystem. Training and education programs should be provided to healthcare professionals, private and public sector employees as well as citizens focused on the skills required in the field of health data. In addition, more systematic information should be provided to the public on the benefits of using technologies and on building confidence, through a framework that ensures the principles of ethics and transparency. According to the participants, the provision of training to the respective actors in different topics around health data e.g. data collection, use of coding, would be beneficial also for the assurance of the health data quality. Furthermore, the paradigm of Finland was mentioned by participants as a good practice in terms of data privacy and of the responsible authority for the data access. The expertise exchange, technical advice, and collaboration with experts from technically advanced countries was also proposed.

## Romania

Most interviewees highlight that in Romania, particularly within the public health system, there is currently a lack of professionals specialized in health data management, despite a clear need for such expertise. The interviews also show a lack of technical specialization of the health professionals. Therefore, the need for technical specialisation of the workforce was identified, family doctors training is crucial (as they are the ones who centralize a patient's medical records/ diseases history currently mainly on paper files still), also nurses, community medical assistants and even other doctors need to develop digital skills preferably in the same easy-to-use system and new technologies.

In the educational context, it is observed that there is a gap between the theory taught and medical practice, with examples of biomedical engineering students who do not have access to modern equipment during their studies. Also, research activity is disregarded during medical studies, PhD not being a priority for the medical staff.

For solving the human resources issues, it is necessary to go through a series of steps in several directions, the first of them being to update the nomenclature of occupations in Romania – COR with the position of "medical data analyst". Step two could be the solution to another important aspect, underlined by some of the interviewees, related to the need of hiring well prepared and well-paid support staff (data stewards and analysts, security experts) to create a competitive environment in terms of IT prepared employees.

### 4.3.5 Legal and regulatory framework regarding health data spaces

The legal and regulatory frameworks regarding health data spaces within the European Union (EU) are critical for ensuring the protection of personal health information while promoting health research and public health. This report focuses on the specific legal and regulatory environments of Bulgaria, Cyprus, Greece, and Romania as outlined in the EU GDPR (EU, 2016).

## Bulgaria

There is still no explicit legislation regulating the data spaces topic. The only document in Bulgaria mentioning the term "data spaces" is the Operational program Research, innovation, and digitization for intelligent transformation 2021-2027. The operational program plans for development of several data spaces in the main sectors in Bulgaria, including education, healthcare, transport, etc. The budget for the planning and development of all data spaces is above EUR 12 million and should be distributed in the next 2 years for all data spaces to be developed and operational until 2027.

The development of the data spaces is preceded by analysis of the relevant sectors and their needs which is performed by experts from the World Bank. The analysis is currently in its first phase, whereas it is about to start in the next month or two. The analysis should be finalized by mid-2024. Afterwards the development of the data spaces will start simultaneously for all data spaces to be ready until 2027. The Ministry which is the main beneficiary in this operational program axis is the Ministry of Electronic Governance (MEG), which is also a partner in the VELES project.

## Cyprus

The Ministry of Health and the National Bioethics Committee play pivotal roles in the evaluation of research applications related to health data. The National Bioethics Committee, composed of three Review Bioethics Committees, oversees protocols relating to biomedical research on human beings and their biological substances, clinical trials on medicinal products for human use, and medical devices applied on human beings. For pseudonymized data, the Committee's approval is necessary, indicating a requirement for ethical consideration even when identifying information is obscured. An application fee of 50 Euros is required, with no additional fees payable, suggesting a structured yet accessible approach to health data research oversight (Ministry of Health Cyprus, n.d).

## Greece

The GDPR and the implementing Law 4624/2019 set the conditions under which the processing of personal health data is lawful. Nevertheless, many questions arise when applying these provisions for the secondary use of data, as the framework set out is not entirely clear and causes legal uncertainty for both data holders and data users. The legal issues that arise relate to the choice of the legal basis for processing, the form and content of consent, the definition of scientific research, the definition of the terms and conditions to ensure the compatibility of the secondary purposes and the rights of data subjects in the case of scientific research. Law 4600/2019 allows, by decision of the Minister of Health, the controller, grants permission to the data processor (i.e., IDIKA) to publish or grant access, on a subscription or special fee basis, to statistical data that no longer identifies data subjects and comes from the operation of the Individual Electronic Health Record archiving system (AHFY). However, this provision has never been exercised.

## Romania

The National Health Insurance House (CNAS)<sup>25</sup> manages data storage, including data from Electronic Health Records (EHRs). However, the system is not yet fully functional and needs harmonization, leaving currently no procedure applicable for researchers seeking access to health data. Romania, as an EU Member State, adheres to the General Data Protection Regulation (GDPR), which sets a high standard for the protection of personal data, including health information. Laws such as Law No. 46/2003 on Patient Rights, Law No. 95/2006 on Healthcare Reform, and Law No. 677/2001 on the Protection of Individuals regarding the Processing of Personal Data establish the legal foundation for health data management, ensuring patient privacy and data security.

## Comparative analysis

Below is a comparative analysis in table format, highlighting **the similarities and differences in health data governance** across Cyprus, Romania, Bulgaria, and Greece within the EU framework (Policy Department for Economic, Scientific and Quality of Life Policies, Directorate-General for Internal Policies, 2022):

---

<sup>25</sup> <http://www.casan.ro/default/index/index/lang/EN>

Table 1 Snapshot of how each country approaches the governance, access, and interoperability of health data, showcasing the variety in regulatory environments and operational practices within the context of the GDPR.

Country	Legal Framework & Governance	Access Mechanism & Data Sharing	Stakeholder Engagement & Interoperability
<b>Bulgaria</b>	National Centre of Public Health and Analyses provides statistical information following the Health Act and Personal Data Protection Act. Limited to public information access.	Written application for access to data, mainly public information. Shows a structured but limited approach.	NCPHA's role in health information suggests a centralized approach yet with potential interoperability and data sharing limitations.
<b>Cyprus</b>	Ministry of Health and National Bioethics Committee evaluate research applications. Three Review Bioethics Committees review protocols. Pseudonymised data requires ethics decision.	Application to Ministry of Health with National Bioethics Committee decision. 50 Euro application fee.	National Bioethics Committee plays a crucial role in research application evaluations.
<b>Greece</b>	The Minister of Health, as data controller, allows the data processor (i.e., IDIKA) to publish or grant access, on a subscription or special fee basis, to statistical data that no longer identifies data subjects and comes from the operation of the Individual Electronic Health Record archiving system (AHFY). Each organization's Ethical Committee approves data collection for research purposes within the context of specific research projects.	Application to the Ministry of Health for getting permission to access health data processed by IDIKA.	Legislation supports data sharing for scientific research with safeguards for data protection. However, detailed mechanisms for stakeholder engagement not specified.
<b>Romania</b>	The National Health Insurance House is collecting and managing data for reimbursement purposes. The National Institute of Public Health is collecting aggregated data from hospitals and other institutions. Data for research is obtained based on each organization's Ethical Committee approval.	Challenges due to lack of specific legislation impacting cross-border health data sharing for care purposes.	Identified legal fragmentation and complexity in exchange of information, hindering interoperability.

The legal and regulatory frameworks for health data spaces in Bulgaria, Cyprus, Greece, and Romania demonstrate the EU's commitment to both protecting individual privacy and advancing public health and research. While Cyprus and Bulgaria have established mechanisms for ethical review and statistical data provision, respectively, Romania faces challenges with a non-functional system. Greece, on the other hand, has a specific agency dedicated to managing technical access, following granted permission by the Ministry of Health. Each country's approach reflects its unique legal, ethical, and operational frameworks within the broader context of GDPR compliance and the pursuit of harmonizing health data management across the EU.

This comparative analysis highlights the diverse approaches within the EU to managing health data spaces, underlining the importance of national legislation in complementing EU-wide data protection standards to facilitate health research, public health monitoring, and the secure and ethical use of health data.

#### 4.3.6 Stakeholders' role in the National, regional, local ecosystems

The stakeholders in the health data ecosystems across Bulgaria, Cyprus, Greece, and Romania are diverse, with common challenges such as data fragmentation and a focus on improving transparency, communication, and stakeholder involvement. Each country presents unique initiatives and approaches to address these challenges and enhance their health data systems:

##### Bulgaria

The health system in Bulgaria involves numerous stakeholders with varying levels of awareness and engagement. Key players include government bodies, health insurance institutions, medical professionals, and advocacy groups. The **Ministry of Health (MH)**, **Ministry of Electronic Governance (MEG)**, and **National Health Insurance Fund (NHIF)** play pivotal roles. MH is responsible for the overall management of the healthcare system and coordination among all participants in the healthcare sector; it is in charge of implementing the Strategy and developing the electronic healthcare system. It aims to create a management model that ensures active participation of all stakeholders. MEG has the role to achieve effective electronic governance in all sectors and is responsible for approving sectoral strategies for the development of electronic governance. NHIF is organizationally separated from the MH's system, with its own governing bodies and separate budget, managing the mandatory health insurance system in Bulgaria. The institution's legal functions are divided between the central administration and 28 regional health insurance funds (RHIF).

The non-operational status of key councils and limited citizen awareness of data protection rights pose challenges. However, proposed measures, including an **Advisory Council** and planned annual reports of the MH, present opportunities for improving transparency, communication, and overall system efficiency. The proposed Advisory Council emphasizes collaboration among key stakeholders, reflecting a recognition that success in electronic healthcare initiatives relies on collective efforts.

##### Cyprus

The health data sharing ecosystem encompasses a diverse network of stakeholders, including frontline healthcare providers, medical practitioners, research scholars, policy experts, patient advocacy groups, regulatory authorities, and private sector participants. This broad framework is vital in shaping the health data domain in Cyprus. Patient advocacy organizations, research scientists, and policymakers are also identified as pivotal figures actively driving stakeholder engagement. The Cyprus Bioethics Committee is identified as a central and operational authority overseeing the ethical aspects of medical data sharing for research. Its pivotal role in regulatory processes highlights the importance of ethical considerations in the evolving health data ecosystem. As provided in the country analysis, below is the current and desirable involvement of the different categories of stakeholders in Cyprus:

Table 2 Stakeholders Involvement in Cyprus

Stakeholder type	Level of Involvement/ Representation		Description / Notes
	Current	Desirable	
<b>Government Regulatory Bodies</b>	Medium	High	Primary role in setting policies and regulations for health data management.
<b>Healthcare Providers (Hospitals, Clinics)</b>	Low	Medium	Directly involved in collecting and using health data but with varying degrees of engagement in broader initiatives.
<b>IT and Data Management Companies</b>	Medium-High	Medium-High	Provide technical solutions and support for health data systems.
<b>Patient Advocacy Groups</b>	Medium	High	Advocating for patient rights and privacy has a significant but not leading role.
<b>Research Institutions</b>	Medium	Medium-High	Engage in health data for research purposes, dependent on data availability.
<b>Insurance Companies</b>	Low	Medium	Use health data for policy design and risk assessment, interested in data access.
<b>Pharmaceutical Companies</b>	Low	Low	Interested in health data for research and development but less directly involved in data collection or management.
<b>Public/Citizens</b>	Variable	High	The ultimate source of health data; their involvement varies widely based on public awareness and engagement initiatives.

## Greece

The Ministry of Health and the healthcare organizations it supervises are key stakeholders of the health ecosystem in Greece. Key stakeholders also include IDIKA, GRNET<sup>26</sup> (both supervised by the Ministry of Digital Governance), the research and academia community, vendors, IT providers, patients, healthcare providers from both the public and private sectors, and the pharma industry. Addressing issues like data fragmentation and establishing effective governance are seen as crucial for the successful implementation of health data initiatives. There is insufficient communication and cooperation between the different Ministries and stakeholders, including pharmaceutical and technological companies, health professionals/doctors and citizens. To address the issue of fragmentation, the Greek Ministry of Health is doing efforts through a mapping of the sources of health data in Greece, as well as the structures that collect data and a preparatory work is carried for the European Health Data Space (EHDS).

In terms of authorities for the health data, it is stressed by interviewees in the public sector the need to have a public authority e.g., the Ministry of Health in the role of the “Health Data Access Body (HDAB)”, as it is happening in other countries, while interviewees from the private sector believed that an independent authority with sufficient personnel would be more efficient.

<sup>26</sup> GRNET S.A. – National Infrastructures for Research and Technology, <https://grnet.gr/en/>

There is a need for a strong ecosystem and network of stakeholders, patients, and interested parties during the transformative period around health data in Greece. Strategic planning with specific milestones and the creation of committees with stakeholder groups are recommended for a successful transformation process. Also, the need for active involvement of users - citizens, healthcare professionals, IT vendors, and innovation clusters is highlighted to prevent design failures during implementation.

## Romania

In Romania's health data system, a diverse range of stakeholders, including public and private entities, NGOs, academic institutions, and patients, contribute significantly to its functionality. Public Health Authorities, exemplified by the **Ministry of Health**, play a crucial role in regulating standards, managing data, and fostering technological adoption. The **private sector**, represented by innovative companies like Infoworld and IC Med, drives technological evolution, offering solutions for efficient data management and improved doctor-patient interactions. **NGOs**, such as Asociația Dăruiește Aripă, advocate for standards, transparency, and data protection, influencing policies and contributing to vital projects like the National Registry of Paediatric Onco-Hematology. **Hospitals and academic institutions** act as key data owners/providers, with a symbiotic relationship supporting research and skills development. **Patients**, though indirectly involved, shape a patient-centric system, as emphasised by the Coalition of Patients with Chronic Diseases. **The European Digital Innovation Hubs (E-DIH's)** are the newcomers, starting with 2022, in the landscape of digital transformation and in the case of Romania, **all 7 hubs selected by EC and currently running, are addressing the e-health sector.**

A strong collaboration among the diverse stakeholders and working close with the authorities to develop policies and legislation to encourage data sharing is crucial, along with promoting standards and protocols that ensure safe and ethical data sharing. Encouraging partnerships between different sectors, such as public, private and academic, is vital to overcoming technical and legislative obstacles.

To effectively delineate the roles and involvement of these diverse stakeholders, it is imperative to address the **underlying issue of public trust in the medical system and the use of health data in Romania**. Establishing an **Ethics Committee** comprising trusted individuals and operating transparently could significantly enhance this trust. Such a committee would not only bolster public confidence but also clarify and strengthen the roles and responsibilities within the health data system, ensuring that it operates ethically and effectively for the benefit of all stakeholders.

## 4.4 Good Practices in widening countries

The conducted research has identified several good practices from the four widening countries in terms of operating systems, technical infrastructure, health data records, health registries and other.

### 4.4.1 Bulgaria

The identified good practices refer to:

- 1) Centralised digitization and control of health data, including health records and electronic prescriptions, providing access to each person's health record, and eliminating paper media.
- 2) Bulgaria's strengths, reflected in the SWOT analysis;
- 3) Operating systems, technical infrastructure, health data records, health registries;
- 4) Some “soft practices” that have an indirect impact on the better adoption of innovations and shared data spaces among patients, medical professionals, academia, etc. They reflect the specifics of the sector and the good practices of institutions, academia, civil society and business.

*Table 3 Good practices in Bulgaria*

Practice	Explanation
<b>New curricula in medical universities</b>	New curricula have been introduced in the medical universities in Bulgaria to prepare doctors to work in a digital environment, such as the "Course in Digital Health Care and Innovations" at Medical University-Sofia and the web-based course in "Digital Medicine" at the Medical University of Plovdiv.
<b>Access to personal health Information, eHealth App.</b>	Patients have legally established rights to access their health information. Quick and secure access for all citizens to their personal patient file through the <b>eHealth mobile application</b> . Everyone can access all electronic health documents entered into the National Health Information System.
<b>Increased digital health literacy</b>	Increased digital health literacy of the population through new programs provided by civil organisations, such as the National Patient Organisation, the Bulgarian Association for Personalised Medicine and the DHI (Digital Health and Innovation) cluster, which created the ground for the good adoption of innovations in the digitalisation of health care in the context of data spaces.
<b>Private value-added initiatives</b>	Private value-added initiatives that result in a wide range of expert solutions for the healthcare industry, such as solutions for patients to have timely access to the medications they need and quality care throughout their treatment journey. Examples: SAT Health - an innovative service provider for Patient Support Programs as performing expert healthcare

	system analysis and providing effective technology solutions and encouraging business initiatives for innovation in the real-time data exchange and use.
<b>Patient advocacy groups</b>	Patient advocacy groups were established for the different socially relevant diseases to protect patients' rights and support patients and families in their journey to access the relevant information and receive the best treatment for them.
<b>National Health Insurance System/File</b>	A National Health Insurance (NHI) System of the NHI Fund was built, working with entirely digitized data. In addition, the system offers numerous e-services for citizens <sup>27</sup> . The data and services of the system are constantly being enriched and expanded in scope. Every citizen has access to their health insurance file.
<b>National Health Information System/File</b>	<p>The National Health Information System (NHIS)<sup>28</sup> is being built in stages, with the following fully electronic at the moment:</p> <ul style="list-style-type: none"> <li>• Examinations by GPs and outpatient medical care/dental care specialists<sup>29</sup>Prescriptions issued (currently, all prescriptions are digital)<sup>30</sup></li> <li>• The issued referrals for consultation to a specialist; laboratory referrals; referrals to a hospital treatment facility; referrals to labor-expert medical committee; hospital papers; medical notes for students;</li> <li>• Electronic file/booklet of the chronically ill;</li> <li>• Protocols for treatment with expensive medicinal products;</li> <li>• The performed laboratory tests and their results;</li> <li>• Dispensing from pharmacies of medicinal products according to electronic prescriptions;</li> <li>• Hospital medical care performed during hospitalization of patients activity, used medical devices, applied medicinal products<sup>31</sup></li> <li>• Rental, repair and maintenance of aids, devices, equipment, and medical devices for people with disabilities;</li> <li>• Electronic health record (patient file)<sup>32</sup></li> <li>• E-health – a mobile application allowing everyone to access their patient file<sup>33</sup></li> <li>• Register of newborns.</li> </ul>

<sup>27</sup> <https://www.nhif.bg/bg/people/e-services>

<sup>28</sup> <https://www.his.bg/bg/about>

<sup>29</sup> <https://www.his.bg/bg/medicinski-specialisti/opl>

<sup>30</sup> <https://www.his.bg/bg/medicinski-specialisti/apteki>

<sup>31</sup> <https://www.his.bg/bg/medicinski-specialisti/bolnici>

<sup>32</sup> <https://my.his.bg/login>

<sup>33</sup> <https://his.bg/ezdrave/>

#### 4.4.2 Cyprus

The approach taken by Cyprus, particularly the involvement of the National Bioethics Committee in the evaluation of research applications, stands out as a best practice. This ensures that all health data research adheres to strict ethical standards, balancing innovation with the protection of individual rights. The application process, including the requirement for ethics approval and the nominal application fee, exemplifies a structured and transparent mechanism for health data management.

- **Ethical Review Process:** Cyprus employs a robust ethical review process for research applications involving health data, managed by the Ministry of Health and the National Bioethics Committee. This committee plays a crucial role in evaluating research protocols, ensuring that biomedical research, clinical trials, and medical device applications meet high ethical standards. Including a detailed examination of this process could highlight Cyprus's commitment to ethical considerations in health data use.
- **Pseudonymisation and Privacy Protection:** The requirement for researchers to obtain approval from the National Bioethics Committee, even for pseudonymised data, showcases Cyprus's dedication to privacy protection. This practice ensures that all health data research respects the privacy and rights of individuals, aligning with GDPR's stringent requirements for data protection.
- **Data Governance Frameworks:** Cyprus has established a data governance framework that delineates clear responsibilities and processes for accessing, using, and sharing health data securely and ethically.
- **Public Engagement and Transparency:** Cyprus is engaging the public and the patients' associations (one official of the Patients' Association sits on the Board of NEHA, having been appointed by the Council of Ministers) and ensures transparency in how health data is used, which helps to build trust and support from citizens towards health data initiatives.
- **Cross-border Data Sharing Initiatives:** Cyprus participates actively in EU-wide health data sharing projects or initiatives, demonstrating Cyprus's commitment to contributing to and benefiting from shared European health data resources.

#### 4.4.3 Greece

Several good practices exist in the country, in line with the national strategy for the digital transformation of the entire Greek society and economy, as developed by the Ministry of Digital Governance for the sector of Health & Decent Living (Hellenic Ministry of Digital Governance, 2021). In the domain of Health, the pandemic crisis accelerated the implementation of projects that were needed for decades within the national health system. Good practices include:

- The National Electronic Prescription System<sup>34</sup>, which was first introduced in Greece in 2010, with >98% coverage of doctors and pharmacists, supports the systematic recording of electronic prescriptions, dispensations and referrals, paperlessly as dictated by the law.
- The COVID-19 patient registry was put into operation in 2020. It allows patients diagnosed with COVID-19 to be monitored by treating physicians to ensure continuity of care simplifying communication between doctor and patient with COVID-19 (through teleconsultation and immaterial and remote prescribing), as well as easing and making more effective the cooperation between the National Public Health Organization (EODY-NPHO) and the General Secretariat of Civil Protection.
- GRNET has installed and operates a data and services centre in the cloud environment that serves, amongst others, the health sector including hospitals. As a result, the long-term archiving and retrieval service of imaging examinations in the health sector is modernised and services offered to citizens of the country are improved.
- The Personal Health Insurance Record<sup>35</sup>, operated by EOPYY, is an innovative application that contains data on all recorded hospitalizations, health services, materials, diseases and diagnoses that exist in electronic records and refer to almost all of the country's insured population. It enables the users to monitor and manage electronically all the services they have received (hospitalizations, materials, diagnoses, etc.), as well as the costs charged to their National Registry of the Social Security Number (AMKA).
- The Social Security Number (AMKA) which has been established as the employment and social security identification number of all citizens in Greece. AMKA facilitates the linking of patient information among EHR systems in the country.
- Ministry of Health's initiative for the development of an interoperability framework for the health domain in the country (Hellenic Ministry of Health, 2021).
- The recently introduced myHealth Mobile App<sup>36</sup>, through which citizens can access and manage a range of their medical data. Through MyHealth, the users can manage and view information about their prescriptions and referrals, have immediate and easy access to their physical prescription history and receive notifications about new prescriptions and exam referrals, and issue medical certificates that the doctors have registered in the Electronic Prescription System. The application is constantly enriched with new features.
- The national health and pharmaceuticals research infrastructures (NRIs) that span a wide array of analytical capabilities pertinent to various aspects of biomedical research. More specifically, the bioinformatics initiative ELIXIR-GR<sup>37</sup>, has the broadest scope encompassing research from basic

---

<sup>34</sup> Find out more at <https://www.e-prescription.gr/>

<sup>35</sup> <https://www.gov.gr/en/ipiresies/ugeia-kai-pronoia/phakelos-ugeias/phakelos-asphalises-ugeias-phau>

<sup>36</sup> <https://www.gov.gr/en/ipiresies/ugeia-kai-pronoia/phakelos-ugeias/epharmoge-gia-kinetes-suskeues-myhealth>

<sup>37</sup> <https://www.elixir-greece.org/>

biological sciences to clinical applications. BIOIMAGING-GR<sup>38</sup> primarily supports basic science, especially cell biology, which is known to have the most significant impact in the basic biomedical research domain. As research progresses towards translational applications, resources such as mouse models for exploring the connection between molecular mechanisms and diseases (INFRAFRONTIER-GR<sup>39</sup>), along with 'omics' technologies (pMedGR<sup>40</sup>), are strategically positioned to facilitate medical applications. Additionally, services integral to the drug discovery process, including the identification of bioactive molecules (OPENSREEN-GR<sup>41</sup>) and strategies for initial drug development (INSPIRED<sup>42</sup>), are offered. Support infrastructure for pre-clinical trials in translational research (EATRIS-GR<sup>43</sup>) is also available, and the coordination of Greek biobanking efforts (BBMRI-GR<sup>44</sup>) supports the continuum from pre-clinical to clinical stages in biomedical research. Due to the lack of a unified legal structure, the operational methods of these NRIs vary significantly.

- Active participation in a number of relevant EU projects, such as the ones for the provision of cross-border eHealth services to EU citizens (currently for ePrescription and patient summary), the JA-09 Joint Action on primary use of health data, xShare and GR-HDAB.
- Prioritising the expansion of the national health system Electronic Health Record, alongside key initiatives like enhancing hospitals' digital infrastructure and expanding patient registers, utilising funds reserved through RRF. Furthermore, advancing telemedicine services for people living in isolated regions highlights a health policy centred on the individual. Concurrently, other pioneering measures are being encouraged, including genomic research.

#### 4.4.4 Romania

In May 2023, Romania joined the European initiative „1+ Million Genomes” (1+MG) which aims to enable secure and federated access to relevant genomic and clinical data from across the EU for high-level research, personalized healthcare and health policy development. A key project in this sense at the national level is the strategic project "Development of genomic research in Romania" (ROGEN) dedicated to developing the genomic medical research in Romania. The ROGEN project also includes the creation of a reference genome for Romania and the standardization of the system. The project created a national research network (major RPOs) in genomics and will ensure the development of the Genomics Research and Development Institute (ICDG). ROGEN is funded with 85 mil. euros (through ERDF - the Health Operational Program) plus 4 mil. Euros (ESF funds) for the training of staff who will work within the network, as well as at the ICDG. The

---

<sup>38</sup> <https://bioimaging.gr/>

<sup>39</sup> <https://www.infracontier.gr/>

<sup>40</sup> <https://physiology.med.uoa.gr/en/research-infrastructure-services/infrastructures/pmed/>

<sup>41</sup> <https://openscreen.bio.demokritos.gr/>

<sup>42</sup> <https://www.inspired-ris.gr/>

<sup>43</sup> <https://tinyurl.com/eatrisgr>

<sup>44</sup> <https://www.bbmri-eric.eu/national-nodes/greece/>

project is supported by the involvement of international genomics experts from prestigious universities in the USA and/or the UK/EU.

The National Electronic Vaccination Record (RENV) in Romania stands out as an exemplary practice within the healthcare system. RENV is owned and managed by the National Institute of Public Health (INSP), through the National Center for Surveillance and Control of Communicable Diseases (CNSCBT). It has been established by a Ministerial Order in August 2011 and in its current version contains data on all vaccines administered in Romania (whether is flu vaccine, COVID-19 or other optional vaccines purchased by parents or individuals who want to be vaccinated). It serves as a centralized repository of vaccination records accessible through an individual's personal identification number (CNP), allowing for real-time access to vaccination information. One of RENV's notable strengths lies in its interoperability, particularly for family doctors. Through their credentials within RENV, family doctors can seamlessly access screening applications wherein they actively participate. This integrated access eliminates the need for separate applications, streamlining their workflow and making it more efficient.

Romania is the only European country that introduced in legislation the citizen's right to personalized medicine. The law 406/2003 on patients' rights has been amended in 2023 by provisioning that the patient has the right to personalized medicine. The specialist physician has the obligation to provide the patient with reliable, relevant, and easily understandable information regarding the options for proposed medical interventions, including their anticipated benefits and risks. The collection, sharing, management, and standardization of data necessary for the development and implementation of personalized medicine are carried out in accordance with data protection legislation.

## 5 SWOT Analysis

A SWOT analysis was performed to evaluate the Strengths, Weaknesses, Opportunities, and Threats as part of the state of play of each ecosystem based on the research that was conducted in the four widening countries. It involved identifying internal and external factors that are favourable or unfavourable to achieving the development of health data spaces. The SWOT analysis can act as a strategic tool to help ecosystems identify areas where they excel, areas where they need to improve, potential avenues for growth, and external challenges they may face. It serves as a basis for developing strategies to capitalise on strengths, address weaknesses, exploit opportunities, and mitigate threats.

## 5.1 SWOT analysis per country

### 5.1.1 Bulgaria

STRENGTHS	WEAKNESSES
<p><b>Technical infrastructure:</b> Health network covering the entire country. National use of information systems for accounting and electronic reporting. Local ICT companies developing e-health solutions in Bulgaria.</p> <p><b>Governance:</b> Existence of NHIS and a national health strategy for digital healthcare. Stakeholder mapping in national strategic documents.</p> <p><b>Human Resources:</b> High proportion of skilled workforce with digital skills and competencies. Well-developed medical education system.</p> <p><b>Legal and regulatory:</b> Laws for cybersecurity and identification. Outpatient care legislation could be used to legally regulate telemedicine. Patients have legally established rights to access their health information stored by healthcare facilities.</p>	<p><b>Technical infrastructure:</b> Outdated NHIS. Expensive and slow-to-deploy technology. Lack of standards and technical requirements.</p> <p><b>Data readiness:</b> EHR lacking patient history data, does not follow standards for security, privacy, and operational compatibility. Both digital and paper.</p> <p><b>Governance:</b> Inappropriate and ineffective collaborations. Lack of e-consent, rules and protocols for exchange or secondary use. No control over unauthorized use of health data.</p> <p><b>Human resources:</b> Lack of skilled personnel, motives and incentives, resources for training.</p> <p><b>Legal and regulatory:</b> Lack of a framework for regulating HDS, consent, storage, and access to data GDPR compliant, requirements. Telemedicine, not explicitly regulated.</p>
OPPORTUNITIES	THREATS
<p><b>Technical infrastructure:</b> Expand NHIS for federated data-sharing. Automate data management and sharing.</p> <p><b>Data readiness:</b> Rules about format, structure, and technical standards for registries.</p> <p><b>Governance:</b> Secondary use enablement. Medical research projects. Technology transfer and data use. Digitization Maximizing digitization of consent and control over data usage. eHealth strategy implementation. EU and national funds.</p> <p><b>Human resources:</b> Enhance collaborations, competencies and motivation of professionals. Increase health literacy.</p> <p><b>Legal and regulatory:</b> Bulgarian National Framework for Operational Compatibility for Information Systems in the Executive Power, Digital Transformation Strategy project.</p>	<p><b>Technical infrastructure:</b> Access control to sensitive health data may create violations of GDPR.</p> <p><b>Data readiness:</b> Distortion of generated data compromises reliability and use of data.</p> <p><b>Governance:</b> Lack of systematic rules and funding for the implementation of innovations result in missed opportunities and risks.</p> <p><b>Human resources:</b> Lack of awareness, trust, and acceptance of eHealth systems. Limited competence and digital literacy. Lack of training on data privacy and data handling can lead to system failures and sabotage by certain public groups. Low percentage of people with basic digital skills.</p> <p><b>Legal and regulatory:</b> Failure to update and structure the legal framework.</p>

## 5.1.2 Cyprus

STRENGTHS	WEAKNESSES
<p><b>Technical infrastructure:</b> Centralized online portals for patients to access their health records, improving health management.</p> <p><b>Data readiness:</b> Advances in interoperability across health information systems for seamless data exchange.</p> <p><b>Governance:</b> Active engagement in EU health data projects, aligning with European standards. Effective partnerships between public and private sectors in healthcare, enhancing data sharing.</p>	<p><b>Technical infrastructure:</b> Existing data sharing infrastructure is limited and not fully developed. Difficulty in integrating diverse health data collection systems.</p> <p><b>Data readiness:</b> Existing data readiness is limited and not fully developed. Inconsistent data practices and concerns over privacy and data protection.</p> <p><b>Governance:</b> Existing data sharing systems governance. Ethical approval and patient consent complexities hinder data sharing efforts.</p> <p><b>Human resources:</b> Limited involvement from various healthcare stakeholders, affecting data sharing impact.</p> <p><b>Legal and regulatory:</b> Ambiguities in health data laws may deter participation and trust in data sharing.</p>
OPPORTUNITIES	THREATS
<p><b>Technical infrastructure:</b> Potential to leverage new tech for more efficient data sharing and management.</p> <p><b>Data readiness:</b> Data exchange protocols among healthcare providers enhancing the quality and breadth of clinical data.</p> <p><b>Governance:</b> Opportunity to utilize EU resources for improving digital health infrastructure.</p> <p><b>Human resources:</b> Potential to enhance clinical data quality and accessibility through increased collaborations. Enhancing public trust and understanding of health data initiatives through education and awareness campaigns.</p> <p><b>Legal and regulatory:</b> EU proposal EHDS regulation.</p>	<p><b>Technical infrastructure:</b> Ongoing threats to sensitive health data necessitate strong security measures to minimize cybersecurity risks.</p> <p><b>Data readiness:</b> Disparities in data collection methods, coding standards, and storage practices. Absence of standardized data sharing protocols.</p> <p><b>Governance:</b> Privacy and control concerns may hinder participation in health data sharing.</p> <p><b>Human resources:</b> Limitations in skills, technology, and funding could restrict health data initiatives.</p> <p><b>Legal and regulatory:</b> Potential for health data exploitation, underscoring the need for a robust ethical framework. Legal ambiguities may discourage stakeholder engagement with health data systems.</p>

### 5.1.3 Greece

STRENGTHS	WEAKNESSES
<p><b>Technical infrastructure:</b> Recent developments e.g., COVID-19 registry and a long-term archiving and retrieval service of imaging data in the cloud environment of GRNET.</p> <p><b>Data readiness:</b> Existence of reliable data e.g., electronic prescriptions and electronic referrals. Existence of data repositories from EOPYY, IDIKA, medical companies, the Ministry of Health (BI-Health) and research infrastructures. Inclusion of RRF projects e.g., National EHR.</p> <p><b>Governance:</b> Interoperability framework for health. Capacity of governmental bodies e.g., GRNET, IDIKA, to extract data.</p> <p><b>Human resources:</b> Development of inventories</p> <p><b>Legal and regulatory:</b> Integration of the Open Data Directive.</p>	<p><b>Technical infrastructure:</b> Insufficient interconnection between units managing RWD</p> <p><b>Data readiness:</b> Fragmentation. Lack of structured and quality data.</p> <p><b>Governance:</b> Lack of basic registries, procedures for secondary use, EHR data model, governance structures. Fragmented policy actions without strategy and vision</p> <p><b>Human resources:</b> Lack of specialised personnel. Limited financial benefits and motivation. Majority of health professionals not convinced of the value of EHR data recording. Multiple stakeholders need to cooperate.</p> <p><b>Legal and regulatory:</b> Ambiguities in the application of GDPR. Strict and not flexible legislation.</p>
OPPORTUNITIES	THREATS
<p><b>Technical infrastructure:</b> Many EU registries already exist and can serve as an example. The infrastructure guidelines within the EHDS proposal regulation. Several research, innovation and operational infrastructures that are already developed and used in Greece</p> <p><b>Data readiness:</b> Need of data for new markets e.g., medical tourism for assisted human reproduction, for facilitation of clinical trials, for secondary use for research.</p> <p><b>Governance:</b> Funding through RRF. Mechanisms for evaluation of DRGs. New National Interoperability Framework for Public Services. Proposal for EHDS Regulation and implementation. Pre-commercial procurement projects.</p> <p><b>Human resources:</b> Technological advancements e.g., AI, personalised medicine beneficial impact for stakeholders.</p>	<p><b>Technical infrastructure:</b> Fragmentation of registries at technical, semantic, organisational, legal levels. Creation of registries is a time-consuming process.</p> <p><b>Data readiness:</b> Lack of quality data.</p> <p><b>Governance:</b> Lack of vision &amp; political will. Corruption, suspicion &amp; feelings of mistrust to the use of data. Monopolies and oligopolies in the ecosystem. Sustainability due to insufficient funding for systems maintenance</p> <p><b>Human resources:</b> Lack of skilled personnel. Lack of incentives to record quality data. No engagement of medical community. Brain-drain, understaffing.</p> <p><b>Legal and regulatory:</b> Frequent change in protocols and standards.</p>

## 5.1.4 Romania

STRENGTHS	WEAKNESSES
<p><b>Technical infrastructure:</b> A growing number of healthcare providers are using digital systems to collect and manage patient data. A growing number of private companies developing innovative health data solutions.</p> <p><b>Data readiness:</b> Functional data registries like rare diseases, cancer, vaccines provide valuable data despite lacking interoperability. Local successes in certain areas, e.g., Timisoara, that showcase successful digitalization in specific sectors like radiology.</p> <p><b>Human resources:</b> Involvement of public &amp; private entities, NGOs, academic institutions, and patients ensures a multifaceted approach.</p> <p><b>Legal and regulatory:</b> Existing laws and strategies (albeit evolving) outline the management and protection of health data.</p>	<p><b>Technical infrastructure:</b> Fragmented infrastructure., hindering data exchange and patient journey monitoring.</p> <p><b>Data readiness:</b> Disconnected systems in public and private healthcare limit data sharing and interoperability. Disparities in data formats, storage and collection impede efficient utilization.</p> <p><b>Governance:</b> Lack of transparent and clear framework for access to data for secondary use.</p> <p><b>Human resources:</b> Shortage of specialized personnel in health data management &amp; limited technical skills among health professionals.</p> <p><b>Legal and regulatory:</b> Lack of unitary and clear approach to security issues related to patient data compromise trust &amp; reliability of e-health records.</p>
OPPORTUNITIES	THREATS
<p><b>Technical infrastructure:</b> National Recovery and Resilience Plan that aims to develop a systemic framework for data governance. The development of the National Observatory for Health Data is a promising strategic intervention.</p> <p><b>Data readiness:</b> Health data use is becoming increasingly regulated and standardized in EU level.</p> <p><b>Governance:</b> Development of e-health strategy and participation in EU level health data initiatives. New opportunities for using health data due to growing demand for personalized medicine.</p> <p><b>Human resources:</b> Planned investments in IT infrastructure and continuous professional training offer new opportunities. A growing number of private companies developing innovative solutions for managing health data.</p>	<p><b>Technical infrastructure:</b> Dispersed funding models might lead to fragmented implementations across healthcare units.</p> <p><b>Governance:</b> Political transitions and shifts could disrupt ongoing initiatives and impact their continuity. The lack of clear national health data strategy could lead to fragmentation and inefficiencies.</p> <p><b>Human Resources:</b> The increasing volume and complexity of health data could be overwhelming for healthcare providers. Lack of trust in the system and transparency issues could impede effective data sharing and utilization</p> <p><b>Legal and regulatory:</b> Inadequate or contradictory laws may hinder progress related to interoperability and data sharing.</p>

## 5.2 SWOT Critical Analysis

**Existing implementation capabilities were identified** in all 4 countries in relation to the transformation towards the Regional Smart Health Data Space. This establishes a knowledge base of costs, accuracy, governance, and timeframes for health data collection and for navigating the politics of shifting public care funding between intervention and prevention. Furthermore, the relative digital maturity of private healthcare providers identifies the need to strengthen innovation and investment for the public benefit. Common data ownership principles, as well as common challenges of consent management and public engagement represent areas of universal interest outside these 4 widening countries, highlighting an interesting place to leverage the development of infrastructure and learnings from advanced countries through collaborations aligned with local place-based data spaces.

**Barriers of implementation** include the lack of defined coordination and alignment mechanisms for standardisation for data collection methods, coding, storage practices, data sharing protocols. In particular, the lack of data quality assurance or access control standards represents a foundational risk to the credibility of any data utilisation. Conversely, the suggestion of utilising the data spaces as a mechanism for the continuous evaluation of diagnosis related groups (DRGs) represents a powerful application to drive health care economics and political will. Investment in health care capacity for broad change implementation (data culture and streamlined data-driven change management) will be key to realising both the data space and its most important benefits.

**Data integration and interoperability** was naturally raised; however, this needs to be validated carefully to consider where variations in care delivery design (flowing from devolved care) need to be interoperable while maintaining semantic integrity. Balancing the need for quality secondary use with devolved, evolvable care is a universal challenge for pooled health analysis. Reframing the dialogue about data quality to carefully delineate the richness of diversity of care delivery designs (i.e., semantic or care interoperability) from data interoperability limitations will be explored during validation – i.e., in the context of how the quality of the data (fitness) may be determined by the appropriateness of the question being asked of it.

**Retaining professionals with data and IT skills** was also raised, however this needs to be validated in its context carefully – as data spaces could be designed to limit the dependence on such scarce resources. Indeed, the issues raised by fragmentation of digital systems, governance models and data protection mechanisms are all driving the divergence and proliferation of skills requirements, exacerbating the scarcity of skills. In contrast, crystallising the visions for place-based data spaces to utilise common modular elements, could greatly minimise the need for distributed high skills to support data spaces. Indeed, common processes across countries could allow for more efficient distribution of resources by relying on advanced countries to bear the cost of ultra-skilled expertise to support common technology and curriculum development, while reducing the cost of targeted upskilling of a broader range of distributed workers (i.e., local nurses, admin, doctors, vendors).

**Dispersed funding models were raised as a risk for uncoordinated implementation** of data spaces within and between European nations. Given that the funding for data space implementations or the funding sources are not yet established, flexible funding models may be necessary. Indeed, industry access to data and low-cost open-source data transformation solutions both represent potential non-government value sources for health data space establishment. Furthermore, the rapid expansion of open-source data transformation and analytic capabilities across health ecosystems must be considered as a potentially self-perpetuating 'uncoordinated' implementation strategy with low costs, medium skill requirements and high scalability.

**Disparities of secondary use** giving advantage to local clinicians and government while limiting access to other users (including industry) was raised. For example, trusted access by local doctors and government may represent a fair risk/benefit analysis of the safer context of data sharing or it could represent a disparity of access, 'gate-keeping' data insights to monopolise IP, publications and innovation. Procedural transparency could cut both ways, but standardising approaches to quantitating privacy risk (privacy interoperability) may not be easily compatible with the social licence granted by the community for secondary use. This question of standardising assessment of social licence and then balancing this with medical, innovation, clinical, economic, and political imperatives, while simultaneously guarding against undue commercial influence is undoubtedly complicated. However, this has been addressed in a variety of ways in certain health systems globally that should inform vision setting. Conversely, scepticism or caution towards data sharing (whether motivated by privacy, data control, or transparency) may impact stakeholder support for data access initiatives, highlighting the function of data-culture and data-literacy investments to focus implementation on shared values and benefits of data utilisation.

Several parameters are likely critical to realise national health data spaces, and these exist currently to a limited extent i.e., funding availability, platform governance and design, skill base and implementation knowledge.

## 6 Recommended actions to support the ecosystems transition path

Based on the above analysis, the following actions need to be implemented to support the ecosystem transition path within the four targeted widening countries. Even though each country has its specifics, several common action points have been identified during the research conducted.

### **Action point #1: Development of the Legal Framework and Institutional Work / Governance Framework**

The primary and most emphasised aspect to consider is the necessity for developing a **coherent legal framework**. Currently, the legal framework does not adequately address the requirements for electronic healthcare or data sharing (Bulgaria and Romania), lacks patient-centricity in Romania, is ambiguous and unclear, leading to erosion of trust (Cyprus) and regulations that exist may not be implemented (Greece). Therefore, there is an urgent need to **transition to a legal and regulatory framework that will create the conditions for quality data collection and secure secondary use**. Systems should be developed incrementally, with models such as those developed in the VELES research project, shifting the focus from data collection platforms to data spaces.

Another crucial aspect is the necessity for developing a systematic legislative approach regarding personal data protection in healthcare. Additionally, there is a continuous need for thorough information and education of all parties involved regarding their rights and obligations under the law.

### **Action point #2: Technical infrastructure for primary and secondary use**

When considering data for primary and secondary use, the crucial aspect lies in the **harmonisation of formats and rules for data registries**. Establishing **clear rules for the structure of registries and technical standards for interoperability** could enhance the **quality of collected health data** and facilitate broader **secondary usage of information for research and statistical purposes**. A comprehensive analysis, involving end-users, prior to the acquisition, development, and deployment of the system is imperative.

What is essential is the establishment of a **simplified system for obtaining consent for data collection, processing, and usage**, along with a transparent model for controlling data usage. This model should provide citizens with real and effective control over their personal data, including the right to utilise this data for research and statistical purposes.

In building a robust health data innovation ecosystem, strategic investments are essential. In respect of technical infrastructure, investments are still needed in the existing infrastructures to support structured and interoperable EHRs. Cloud-based storage solutions ensure scalability and accessibility, while standardised data formats and protocols facilitate interoperability. Integrating advanced technologies like blockchain enhances security for data transactions and decentralised storage, safeguarding data integrity and privacy. Together, these investments fortify the ecosystem's foundation and drive transformative advancements in healthcare delivery and research.

### **Action point #3: Enhancing Citizen's Digital and Functional Health Literacy**

To raise awareness of the importance of data sharing, it is essential to take a comprehensive approach that includes **education and awareness through seminars, workshops, and conferences, as well as presenting case studies and success stories that highlight the concrete benefits of this practice.**

The understanding and general assumption that the reliability of the data/information provided by a patient or health professional is returned as knowledge that is further utilised for the benefit of society is of utmost importance.

There is a need for Functional Health Literacy (FHL) for citizens to enhance the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.

Launching an educational campaign among the public about what is and the nature of data sharing spaces - how they work and how participants (users and data providers) can engage in such spaces could be an example of action.

On another hand, creation of incentives for the recording of medical data in every contact of citizens with the health system could be also another action.

### **Action point #4: Enhancing Competencies and Motivation of Medical Professionals / Human Resources, Skills, and Training**

In nurturing a skilled workforce for the health data innovation ecosystem, a multifaceted approach is key. Continuous education programs focusing on data literacy, analytics tools, and research methodologies equip professionals with essential knowledge. Supplementing this education with mentorship opportunities and hands-on projects allows individuals to apply their skills in practical settings, fostering deeper understanding and proficiency. Moreover, by encouraging interdisciplinary collaboration among healthcare professionals, data scientists, and domain experts, the ecosystem promotes innovation and the exchange of diverse perspectives, ultimately driving forward progress in healthcare research and delivery.

To significantly improve health data management quality, investments in human resource training are necessary, along with creating additional incentives to enhance motivation and awareness in data sharing and control in compliance with legislation. Internal training can be organised for staff, focusing on understanding data significance and its use in enhancing health services and patient care.

Updating the regulatory framework of the occupation nomenclature by introducing new positions such as medical data analyst and employment of staff dedicated to data stewardship and security experts is also suggested.

### **Action point #5: Enhancing Trust and Ethics and Building on Best Practices**

To effectively delineate the roles and involvement of these diverse stakeholders, it is imperative to address the underlying issue of public trust in the medical system and the use of health data.

For example, in Romania, establishing an Ethics Committee comprising trusted individuals and operating transparently could significantly enhance this trust. Such a committee would not only bolster public confidence but also clarify and strengthen the roles and responsibilities within the health data system, ensuring that it operates ethically and effectively for the benefit of all stakeholders.

As such, in Bulgaria, establishing an Advisory Council for Electronic Healthcare and publishing annual reports on Strategy implementation to ensure transparency through regular updates to stakeholders about progress in measures, projects, and activities related to electronic healthcare, and their impacts or outcomes.

An important suggestion is the fully digitising of the consent process, controlling usage, and ensuring ethics and legality in both primary and secondary data use.

In the pursuit of a robust health data innovation ecosystem, enhancing trust and ethics is paramount. By prioritising transparency, accountability, and data privacy, stakeholders can cultivate a culture of trust among participants. Building on existing best practices, ensures responsible data stewardship and fosters confidence in the ecosystem's integrity. Through ongoing dialogue, collaboration, and continuous improvement, the ecosystem can uphold ethical standards, promote trustworthiness, and inspire confidence in its ability to harness health data for improved healthcare services.

#### **Action point #6: Using State of the Art Cybersecurity and AI technologies**

Confronting privacy and security threats requires stringent cybersecurity measures and data protection protocols. This is essential for safeguarding the integrity and confidentiality of health data.

In safeguarding the integrity and security of health data within the innovation ecosystem, leveraging state-of-the-art cybersecurity and AI technologies is paramount. Advanced cybersecurity measures, including encryption, intrusion detection systems, and multi-factor authentication, fortify defences against cyber threats and unauthorised access. Additionally, AI technologies such as machine learning algorithms can proactively identify and mitigate potential security risks by analysing vast amounts of data in real-time. By integrating these cutting-edge technologies, the ecosystem can ensure robust protection of sensitive health information, bolstering trust among stakeholders and enabling the safe and responsible utilisation of data for innovation and research.

#### **Action point #7: Enhanced stakeholder engagement and collaboration**

To bolster the health data innovation ecosystem, enhanced stakeholder engagement and collaboration are essential. By fostering open communication channels and inclusive decision-making processes, stakeholders can collectively drive innovation forward. Through strategic partnerships between healthcare providers, researchers, technology experts, policymakers, and entrepreneurs, valuable insights and resources can be

shared, accelerating the development and adoption of innovative solutions. Moreover, by promoting a culture of continuous learning and knowledge exchange, the ecosystem can remain agile and responsive to evolving needs and opportunities. This collaborative approach not only enhances competitiveness but also propels the ecosystem towards the forefront of innovation in healthcare delivery and research.

There is a notable need for more stakeholder participation. Efforts must be made to foster greater participation across the spectrum of stakeholders, incorporating their perspectives in decision-making, planning, and execution of health data projects. This involves developing cohesive multi stakeholder collaboration constructs, leveraging formal governance and stakeholder engagement to unlock the synergistic potential of the health data sharing process.

### **Action point #8: Fostering data-driven healthcare innovation**

In the context of data-driven healthcare innovation, a productive innovation ecosystem facilitates knowledge and idea sharing between industry, care providers and researchers. This requires a level playing field for data access that fairly acknowledges the inherent differences in the alignment of industry contexts and use cases with social license for data use. Legal support and education are required to enable collaborations that effectively protect innovations and enable commercialization. The government is required to address the needs of these three stakeholder groups to both guard the public sector from undue commercial influence while simultaneously removing barriers to collaboration. Public involvement should also be considered for the important function of embedding end-users early in the innovation process and providing early access to the benefits of new innovations. By fostering productive interactions between innovation stakeholders in these ways, not only can new applications for data driven-care reach patients faster, but the infrastructure for data utilisation can be better informed and faster established to address innovation needs.

## 7 Innovation ecosystem transition path

### 7.1 Overall strategy for innovation ecosystem transition path

Creating innovation ecosystems and building regional health data spaces involves integrating various dimensions such as technical infrastructure, data readiness, governance, human resources, skills and training, and legal and regulatory aspects. For each dimension the strategy and transition path are defined based on the research findings of the state of play analysis of the four widening country ecosystems.

#### 1. Technical Infrastructure:

- **Strategy:** Develop robust and interoperable technical infrastructure capable of securely storing, managing, and exchanging health data.
- **Transition Path:**
  - Invest in cloud-based storage solutions to enable scalability and accessibility.
  - Implement standardised data formats and protocols to facilitate interoperability.
  - Integrate advanced technologies like blockchain for secure data transactions and decentralised storage.

#### 2. Data Readiness:

- **Strategy:** Ensure that health data is clean, comprehensive, and accessible for analysis and innovation.
- **Transition Path:**
  - Establish data quality standards and procedures for data collection, cleaning, and validation.
  - Invest in data integration tools to aggregate data from disparate sources.
  - Implement data governance frameworks to ensure data consistency, accuracy, and privacy.

#### 3. Governance:

- **Strategy:** Establish clear governance structures and policies to guide the use and sharing of health data.
- **Transition Path:**
  - Formulate data governance committees comprising stakeholders from healthcare, government, industry, and academia.
  - Develop data sharing agreements and consent frameworks to address privacy and security concerns.

- Implement mechanisms for transparent decision-making and accountability in data management.

#### 4. Human Resources:

- **Strategy:** Build a skilled workforce capable of leveraging health data for innovation and research.
- **Transition Path:**
  - Offer training programs and workshops on data analytics, machine learning, and health informatics.
  - Collaborate with academic institutions to develop curriculum tailored to the needs of the health data ecosystem.
  - Foster partnerships with industry experts and mentors to provide practical experience and guidance.

#### 5. Skills and Training:

- **Strategy:** Enhance the skills of existing healthcare professionals and researchers to effectively utilise health data.
- **Transition Path:**
  - Offer continuous education programs on data literacy, analytics tools, and research methodologies.
  - Provide mentorship opportunities and hands-on projects to apply learned skills in real-world scenarios.
  - Encourage interdisciplinary collaboration among healthcare professionals, data scientists, and domain experts.

#### 6. Legal and Regulatory:

- **Strategy:** Navigate complex legal and regulatory landscapes to ensure compliance and foster trust in the health data ecosystem.
- **Transition Path:**
  - Stay updated with evolving regulations such as GDPR, EU regulations, and data protection laws.
  - Establish data governance policies aligned with regulatory requirements and ethical guidelines.
  - Engage with policymakers, legal experts, and industry associations to advocate for supportive regulatory frameworks.

By implementing these strategies and transition paths, stakeholders can collaboratively create robust health data space innovation ecosystems that harness the power of data to drive transformative advancements in healthcare delivery, research, and outcomes.

## 7.2 Innovation pathways

Innovation within health data ecosystems can emerge through various pathways enabled by the strategies and transition paths outlined earlier:

1. **Iterative Development and Experimentation:** With improved technical infrastructure and data readiness, innovators can rapidly prototype and iterate upon new ideas and solutions. By leveraging standardised data formats and advanced technologies like blockchain, developers can experiment with novel applications and services, refining them based on real-world feedback and data insights.
2. **Collaborative Research and Development:** Enhanced stakeholder engagement and interdisciplinary collaboration foster a culture of knowledge sharing and co-creation. Researchers, healthcare providers, data scientists, and technology experts can collaborate on projects that leverage their respective expertise to tackle complex healthcare challenges. This collaborative approach encourages the cross-pollination of ideas and sparks innovation through the integration of diverse perspectives and insights.
3. **Data-Driven Insights and Decision-Making:** A skilled workforce equipped with data literacy and analytics expertise can extract valuable insights from health data, driving evidence-based decision-making and innovation. By applying advanced analytics techniques to large datasets, innovators can uncover patterns, trends, and correlations that inform the development of new diagnostics, treatments, and interventions.
4. **Entrepreneurship and Startup Ecosystems:** A supportive ecosystem that offers mentorship, funding, and resources can catalyse entrepreneurship and the formation of startups focused on health data innovation. Entrepreneurs can identify unmet needs and market opportunities within the healthcare landscape, developing innovative solutions that address these challenges. By fostering a culture of innovation and risk-taking, the ecosystem encourages entrepreneurial ventures that drive forward transformative advancements in healthcare.
5. **Ethical and Responsible Innovation:** Adherence to legal and regulatory compliance ensures that innovation within the ecosystem is conducted ethically and responsibly. Innovators prioritize patient privacy, data security, and ethical considerations in their development processes, building trust and confidence among stakeholders. By embracing ethical principles and best practices, the ecosystem fosters sustainable innovation that benefits both individuals and society as a whole.

Overall, innovation within health data ecosystems emerges through a combination of technical advancements, collaborative efforts, data-driven insights, entrepreneurial initiatives, and ethical considerations. By creating an enabling environment that supports experimentation, collaboration, and responsible innovation, the ecosystem can unlock the full potential of health data to drive transformative change in healthcare delivery and outcomes.

## 8 Conclusions

Deliverable 2.1 of the VELES Excellence Hub project consolidates the evaluation of the state of play and the innovation ecosystem strategy and transition path for Bulgaria, Cyprus, Greece, and Romania to create a South-East Europe Smart Health Innovation Ecosystem enabled by a Regional Smart Health Data Space (RSHDS). The state of various dimensions of health data space preparedness are documented, identifying broad commonalities across the 4 widening nations, and some differences. Most notably, further investments in technical, human, governance and legal resources need to be provided for establishing robust health data spaces. This is in line with the experiences of the advanced partner countries, signifying that health data ecosystems remain in the early stages of establishment.

In conclusion, the strategies and transition paths outlined pave the way for a dynamic and collaborative health data ecosystem where innovation thrives. By investing in robust technical infrastructure, promoting data readiness and governance, nurturing a skilled workforce, and ensuring legal and regulatory compliance, stakeholders create an environment conducive to innovation. Through iterative development, collaborative research, data-driven insights, entrepreneurship, and ethical considerations, innovation emerges organically, driving transformative advancements in healthcare delivery and outcomes. By leveraging the full potential of health data and embracing a culture of innovation, the ecosystem stands poised to address complex healthcare challenges, improve patient outcomes, and ultimately shape the future of healthcare for the better.

The next step of VELES is to formulate a transformational framework to be incorporated in the validation exercises taking into consideration common practices and existing gaps and constraints, including security. It will propose a joint framework for digital transformation and delivery projects around four pillars:

- i) Health Industry Digital Culture,
- ii) Health industry place-based innovation ecosystem (innovative startups and SMEs),
- iii) Digital approach (dream, design, deliver) and,
- iv) Data and Cybersecurity preparedness pathway.

The validation of the transformational framework will be achieved with discussion sessions among partners or key stakeholders and through workshops in each ecosystem using a series of Dream, Design, Deliver validation exercises on a place-based principle, clarifying in more detail, the health data space design constraints, resources and requirements along the innovation ecosystem transition path. The relevant experience from existing and new projects will be leveraged for driving the solution design, exploration and pilot activities of VELES.

## 9 References

### EU Reports & articles:

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (2021). An analysis of SMEs' needs in public procurement. [https://single-market-economy.ec.europa.eu/publications/analysis-smes-needs-public-procurement\\_en](https://single-market-economy.ec.europa.eu/publications/analysis-smes-needs-public-procurement_en)

EIT Health (2023). Implementing the European Health Data Space in Sweden - EIT Health EHDS Report 2023. 27 June 2023 workshop proceedings. <https://eithealth.eu/wp-content/uploads/2023/11/Implementing-the-European-Health-Data-Space-in-Sweden.pdf>

Ejehiohen Iyawaa, G., Herselmana, M., Bothaa, A. (2016). Digital health innovation ecosystems: From systematic literature review to conceptual framework. Conference on ENTERprise Information Systems. <https://core.ac.uk/download/pdf/82330447.pdf>

European Commission (2022). Horizon Europe Work Programme 2021-2022 11 - Widening participation and strengthening the European Research Area. [https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-11-widening-participation-and-strengthening-the-european-research-area\\_horizon-2021-2022\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-11-widening-participation-and-strengthening-the-european-research-area_horizon-2021-2022_en.pdf)

European Commission (2024). Second staff working document on data spaces. <https://digital-strategy.ec.europa.eu/en/library/second-staff-working-document-data-spaces>

European Union (2016). General Data Protection Regulation (GDPR). <https://eur-lex.europa.eu/eli/reg/2016/679/oj>

European Union (2020a). COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS A European strategy for data. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066>

European Union (2020b). Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act). <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767>

European Union (2022). Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197>

European Union (2024). SUMMARY RECORD PERMANENT REPRESENTATIVES COMMITTEE 4, 5, 6, 8, 10, 11 and 12 December 2023. <https://data.consilium.europa.eu/doc/document/ST-16641-2023-INIT/en/pdf>

Foray, D., Goddard, J., Goenaga Beldarrain, X., Landabaso, M., McCann, P., Morgan, K., Nauwelaers, C., and Ortega-Argilés R. (2012). Guide on Research and Innovation Strategies for Smart Specialisation (RIS3

Guide). <https://s3platform.jrc.ec.europa.eu/en/w/guide-on-research-and-innovation-strategies-for-smart-specialisation-ris3-guide->

OECD (2017). OECD Recommendation on Health Data Governance. <https://www.oecd.org/els/health-systems/health-data-governance.htm>

Policy Department for Economic, Scientific and Quality of Life Policies, Directorate-General for Internal Policies (2022). The European Health Data Space: Study Requested by the ITRE Committee. [https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL\\_STU\(2022\)740054\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL_STU(2022)740054_EN.pdf)

Strategic Forum on Important Projects of Common European Interest (IPCEI) (2018). Strengthening Strategic Value Chain for a future-ready EU industry - Report on the Strategic Forum on IPCEI. <https://ec.europa.eu/docsroom/documents/37824/attachments/2/translations/en/renditions/native>

## **Bulgaria**

Bulgarian Commission for Personal Data Protection (n.d.). Personal Data Protection Act. <https://www.cdpd.bg/en/index.php?p=element&aid=164>

eHealth mobile. <https://his.bg/ezdrave/>

Ministry of Health. <https://www.mh.government.bg/>

Ministry of Electronic Governance (MEG). <https://egov.government.bg/>

National Health Insurance Fund (NHIF), National Health Insurance system. <https://www.nhif.bg/bg/people/e-services>

National Health Information System (NHIS). <http://www.his.bg>

## **Cyprus**

Ministry of Health Cyprus. (n.d.). National Bioethics Committee. [https://www.bioethics.gov.cy/moh/cnbc/cnbc.nsf/index\\_en/index\\_en?OpenDocument](https://www.bioethics.gov.cy/moh/cnbc/cnbc.nsf/index_en/index_en?OpenDocument)

National Center of Public Health and Analyses. (n.d.). About us. [https://www.ncpha.government.bg/?page\\_id=27&lang=en](https://www.ncpha.government.bg/?page_id=27&lang=en)

Republic of Cyprus (2014). eHealth Law of Cyprus. [https://www.cylaw.org/nomoi/indexes/2019\\_1\\_59.html](https://www.cylaw.org/nomoi/indexes/2019_1_59.html)

## **Germany**

Bundesgesundheitsministerium (2019). Digitale-Versorgung-Gesetz – DVG. <https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/detail/digitale-versorgung-gesetz-dvg.html>

Bundesgesundheitsministerium (2020a). Verordnung über das Verfahren und die Anforderungen zur Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der gesetzlichen

Krankenversicherung (Digitale Gesundheitsanwendungen-Verordnung - DiGAV). <https://www.gesetze-im-internet.de/digav/BJNR076800020.html>

Bundesgesundheitsministerium (2020b). Patientendaten-Schutz-Gesetz - PDSG. <https://www.bundesgesundheitsministerium.de/patientendaten-schutz-gesetz>

Bundesgesundheitsministerium (2023a). GEMEINSAM DIGITAL. Digitalisierungsstrategie für das Gesundheitswesen und die Pflege. [https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3\\_Downloads/D/Digitalisierungsstrategie/BMG\\_Broschuere\\_Digitalisierungsstrategie\\_bf.pdf](https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/D/Digitalisierungsstrategie/BMG_Broschuere_Digitalisierungsstrategie_bf.pdf)

Bundesgesundheitsministerium (2023b). Bundesgesundheitsminister legt Digitalisierungsstrategie vor: „Moderne Medizin braucht digitale Hilfe“. <https://www.bundesgesundheitsministerium.de/presse/pressemitteilungen/digitalisierungsstrategie-vorgelegt-09-03-2023.html>

Bundesgesundheitsministerium (2023c). Die elektronische Patientenakte (ePA). <https://www.bundesgesundheitsministerium.de/elektronische-patientenakte>

Bundesgesundheitsministerium (2023d). Nationale Pharmastrategie beschlossen. <https://www.bundesgesundheitsministerium.de/presse/pressemitteilungen/nationale-pharmastrategie-beschlossen-pm-13-12-23>

Bundesgesundheitsministerium (2024a). Gesundheitsdatennutzungsgesetz – GDNG. <https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/detail/gesundheitsdatennutzungsgesetz.html>

Bundesgesundheitsministerium (2024b). Krankenhaustransparenzgesetz. <https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/detail/krankenhaustransparenzgesetz.html>

Bundesgesundheitsministerium (2024c). Medizinforschungsgesetz. <https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/detail/medizinforschungsgesetz.html>

Bundesministerium für Wirtschaft und Klimaschutz (n.d.). Exportinitiative Gesundheitswirtschaft. <https://www.bmwk.de/Redaktion/DE/Artikel/Aussenwirtschaft/exportinitiative-gesundheitswirtschaft.html>

GTAI - Germany Trade & Invest (n.d.). HEALTH MADE IN GERMANY - Finding Partners. <https://www.gtai.de/en/invest/industries/healthcare-market-germany/health-made-in-germany>

McKinsey (2024). Studie: Apps auf Rezept werden häufiger verschrieben – aber Digitalisierung im Gesundheitswesen geht nur stockend voran. <https://www.mckinsey.com/de/news/presse/2024-01-24-e-health-monitor-2023-24>

## Greece

Hellenic Ministry of Digital Governance (2021). The Digital Transformation Bible 2020 – 2025.

[https://digitalstrategy.gov.gr/website/static/website/assets/uploads/digital\\_strategy.pdf](https://digitalstrategy.gov.gr/website/static/website/assets/uploads/digital_strategy.pdf)

Hellenic Ministry of Health (2021). Newsletter on the progress of the project Design and Implementation of the National eHealth Interoperability Framework (NeHIF) - July 2021.

<https://www.moh.gov.gr/articles/ehealth/9050-newsletter-on-the-progress-of-the-project-design-and-implementation-of-the-national-ehealth-interoperability-framework-nehif-july-2021>

Law 4600/2019, Art. 84. <https://www.kodiko.gr/nomothesia/document/501691/nomos-4600-2019>

Law 4624/2019 Issue A' 137/29.08.2019, Art. 22. [https://www.dpa.gr/sites/default/files/2020-02/nomos\\_4624\\_2019.pdf](https://www.dpa.gr/sites/default/files/2020-02/nomos_4624_2019.pdf)

Horizon Europe Policy Support Facility (2022). Support to Greece for policies developing research infrastructures and the R&I ecosystem. <https://gsri.gov.gr/wp-content/uploads/2022/10/Support-to-Greece-for-policies-developing-research-infrastructures-and-the-RI-ecosystem.pdf>

Pontikakis D. (2020). Presentation at JRC about Smart Specialisation in Greece: experience and future opportunities. <https://tinyurl.com/maktusb7>

## Romania

Adrnordest (n.d.). SMART SPECIALIZATION. <https://www.adrnordest.ro/en/what-we-offer/smart-specialization/>

CNAS (2021). COMUNICAT – Dosarul Electronic de Sănătate a redevenit functional.

<https://cnas.ro/2021/12/22/comunicat-dosarul-electronic-de-sanatate-a-redevenit-functional/>

CNAS (n.d.). Cardul național de asigurări de sănătate. <https://cnas.ro/cardul-national-de-asigurari-de-sanatate/>

CNAS (n.d.). Sistemul Informatic de Prescripție Electronică. <https://tinyurl.com/3v8hn3k9>

CNAS Unic Integrat (n.d.). Portal CNAS-SIUI Sistemul Informatic. [http://siui.casan.ro/cnas/despre\\_siui](http://siui.casan.ro/cnas/despre_siui)

Law 95/2006. <https://tinyurl.com/Law-95-2006>

Ministerul Investițiilor și Proiectelor Europene (2021). PLANUL NAȚIONAL DE REDRESARE ȘI REZILIENȚĂ AL ROMÂNIEI. <https://mfe.gov.ro/wp-content/uploads/2021/10/facada6fdd5c00de72eecd8ab49da550.pdf>

## Annex I. Definitions

**Access:** ‘Access’ means processing by a data user of data that has been provided by a data holder, in accordance with specific technical, legal, or organizational requirements, without necessarily implying the transmission or downloading of such data [*Data Governance Act COM/2020/767 final*].

**Data:** ‘Data’ means any digital representation of acts, facts or information and any compilation of such acts, facts or information, including in the form of sound, visual or audiovisual recording [*Data Governance Act COM/2020/767 final*].

**Data holder:** ‘Data holder’ means a legal person or data subject who, in accordance with applicable Union or national law, has the right to grant access to or to share certain personal or non-personal data under its control [*Data Governance Act COM/2020/767 final*].

**Data Governance framework:** A data governance framework is a set of rules, processes, and responsibilities that dictate how an organization collects, organizes, stores, and uses its data. The goal of a data governance framework is to set a standard on how data is managed (to ensure its integrity), leveraged by internal teams, and protected from security risks [*Segment*<sup>45</sup>].

**Data readiness:** Data readiness can be expressed as a hierarchical conceptual framework involving four constructs: data quality, data availability, interoperability, and data provenance [*Douthit, et al., 2021*].

**Data sharing:** ‘Data sharing’ means the provision by a data holder of data to a data user for the purpose of joint or individual use of the shared data, based on voluntary agreements, directly or through an intermediary [*Data Governance Act COM/2020/767 final*].

**Data user:** ‘Data user’ means a natural or legal person who has lawful access to certain personal or non-personal data and is authorised to use that data for commercial or non-commercial purposes [*Data Governance Act COM/2020/767 final*].

**Data quality:** ‘Data quality’ means the degree to which characteristics of electronic health data are suitable for secondary use [*EHDS COM/2022/197 final*].

**Digital Health Ecosystem:** ‘Digital Health Ecosystem’ means domain specific ecosystem that supports the transformation of the organization-centered healthcare model into a patient-centered model. The main purpose of this system is to deliver multidisciplinary and collaborative health services.

**Health Data Space:** ‘Health Data Space’ means health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at: i) empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide, and support to their free movement, as well as fostering a genuine single market for electronic health record systems, relevant medical devices and high-risk AI systems (primary use of data); ii) providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data) [*EHDS COM/2022/197 final*].

---

<sup>45</sup> <https://segment.com/data-hub/data-governance/framework/>

**Electronic health data:** ‘Electronic health data’ means personal or non-personal electronic health data [EHDS COM/2022/197 final].

**Electronic Health Record (EHR):** ‘EHR’ means a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes [EHDS COM/2022/197 final].

**Electronic health record system (EHR system):** ‘EHR system’ means any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records [EHDS COM/2022/197 final].

**Innovation:** ‘Innovation’ means the successful introduction of new services, products, processes, business models and ways of working [The Economic and Social Research Council (ESRC) recommendation].

**Innovation Ecosystem:** ‘Innovation Ecosystem’ means an interconnected network of organizations that coevolve capabilities around a shared set of technologies, knowledge, or skills, and work cooperatively and competitively to develop new products and services [Moore, 1993].

**Interoperability:** ‘Interoperability’ means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support [EHDS COM/2022/197 final].

**IT or Technical infrastructure:** IT or Technical infrastructure refers to the composite hardware, software, network resources and services required for the existence, operation and management of an enterprise IT environment [Techopedia<sup>46</sup>].

**Personal data:** Personal data concerning health should include all data pertaining to the health status of a data subject which reveals information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test [Regulation (EU) 2016/679].

**Personal electronic health data:** ‘Personal electronic health data’ means data concerning health and genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services, processed in an electronic form [EHDS COM/2022/197 final].

---

<sup>46</sup> <https://www.techopedia.com/definition/29199/it-infrastructure>

**Primary use of electronic health data:** ‘Primary use of electronic health data’ means the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services [EHDS COM/2022/197 final].

**Real-world data:** Real-world data are data relating to patient health status and/or the delivery of health care routinely collected from various sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status [FDA<sup>47</sup>].

**Real-world evidence:** Real-world evidence is clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD [FDA<sup>48</sup>].

**Secondary use of electronic health data:** ‘Secondary use of electronic health data’ means the processing of electronic health data for purposes set out in Chapter IV of this Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use [EHDS COM/2022/197 final].

---

<sup>47</sup> <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

<sup>48</sup> <https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

## Annex II. Guidelines for T2.1 Data Collection



# ANNEX II STRENGTHENING THE SOUTH-EAST EUROPE SMART HEALTH REGIONAL EXCELLENCE AND BOOSTING THE INNOVATION POTENTIAL

HORIZON-WIDERA-2022-ACCESS-04-01

## Guidelines for T2.1 Data Collection

[WP2 Smart Health Regional ecosystem enablement and  
transformational framework of change]

Contributions: HDHC, IMAGO-MOL, GATE, BIOBG

## Introduction

This document is developed in the context of *WP2 - Smart Health Regional ecosystem enablement and transformational framework of change* of the “**VELES Excellence Hub - Strengthening the South-East Europe Smart Health Regional Excellence and Boosting the Innovation Potential**” project. WP2 places the grounds for the project with the following activities:

- An analysis of the current state of play and identification of the challenges in each ecosystem in the 4 widening countries – through research of each country practices, law acts, interviews, etc.
- Development of a strategy to strengthen Smart Health innovation ecosystems for the benefit of all stakeholders;
- Development of a transformation framework which aim is to foster development of new, sustainable Smart Health services;
- Validation of the framework through validation exercises.

The current document constitutes the **guidelines for the partners to collect the necessary data for the analysis of the current state of play and identification of the challenges**, which will drive the consortium to the development of *D.2.1 State of play and Strategy for innovation ecosystem transition path* focusing on the development of health data spaces.

## 1. Methodology

The main purpose of task *T2.1 State of play analysis of the four place-based ecosystems* is **to understand the 4 place-based ecosystems** and their potential to establish health data spaces by:

1. examining local problems and challenges,
2. identifying key stakeholders,
3. performing a comparative gap analysis in smart health research, innovation, and business uptake capabilities & needs.
4. The task also includes a review on current legal framework and relevant strategies (incl. RIS3).

Task 2.1 is led by HDHC and the following Contributors: GATE, JOIST, IMAGO-MOL, CIT, BIOBG, UEFISCDI, CYENS, AMEN, NEHA, and 3AeHealth.

With the current methodology, we aim to analyse the current state of play and identify challenges in each ecosystem in the 4 widening countries (Bulgaria, Greece, Cyprus, Romania). By extension, this activity will

support us to defining a strategy to strengthen Smart Health innovation ecosystems for the benefit of all stakeholders. To better approach this requirement, it is important to engage with key stakeholders and discuss their views using a semi structured questionnaire. In parallel, relevant documents for policies and strategies for each country as well as the EU will be collected and analysed to provide a comprehensive profile for each country under study.

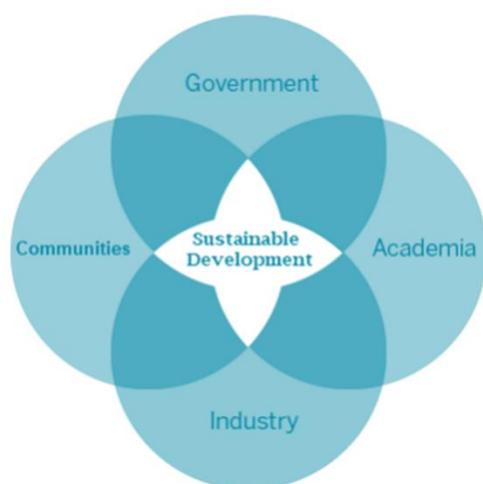
The following steps cover the needed actions to be implemented by the 4 widening partner countries:

### 1<sup>st</sup> step: Development of desk research

Partners from the 4 widening countries will need to conduct desktop research regarding the current situation in their national context. The desktop research should cover the themes which are mentioned in Chapter 3.

All partners involved need to identify key documents that are important as reference material for the needs of WP2.

### 2<sup>nd</sup> step: Identification of key stakeholders & implementation of interviews



The partners should collaborate to **conduct 5 – 7 semi-structured interviews per country with key stakeholders** from their national ecosystems. The interviews can be conducted either online or face-to-face and they will have a duration of around 30'. The interviewing partners should follow the Interview Questions (Section 4). Based on the status of the interviewee (e.g. medical professional, politician, business representatives, etc.), the interviewers should focus at covering all the topics, but choose which questions are more relevant to the interviewee. Our aim through the interviews is to cover as many topics and thus, as many questions as possible. However, we will need to be flexible and consider the possible time/knowledge

limitations of the interviewee, and conduct the interviews based on the professional's expertise.

The partners will need to identify the key stakeholders based on the Quadruple Helix stakeholder cooperation, coordination and co-development approach (involving public authorities/policy makers, industry, academia/ research, citizen/society). After identifying the stakeholders, the partners will need to fill the "Stakeholders list" document (See Annex I.) This document will help us track the profile and diversity of the stakeholders that will be involved in the research phase. See Annex III for the steps, you will need to do for the interviews.

### 3<sup>rd</sup> step: Country analysis

Partners should use the country analysis report template (See Annex IV) to report the main findings of their research procedures.

## 2. Definition of Data Spaces

Before starting the collection of data, it is important to have a clear definition of Data Spaces among the partnership, which will help us in the collection of data. According to [OPEN DEI](#) (2021)<sup>49</sup>, “A **data space** can be defined as a federated data ecosystem within a certain application domain and based on shared policies and rules.” The users of such data spaces are enabled to access data in a secure, transparent, trusted, easy and unified fashion. This access and usage right can only be granted by those persons or organisations who are entitled to dispose of the data.

The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide, and support to their free movement, as well as fostering a genuine single market for electronic health record systems, relevant medical devices and high risk AI systems (primary use of data) providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities (secondary use of data). As such, the European Health Data Space is a key pillar of the strong European Health Union and it is the first common EU data space in a specific area to emerge from the European strategy for data<sup>50</sup>.

### 3. Desktop research

The partners will collect **EU documents** related to health data spaces and ecosystems. All partners should add important documents that need to be analysed to give an overview of EU developments related to health data spaces, in the **respective file** “[VELES WP2 Bibliography](#)”.

**For each ecosystem**, the partners will need to identify also, the following:

- Policy, strategy, and legal documents about health data and health data sharing
- Health data sharing practices at a national level
  - o capacity for sharing of data for medical care (primary use)
  - o capacity for using real world data (RWD) for research purposes (secondary use)
- National, regional, local initiatives for health data sharing (could be research such as clinical trial network)
- National, regional, local digital health systems and types of data collected.
- OTHER (please specify)

---

<sup>49</sup> <https://www.opendei.eu/wp-content/uploads/2022/03/Position-Paper-Design-Principles-for-Data-Spaces.pdf>

<sup>50</sup> [https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en)

## 4. Interview questions

Before conducting the interviews, the participants will need to sign the consent form of the interview (See Annex II) that includes the necessary information about it.

The following questions are divided in thematic areas. Since we will conduct semi-structured interviews, the interviewer can follow the questions guide according to the responses of the interviewee.

The questions need to focus on the following general dimensions

1. Technical infrastructure for primary and secondary data
2. Data infrastructures and data readiness
  - a. Data collections and sources for primary use and for secondary use
  - b. Data interoperability and standards
  - c. Data quality and integrity including data updates, real time data
  - d. Data security and privacy
  - e. Consent management and patient engagement
3. Governance framework
  - a. Governance bodies
  - b. Governance for accessing data
  - c. Collaboration agreements
4. Human resources, skills and training
5. Legal and regulatory framework
6. Stakeholders and their role in the National, regional, local ecosystems

Data collection will focus on these dimensions. The following section presents the questionnaire for collecting data.

## 5. Preamble & Questionnaire

Dear expert,

We would like to invite you to an interview about health data spaces. The aim of this interview is to provide us with your expert knowledge and advice about creating health data spaces nationally and regionally.

This interview is organized in the context of the Horizon Project “*VELES Excellence Hub - Strengthening the South-East Europe Smart Health Regional Excellence and Boosting the Innovation Potential*” (Project 101087483). VELES aims to foster health data sharing regional and national strategies, to secure improved clinical practice, to preserve patient’s privacy and to empower citizens’ smart healthcare through access to innovative, cyber secure and data driven digital health services.

The interview will last approximately 1 hour. It will take place online or face-to-face based on your availability and will be recorded. The interview and the recording will be confidential.

Your contribution is essential for identifying the current situation in the ecosystem. To participate in the interview, you will need to sign the **Consent Form** which informs you about the data regulation procedures and how they will be used, in compliance with GDPR regulation.

By participating in the interview, you will contribute with your expertise to the analysis of the national context regarding health data spaces and provide information about the strengths, weaknesses, opportunities and threats that might exist.

Your participation to the interview will include you into the broader VELES stakeholders ecosystem that can generate new opportunities for your actions, e.g. participation in events as speaker, citation in papers produced by the project and other opportunities as they may arise. Upon you consent, your name will be mentioned in the relevant Veles white paper to acknowledge your contributions.

Thank you in advance.

The VELES team.

## Questionnaire:

### 1. Technical infrastructure for primary and secondary use

- What digital systems are currently being used in your country for primary health data collection? E.g., Electronic health records, clinical trial data, national registries, e-prescription etc. Mention the most relevant.
- What are the existing infrastructures for data sharing and what are the plans for expansion?
- Who are the providers of technical infrastructure within your area?

### 2. Data infrastructures and data readiness

- a. Data collections and sources for primary use and for secondary use
  - b. Data interoperability and standards
  - c. Data quality and integrity including data updates, real time data
  - d. Data security and privacy
  - e. Consent management and patient engagement
- What type of health data exists and where are data created, produced, stored?
  - Are there any quality assurance measures for the quality of the collection of primary health data?
  - What are the National, regional or local data collections and sources?
  - Who can have access to the data and how is it obtained? If others want to use them, do they have access to them and how? What are the common practices in each community about data sharing? E.g., ask about blockchain cyber security, RWD etc.
  - Is there interorganizational data sharing and/or national data sharing for research or care provision? Do you know of any projects that are doing data sharing for research or other purposes?
  - How do the local ecosystems handle data about their chosen disease (Alzheimer (Bulgaria), Cancer treatment (Greece), Dementia (Cyprus), Cerebral tumours (Romania))?
  - What are the barriers / gaps for data sharing between different organizations, within hospitals and across departments? How can they be improved (to be validated within the demos)?

- What set of rules exist for collecting and sharing this data? Are international standards (technical and semantic) being used or national common data models? Are there national rules? If not, what are the national plans for implementing standards?
- How is privacy and security implemented for creating, storing and sharing these data?
- What are the challenges that you have identified in your area about data collection and data sharing?
- Who has data ownership? What happens in practice?
- What are the measures for consent management and patient engagement?

### **3. Governance framework**

- a. Governance bodies
  - b. Governance for accessing data
  - c. Collaboration agreements
- What is the process for getting access to data for secondary use?
  - Is there in your country, any governance framework?
  - Is there in your country governance body responsible for data sharing?

### **4. Human resources, skills and training**

- What are the existing human resources and are there any types missing? (for example data stewards, data analysts, cybersecurity experts, IT personnel)
- How can we establish a positive approach, and culture towards data collection and data sharing?
- What skills and training are required to create the conditions for establishing health data spaces within the country?
- What are some practical steps towards raising awareness about the importance of data sharing?
- What key stakeholders are important to educate about data sharing to facilitate health data spaces and how?

### **5. Legal and regulatory framework regarding health data spaces**

- Is there a sufficient legal framework?

- Is there legal uncertainty in specific areas?
- Are there strict laws for privacy and data protection?
- Are there legal acts that sufficiently govern data use and re-use and also address other aspects such as cybersecurity and AI?
- Are ethical committees legally required? If yes, please specify the national regulations.
- Is Ethics Committee approval required when initiating and establishing a data sharing process? How ethical principles are protected in data sharing process in your country?
- Are major changes required in the present legal framework to facilitate data sharing?
- Who are the legal and regulatory bodies that are involved in the health data sharing?
- What changes need to be made?
- What are the obstacles currently existing for data sharing?

## **6. Stakeholders and their role in the National, regional, local ecosystems**

- Who are the relevant stakeholders and what is their power?
- How do you encourage/enable/facilitate active engagement and on-going stakeholders' involvement?
  - o Building long-lasting relationships? Regular consultations? Participation in decision-making? Involvement in preparing roadmaps and shaping services?
- Is there a multistakeholder mechanism in place and is it an integral part of the digital health governance?
- What is the role of the Ministry of Health, Ministry of Digital Governance and Ministry of Development in creating health data spaces (any initiatives for data sharing, e.g. research etc)?
- What is the state of play in terms of the relevant stakeholders and their contributions? (e.g., policymakers, healthcare practitioners, researchers, regulators, and consumer advocacy groups)

## **7. General questions about the ecosystem to identify gaps**

- Is there a digital health strategy in place? What are the major objectives?

- What are the major initiatives/projects undergoing at this point? What are your priorities? What are the major short-term, mid-term, long-term plans?
- How about monitoring and evaluation?
- What are your financing policies? How do you ensure sustainability and uptake?
- What are the funding instruments currently available related to data sharing? National or international funds?
- Are there best practices that you would like to mention (i.e. high involvement in EU projects, good collaboration between the public and the private health sector, central citizen portals, advances in interoperability, etc.)?
- What are the existing strengths of your ecosystem? (refers to swot analysis)
- Are there any opportunities that can be taken advantage of? (refers to swot analysis)
- What are the main weaknesses about health data sharing? (refers to swot analysis)
- What are the main threats about health data sharing? (refers to swot analysis)
- What are other obstacles/barriers/problems in health data sharing?
- How can they be addressed and overcome?
- Is the conversion of health data to synthetic data a way to overcome data sharing obstacles?
- How could the transition path – the transformation process towards the development of health data space – be implemented in your country? Who should be accountable for ensuring it?
- What is needed in terms of vision, building blocks, governing bodies, other?

## 8. Key documents

- Could you point out key documents that we can use / refer to, to identify
  - o the state of play in the national digital ecosystem related to health data spaces
  - o ongoing activities such as projects, publications, press conferences etc

[END OF QUESTIONNAIRE]

## 6. Timeline

This is the WP2 related Gantt Chart:

	1-3	4-6	7-9	10-12	13-15	16-18
	Q1	Q2	Q3	Q4	Q5	Q6
<b>WP2: Smart Health Regional ecosystem enablement and transformational framework of change</b>						
T2.1 State of play analysis of the four place based ecosystems			D2.1			
T2.2 Smart Health Regional ecosystem enablement and transition path						
T2.3 Novel transformational framework of change towards Smart Health service provisioning						
T2.4 Series of Dream, Design, Deliver validation exercises on a place-based principle						D2.2

Below are the specific deadlines of the milestones for the implementation of T2.1:

### 1. M2 and M3 (July – August)

Meetings to structure the approach for data collection – **[Completed]**

### 2. M4 – M5 (September-Mid October)

Template for input (including the questions guide & the stakeholders list) – **Until mid-October 15/10**

### 3. M5 – M7 (October – December)

Data collection 4 ecosystems – **Until end of M7 December (31/12)**

Analysis – Extraction of themes in individual interviews - **Until end of M7 December (31/12)**

[Submission of country report - M7 December \(31/12\)](#)

### 4. M8 – M9 (November – February 2024)

Comparative gap analysis; - **Until end of M9 February (29/02)**

Innovation transition pathways; - **Until end of M9 February (29/02)**

Review legal framework and relevant strategies; - **Until end of M9 February (29/02)**

Structure validation exercises - **Until end of M9 February (29/02)**

### 5. M8 – M10 (January – March 2024)

Work on and finalization of *D2.1 - State of play and Strategy for innovation ecosystem transition path* (by HDHC – M10)

### 6. M18 (November 2024)

Lessons learned from the validation exercises and finalisation of *D2.2 - Novel R&I transformational framework* – CIT – M18

All partners should follow the indicated timeline to complete on time the development of the D2.1.



## II. Informed consent form

### Informed Consent Form

#### for participation at the interview for VELES Excellence Hub EU project

This interview aims to provide a better understanding of the current state of play in creating health data spaces and identify challenges in the ecosystem of 4 widening countries (Bulgaria, Greece, Cyprus, Romania). The data collected from the interviews will help us to define a strategy to strengthen Smart Health innovation ecosystems for the benefit of all stakeholders.

The interview is conducted in the context of the Horizon Project “*VELES Excellence Hub - Strengthening the South-East Europe Smart Health Regional Excellence and Boosting the Innovation Potential*” (Project 101087483). The project’s aim is to foster health data sharing regional and national strategies, to secure improved clinical practice, to preserve patient’s privacy and to empower citizens’ smart healthcare through access to innovative, cyber secure and data driven digital health services.

Your participation is voluntary. You may withdraw at any time without giving an explanation by notifying us in writing. Your signature does not oblige you to complete the interview.

#### Subject’s Understanding

- I agree to participate in this interview and allow my personal data to be processed for the project’s research purposes.
- I understand that my participation is voluntary, and the data provided will be treated under the provisions of the General Data Protection Regulation.
- I understand that I may withdraw from the interview at any point.
- I understand that all data collected will be limited for research-related usage and they won’t be shared with third parties.
- I am aware that all records will be kept confidential in the secure possession of the research team.
- I acknowledge that the contact information of the researcher has been made available to me.
- I have received copy of this consent form.
- I will treat the Interview Guide confidentially.
- If you agree your name, position and organization to be mentioned in external sources – white paper, stakeholder lists, quotes etc. only for the purposes of sharing useful information from the interview please tick this box.
- If you do not agree your name/s, position and organization to be mentioned in external sources – interviews, etc. please tick this box.

All rights under the GDPR and the national personal data protection legislation could be exercised by sending an email to: .....

Subject’s Full Name & Affiliation (*if you don’t wish to add your name, you can write only your affiliation*):

\_\_\_\_\_

Subject’s Signature: \_\_\_\_\_ Date Signed: \_\_\_\_\_

Researcher: \_\_\_\_\_ Date Signed: \_\_\_\_\_

### III. Steps for conducting the interviews

1. Identify 5 or more relevant stakeholders
2. Include stakeholders name, position, affiliation etc in stakeholder excel file
3. Contact stakeholder and arrange interview date/time
4. Send relevant material: consent form and questionnaire
5. Conduct interview, record interview, collect notes of important themes.
6. Analyse important themes of the interview and note specific quotes that provide important insights from the conversation.
7. Prepare country analysis report

### IV. Country analysis report

1. Introduction (1 page)
2. Methodology (Profile of Participants, etc.) (1-2 pages)
3. Desk research main findings (around 5 pages)
4. Field research main findings (around 5 pages)
5. Conclusions & recommendations (2 pages)