The Smart Health Excellence Hub in SE Europe

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

HORIZON-WIDERA-2022-ACCESS-04-01

Deliverable D3.1 – Regional Smart Health Data Space Ecosystem

WP3
Regional Smart Health Data Space boosting the R&I potential in Southeast Europe

Type of document:	Report
Dissemination level:	PU - Public
Lead beneficiary:	UEFISCDI
Authors:	Raluca Ciobotaru, UEFISCDI Andreea Popa, UEFISCDI Alexandra Roman, UEFISCDI
Version:	v2
Due Date of document:	31.10.2024
Delivery Date of document:	25.10.2024

Document History

Version	Start Date	Due Date	Contributor	Comments
0.1	02.09.2024	02.10.2024	Raluca Ciobotaru, UEFISCDI Andreea Popa, UEFISCDI Alexandra Roman, UEFISCDI	Development of Deliverable D3.1 structure and content
0.2	02.10.2024	08.10.2024	Lora Georgieva, GATE Irena Pavlova, GATE, Maria Matsangidou, CYENS Andreas Panayides, CYENS CoE Chrystalla Iosif, 3AEHealth Francisco Garcia Miguel, 3AEHealth Daniel Hadjittofi, NeHA Haridimos Kondylakis, HDHC Angelina Kouroubali, HDHC Dimitrios Katehakis, HDHC Aneta Piperkova, BIOBG Nadejda Miteva, BIOBG Olga Galanets, IDSA Miriam Labrado, INNEUROPE Jordan Kane, CIT Morten Kristoffersen, CIT Aleksandra Kempinksa, CIT Georgios Gogolos, JOIST	Content adjustments and harmonisation of the deliverable.
0.3	09.10.2024	22.10.2024	Lora Georgieva, GATE	Quality review
0.4	09.10.2024	22.10.2024	Antonis Stylianides, NeHA Andreas Neocleous, NeHA	Quality review
0.5	22.10.2024	25.10.2024	Raluca Ciobotaru, UEFISCDI Andreea Popa, UEFISCDI Alexandra Roman, UEFISCDI	Final version of D3.1 RSHDS Ecosystem

Executive Summary

This report represents deliverable D3.1 Regional Smart Health Data Space Ecosystem within the VELES project. It provides a comprehensive analysis of the current state of health data ecosystems in four widening countries: **Romania, Bulgaria, Cyprus,** and **Greece** from a viewpoint of the "data space" concept. The primary objective is to identify the key actors involved in these ecosystems, establish their roles and interactions, and assess their contribution to the development of a robust health data space/s. Additionally, the report delves into the **maturity** and **integration** of these systems, evaluating the challenges and opportunities for enhancing **interoperability**, **data sharing**, and **collaboration** across national and regional levels.

The analysis reveals that each country's health data ecosystem presents unique challenges and opportunities. **Romania** and **Bulgaria** face more fragmented systems, while **Cyprus** and **Greece** have more advanced, integrated platforms with higher levels of digitalisation and standardisation. Despite the disparities, all four countries utilise similar types of data, including medical imaging, clinical data, and patient records, managed through various national repositories and platforms. Common issues, such as limited **storage capacity**, lack of **interoperability**, and **fragmented infrastructures**, hinder effective data sharing between healthcare institutions.

Further, the report highlights the degree of collaboration between key actors—**healthcare providers, public authorities, academia,** and **industry**—which varies across the countries. **Cyprus** and **Greece** boast more structured and formal partnerships, while **Romania** and **Bulgaria** experience more fragmented efforts, often limited to local or private-sector initiatives. The analysis also underscores the importance of **cross-border collaborations**, especially considering the forthcoming **European Health Data Space (EHDS)**[1].

---

[1] https://www.european-health-data-space.com/

The **SWOT analysis** reveals both the strengths and weaknesses of each country's health data infrastructure, offering strategic insights into future development paths. **Strengths** include existing collaborative projects, scalable infrastructures, and participation in **European initiatives** like EHDS. On the other hand, **weaknesses** such as **fragmented infrastructures**, **lack of standardisation**, and **human resource limitations** need to be addressed for further progress. **Opportunities** are abundant, especially with the rise of **AI** and **HPC technologies**, while **threats** include **GDPR concerns**, **technological obsolescence**, and **cultural resistance** to digitalisation.

In conclusion, the potential to establish a **Regional Smart Health Data Space** across these four countries is high, given the existing initiatives and willingness to collaborate. However, challenges such as **standardisation**, **interoperability**, and **resource allocation** must be overcome to create a more integrated and efficient healthcare system that can enhance patient outcomes and drive innovation in digital health solutions.

Introduction

Purpose of the deliverable in VELES context

This document represents deliverable **D3.1 RSHDS Ecosystem** and describes the ecosystem around the Regional Smart Health Data Space (RSHDS) at various levels, in line with the objectives of Task 3.1 within the VELES project. The deliverable identifies and engages relevant stakeholders, including data providers, data users, service providers, regulators, across Romania, Bulgaria, Greece, and Cyprus. By analysing their roles, interactions, and the current ecosystem structures, the report outlines key enablers and barriers, providing strategic recommendations to foster the development of a robust and scalable health data space. The findings will also inform the design of pilots to be implemented in Work Package 4, laying the groundwork for data-driven innovations in specific domains in the health sector.

What is a Regional Smart Health Data Space - RSHDS ecosystem

The ***European Health Data Space - EHDS***[2] will be a key pillar of the strong European Health Union[3] and is the first common EU data space in a specific area to emerge from the European strategy for data[4].

In spring 2024, the European Parliament and the Council reached a political agreement on the Commission proposal for the EHDS[5].

The European Health Data Space[6] 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; fostering a single market for electronic health record systems, relevant medical devices and high-risk AI

---

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

[3] https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

[4] https://digital-strategy.ec.europa.eu/en/policies/strategy-data

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0197

[6] https://www.european-health-data-space.com/

systems and providing a trustworthy and efficient set-up for the **use of health data** for research, innovation, policy-making and regulatory activities (secondary use of data).

A ***Regional Smart Health Data Space - RSHDS***, is a framework designed to facilitate secure and innovative data sharing within the regional health ecosystems participating in the VELES project. It integrates multiple perspectives technological, legal, ethical, and business ensuring that health data can be shared across different platforms and stakeholders securely and efficiently.

In developing a **Regional Smart Health Data Space (RSHDS)**, several core components are needed to create a robust and effective framework. Each of these components plays an important role in ensuring that the RSHDS functions smoothly and ethically, while adhering to legal requirements and enabling innovation.

From a **technological** perspective, the priority is on building an infrastructure that guarantees the seamless sharing of health data across platforms. Interoperability is important, ensuring that various systems and tools can communicate with each other using standardized data formats and APIs. Equally important is the need for this data-sharing infrastructure to be both secure and scalable. The design of the system places its users at the center, making sure that it is intuitive and accessible while complying with privacy laws like the General Data Protection Regulation (GDPR[7]).

Regarding the **legal and governance** layer, the foundation of the RSHDS is built upon European Union directives and regulations, with a particular focus on data sovereignty, transparency, and privacy protection. Compliance with key acts such as the Data Governance Act[8] and the European Health Data Space Regulation is mandatory, ensuring that the system aligns with broader EU policies. Within this framework, clearly defined roles for data ownership and governance are established, supported by a strong contractual framework that clarifies the responsibilities and rights of all stakeholders.

Major aspect is also the **ethical** part that shapes the RSHDS. This ensures that the use of health data is handled responsibly, with a focus on fairness, transparency, and accountability. Patient rights are placed at the forefront, and particular attention is given to the ethical challenges presented by the integration of artificial intelligence (AI) in healthcare.

---

[7] https://eur-lex.europa.eu/eli/reg/2016/679/oj

[8] https://eur-lex.europa.eu/eli/reg/2022/868/oj

Another key component is the **business** aspect, whereas the RSHDS explores how health data can be monetized while maintaining the security and privacy of the individuals involved. The creation of data marketplaces is encouraged, where health data can be exchanged in ways that respect accessibility and compliance with relevant laws. This balance between monetization and ethical responsibility is crucial in fostering trust and ensuring that the system serves the best interests of both businesses and patients.

The ***Regional Smart Health Data Space*** framework is designed to create a secure, compliant, and innovative environment for sharing health data across regional ecosystems, ensuring legal compliance, ethical integrity, and technological robustness.

Methodology

The preparation of this document involved a series of steps which included a desk research and field phase, followed by cross-country analysis to provide a comprehensive overview of the RSHDS ecosystem.

Desk research

As part of the initial phase, relevant literature and country reports along with policy documents were reviewed for each of the four widening countries - Romania, Bulgaria, Cyprus and Greece - to gain insight into the structure and key components of the place-based ecosystems and their current development phase and overall understanding around the Data Spaces. However, several "black boxes" were also identified which required further exploration. To address them, an interview guide was developed to consult key players directly involved in each country's place-based ecosystem: Cancer treatment in Greece, Alzheimer's in Bulgaria, Cerebral tumours in Romania, and dementia in Cyprus.

Field research

The field research phase was carried out through a series of interviews and focus groups with key stakeholders from each country. Between June and August 2024, a total of 24 semi-structured interviews and 1 focus group were conducted with representatives from academia, healthcare institutions, civil society, the public sector, and private organisations. All participants provided informed consent, and the interviews were conducted online, with recordings made for accurate data collection and analysis. The findings from these interviews were documented in Stakeholder Mapping exercise, categorizing stakeholders by their role, type of data managed and interactions within the ecosystem.

Country reports

Following the desk and field research, individual country reports were drafted for Romania, Greece, Bulgaria, and Cyprus. These reports provided a detailed overview of the health data ecosystem in each country, covering areas such as data management practices, infrastructure, interoperability, and challenges faced by stakeholders. Each report included an illustration that best depicts the interactions within the data spaces, a SWOT analysis, as well as a set of recommendations based on the conclusions of the findings.

Cross-Country Analysis

Finally, the four country reports were synthesised to produce a comparative analysis and to assess the feasibility of the RSHDS ecosystem. This deliverable (D3.1) identifies common practices in data management, as well as challenges, opportunities, and key areas for strategic intervention across the four countries. The SWOT analyses from each country were cross-referenced, and strategic recommendations were formulated to guide future efforts in developing a more integrated and scalable health data ecosystem in the region. Additionally, best practices for establishing a data space from countries like Germany, Sweden, and Spain were considered, ensuring that the strategic recommendations are not only aligned with the specific challenges of each country but also reflect proven approaches from leading European health data initiatives.

Limitations

Despite the valuable insights resulting from this exercise, several limitations of the current study need to be highlighted. First, the field research was conducted with a limited number of stakeholders, which may not capture the full diversity of perspectives within each country's health data ecosystem. Additionally, while the SWOT analyses offer a structured assessment, the findings are based on the subjective views of the interviewees and may not fully reflect the broader national landscape. Finally, the European Health Data Space (EHDS) is still under development, meaning that certain assumptions made in this report may need to be revisited once EHDS regulations and frameworks are finalised.

Thematic Ecosystem Analysis

3.1 Ecosystem Brief findings/introduction

This section provides a comprehensive analysis of the healthcare data environments in the four countries, illustrating the complex network of key actors, their roles and responsibilities, and the interactions that shape the development and management of health data spaces. Each country's ecosystem is represented through a visual illustration, accompanied by a description that maps out the relationships between public authorities, healthcare providers, research institutions, and private entities. This overview highlights the unique structures and collaborative dynamics that drive digital health initiatives and data integration within each national context.

3.1.1 Romania: Cerebral Tumours Data Space

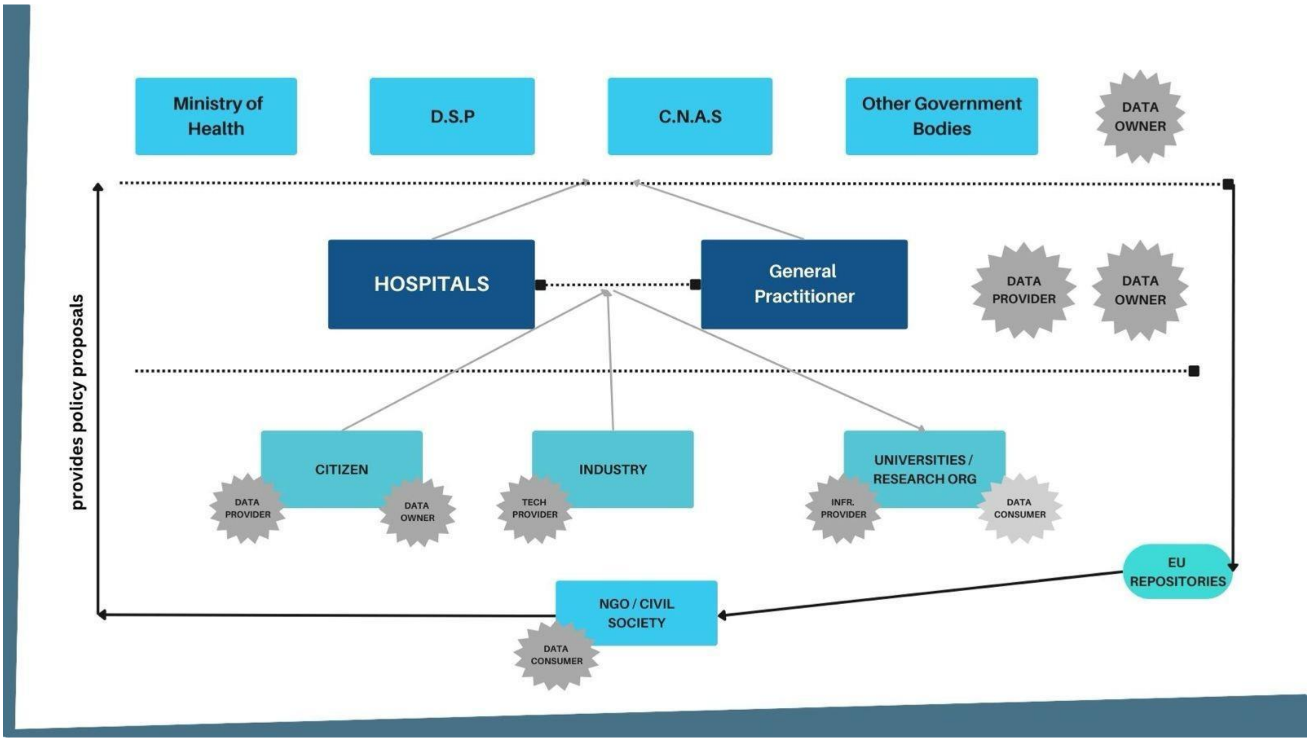


Figure 1: Graphical representation of the health data space ecosystem in Romania.

The Romanian health data space ecosystem is still under development. The **key stakeholders** fall under the following categories (see the illustration): public authorities (Ministry of Health, Public Health District Authority, National Health Insurance House, etc), medical units (e.g. hospitals, GP units. etc.), academia & research (e.g. technical universities), industry (e.g. data processing companies), civil society and repositories at European/national/regional level.

The **roles** they fulfil are (see the illustration): data owner, data collecting and management, data user, data provider, technology and infrastructure provider and data security and privacy.

The **type of data** that is utilised by the key actors within the health data space are medical imaging data, lab results, patient medical history and his/her present medical status.

The most effective and already realised minimal valuable data space concept in the country is the national exchange between healthcare providers and the National Health Insurance House, which operates using a standardised data format. This exchange primarily focuses on service reimbursement, making financial incentives the main driver for data collection and sharing. As a result, stakeholders are less motivated to gather a broader range of health data, and there is no structured template for data that is not legally required to be collected. Another binding data collection is within the Electronic Health Record System.

The regional cerebral tumour data space is a potential scalable system, but at the moment the partnership consists of the Emergency Hospital Prof. Dr. Nicolae Oblu which collects data from their patients, labs or clinics and the Technical University “Gheorghe Asachi” Iasi which provides the storing infrastructure. The hospital has the responsibility of gathering, managing and using the data, in order to carry on future research activities with research organisations.

In a nutshell, data sharing usually happens as a standalone endeavour, negotiated between several partners and best practices can be found at a local or regional level.

3.1.2 Bulgaria: Alzheimer’s Disease Data Space

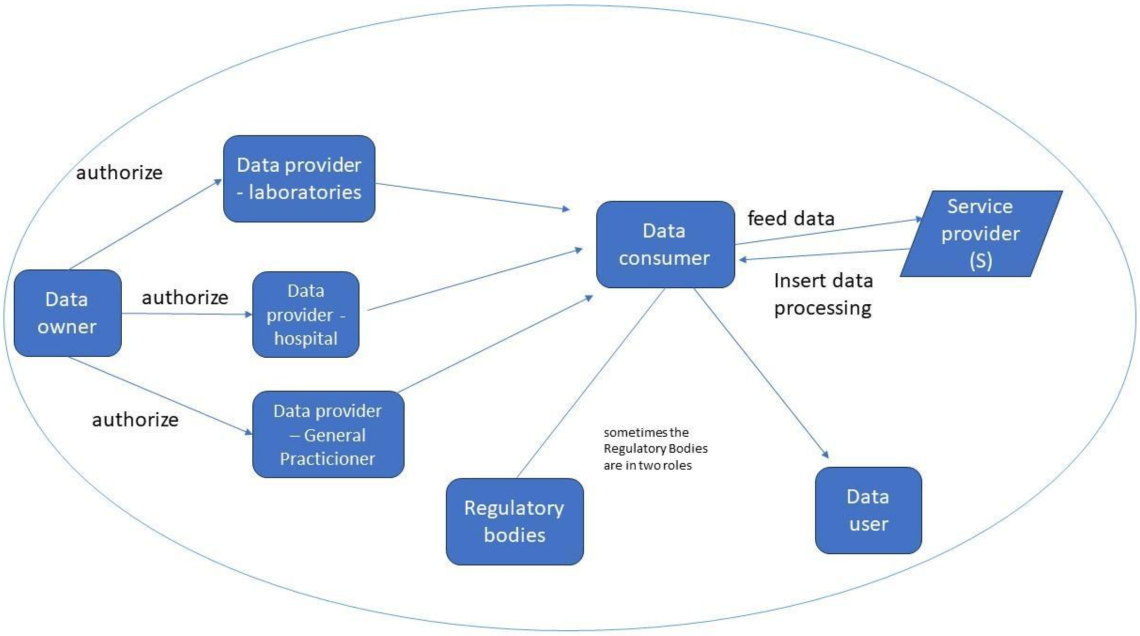


Figure 2: Graphical representation of the health data space ecosystem in Bulgaria.

The Bulgarian health data ecosystem is highly fragmented, but they still have good potential to grow and develop into mature infrastructures.

It is not a highly complex system and it involves the following **key stakeholders**: the regulatory bodies (e.g. National Health Insurance Fund), medical units (e.g. hospitals, GPs, labs) and citizens.

The **responsibilities** they take on are a data owner, data provider, data consumer, service provider and data user.

The **main types of utilised data** are: medical history data, lab results and medical imaging data.

The primary objective of the Bulgarian data space is ensuring the legitimacy and legality of the medical public spendings, thus the most effective and standardised data exchange is between the healthcare providers and the National Health Insurance Fund. Data providers must also feed information within the national health dossier. Even if national and European legislation is binding, key stakeholders do have a degree of freedom when it comes to internal health data processing.

In Bulgaria, bilateral data exchanges prevail, between private hospitals and laboratories.

The Bulgarian authorities are obliged to develop 9 major data spaces in the main sectors of the economy, including healthcare, until 2027. That said, the Bulgarian healthcare data space will be under planning and development in the upcoming year and many of the listed challenges in this report will be addressed accordingly.

3.1.3 Cyprus: Dementia Data Space

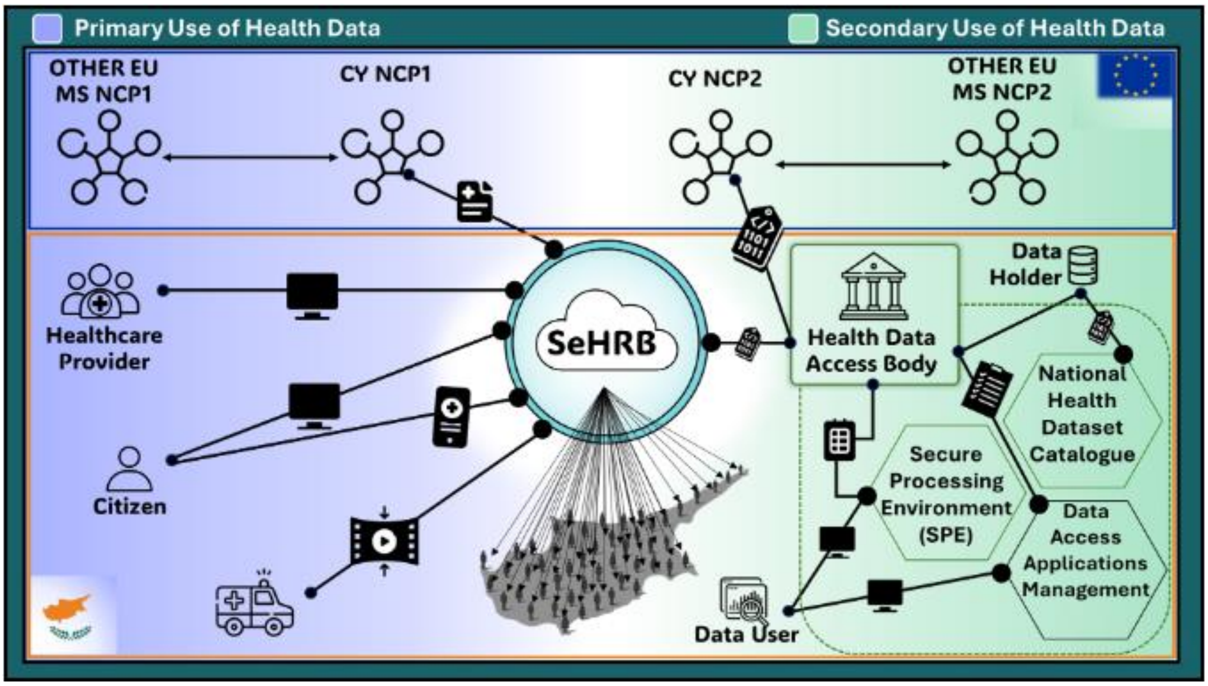


Figure 3: Graphical representation of the health data space ecosystem in Cyprus.

The health ecosystem in Cyprus aims to be a complex network of digitized, interoperable, and standardized systems. Figure 3 provides a graphical representation of the planned health data space ecosystem, illustrating the vision for future development.

The **key actors** are the following: public authorities (e.g. Ministry of Health, National eHealth Authority, Cyprus National Bioethics Committee), industry (e.g. healthcare data analytics enterprises, IT companies, etc.), academia & research, medical units (e.g. hospitals) and the civil society.

The **responsibilities** they assume are that of data collection and management, data utilisation, data exchange and data security and privacy.

They use patient records, medical imaging, lab results and genetic information as the main **kind of data**.

The stakeholder **roles and interactions** are intricate and multi-faceted. The Ministry of Health is responsible for healthcare policies, while the National eHealth Authority of Cyprus (NeHA) handles digital technology innovations. Although the Cypriot eHealth Law, which is similarly aligned with the EHDS regulation outlines the approach for implementing EHRs and data exchanges, no formal guidelines are in place, and it has yet to be enacted. The research institutes, the universities and the private business sector conduct research activities based on the permission gained from bioethics committee. The medical units collect and provide the health data from their pools of patients and collaborate on the research initiatives. On top of those, the civil society supports the patients and advocates for their rights and specialised companies warrants for the data integrity and security.

Cyprus faces various challenges such as various data formats which affect the effectiveness of the interoperability, the scarcity of human resources and the bureaucratic limitation that has an influence on successful partnerships.

3.1.4 Greece: Cancer Treatment Data Space

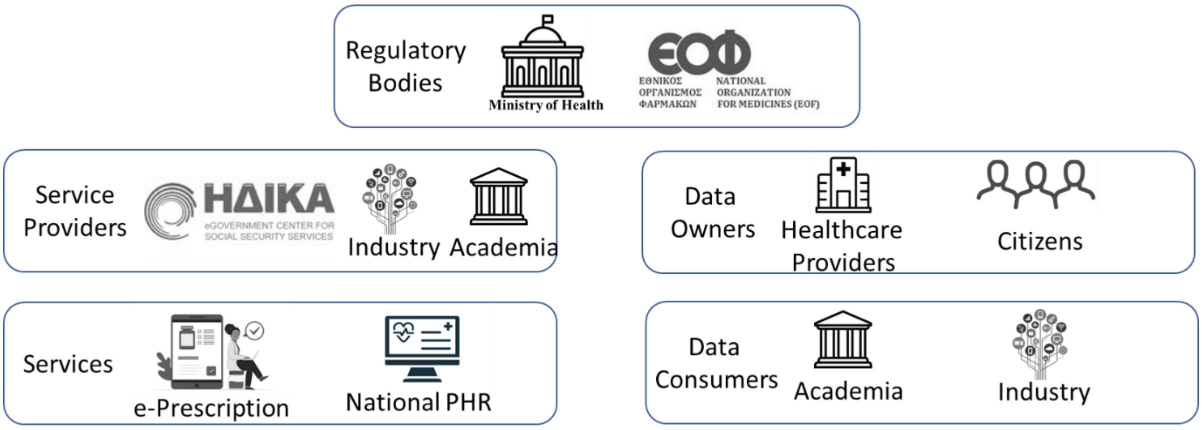


Figure 4: Graphical representation of the health data space ecosystem in Greece

Greece is characterised by a sophisticated network of digitalized, interoperable, and standardised systems, practices and technologies.

The **main actors** are the regulatory bodies (e.g. Ministry of Health, National Organisation for Medicines, Hellenic Data Protection Authority, etc), healthcare providers (e.g. public and private hospitals), digital platforms (e.g. National Electronic Health Records, e-Prescription System), industry (e.g. technology companies) and research & academia (universities and research centres).

They undertake the **roles** of data owner, data consumer, service and data providers.

The authorities oversee and implement the health policies, ensure the law abiding and manage the national digital platforms. In the research realm, the focus is on translating science into practical healthcare solutions and technologies and the industry aims at innovating in health data analytics, digital health repositories and platforms and partnering with other key actors for fostering the overall digital transformation.

3.2 Data Space conclusions

Successful regional (and national) data spaces depend on robust **collaboration frameworks**. Currently, **Cyprus** and **Greece** showcase stronger collaborations between public and private sectors, research entities, and healthcare providers. In contrast, **Romania** and **Bulgaria** face challenges in terms of **stakeholder engagement**, especially in public hospitals and the public sector as a whole. However, the presence of **smaller, private collaborations** (such as in Romania's regional cerebral tumour initiative) offers a basis for broader cooperation and future **regional consortiums and collaborations**.

In conclusion, the health data space ecosystems in the four widening countries — Romania, Greece, Cyprus, and Bulgaria — are defined by a diverse set of actors, distinct roles, and varied interactions.

Each country features a unique blend of public **authorities, healthcare providers, research institutions, private sector entities and the civil society**, playing critical roles in **data collection, management, and sharing,** although the level of involvement and coordination differs. **Cyprus** and **Greece** are more advanced in establishing the roles of each stakeholder in the data space concept, while **Romania** and **Bulgaria** still lack formalised collaboration frameworks.

While their structures and levels of integration vary, a common focus on interoperability and the adoption of international standards is evident.

The interactions within these ecosystems range from stand-alone collaborative efforts for enhancing data exchange to formalised partnerships aimed at advancing national and cross-border health data sharing.

The creation of a **regional health data space** across the four countries would be fruitful and practical exercise and it seems to be feasible, since they have all committed to improve the digitalisation and interoperability levels in the healthcare sector. It would also require clear governance frameworks that assign specific roles and responsibilities to stakeholders from each country, ensuring smooth cooperation and clear data-sharing protocols.

However, it is clear that all their continuous efforts for the creation of local and national (minimal valuable) health data spaces (e.g. the pilot activities) prove the willingness to further work towards a regional smart health data space.

Data Management overview

This section provides an overview of the primary data types and formats, technological infrastructure, and key security measures within the health data ecosystems of the four widening countries (Bulgaria, Cyprus, Greece, Romania).

Bulgaria

Health data in Bulgaria comes in many forms, from personal patient demographics to medical details like diagnostic data, laboratory results, outpatient sheets, and imaging records. These data types are stored across a variety of systems, some proprietary of the hospitals, others state-owned, and a mix of both analogue and digital methods is still in place which is one of the major issues when it comes to interoperability and transferability of the health data.

Interoperability remains a major challenge in Bulgaria's health ecosystem, with many different formats in use, from electronic patient record to PACS (Picture Archiving Communication Systems)[9] and RIS (Radiology Information Systems)[10]. Despite some adherence to international standards like HL7, achieving uniformity across the board remains elusive.

Data collection and storage methods also vary significantly. Some data is stored locally in MySQL databases, while others are sent to national systems like the **NHIS (National Health Information System)**[11] or the **NHIF (National Health Insurance Fund)**[12]. Healthcare providers—primarily hospitals—make decisions about how long to store and archive data. Although archived data is never destroyed, access protocols vary, with hospitals allowing access during treatment, while patients and providers can access NHIS and NHIF data continuously.

A key focus is on software and platforms, which range from organisational Electronic Medical Record systems[13] to national databases. Hospitals primarily use proprietary platforms based on open-source code, while the state owns the major platforms NHIS

---

[9] https://www.techtarget.com/searchhealthit/definition/picture-archiving-and-communication-system-PACS

[10] https://www.postdicom.com/en/services/ris

[11] https://his.bg/

[12] https://www.nhif.bg/

[13] Blumenthal, D., & Tavenner, M. (2010). The "meaningful use" regulation for electronic health records. The New England Journal of Medicine, 363(6), 501-504. https://doi.org/10.1056/NEJMp1006114

and NHIF. Security and maintenance practices vary depending on the data owner, with electronic authentication methods for sensitive health information.

Despite the growing complexity of data collection, access for secondary use—such as research—is extremely limited, due to a lack of regulatory clarity. Much of the data is stored in outdated formats like XML[14], making secondary analysis difficult. Additionally, the focus on financial control, particularly by NHIF, often outweighs patient-centred care.

There are also several pressing needs within the system. Faster access to data, enhanced digitization, improved traceability, and greater integration of telemedicine services are among the key priorities. Broader adoption of international standards, increased funding for local systems, and a national-level data governance policy are seen as critical for the future of Bulgarian healthcare. Ethical guidelines, automation, and better data quality mechanisms are also essential to addressing the system's current limitations.

Several challenges stand out, including issues with interoperability, limited access to data for patient care, and conflicting requirements between the Ministry of Health[15] and NHIF. However, there is optimism about the future, particularly with the potential impact of the European Health Data Space Regulation (EHDSR) and the development of a national genome database, which could open new doors for the healthcare system.

Ultimately, while the health data landscape in Bulgaria is progressing, significant work remains to optimise data flow, improve access, and fully embrace the digital future.

Cyprus

In the health data ecosystem of Cyprus, a wide range of data is managed in various formats to meet the diverse needs of healthcare delivery, research, and policymaking. The system is mainly divided to public and private sector.

1) In 2019, Cyprus introduced a new national healthcare system, representing a significant step toward achieving universal health coverage. The system is financed through a National Health Insurance Fund administered by the Health Insurance Organisation (HIO), which reimburses services provided by both public and private healthcare providers under the General Healthcare System (GHS). To facilitate reimbursements, the GHS employs specific codification standards tailored by HIO for use in Cyprus. The following figure outlines the various

---

[14] Harold, E. R., & Means, W. S. (2004). XML in a nutshell. O'Reilly Media.

[15] https://www.mh.government.bg/

codification standards adopted and adapted exclusively for the country's healthcare needs. However, despite the establishment of a national health insurance system, there are significant issues with its current state: Limited Coverage: The system functions primarily as a reimbursement mechanism, covering only a specific range of services. This limitation can pose problems for individuals who do not have supplementary insurance to cover additional healthcare needs.

2) Lack of Electronic Health Records: The system is not an electronic health record (EHR); its sole purpose is reimbursement.

3) Each private sector healthcare provider uses its own system to store data, without adhering to any standardized guidelines.

As a result, Cyprus currently lacks a comprehensive EHR system for its citizens, which is essential for integrated and accessible healthcare management.

Healthcare Provider	Diagnoses Codification	Procedures Codification	Codification of Services that are reimbursed by the HIO
Outpatient specialists	International Classification of Disease, 10th Edition (ICD-10)/ HIO Codification	Not Applicable (N/A)	Current Procedural Terminology (CPT)
Laboratories	N/A	N/A	Logical Observation identifier Name and Codes (LOINC)
Personal doctors	International Classification of Primary Care II (ICPC II)	Not applicable	HIO Codification for additional services

Inpatient healthcare	International Classification of Disease, 10th edition, Cyprus (ICD-10-CY,V1.0)[16]	CMP-CY,V1.0[17]	Diagnosis Related Groups Cyprus (DRG-CY)
Pharmaceutical products	N/A	N/A	Anatomical Therapeutic Chemical (ATC)+ unique identifier
Medical Devices and Medical supplies	N/A	N/A	HIO Codification
Accident & Emergency Department	HIO Codification	HIO Codification	HIO Codification
Ambulances	N/A	N/A	HIO Codification
Nurses, midwives and allied health professionals	HIO Codification	N/A	HIO Codification
Dentists	N/A	N/A	HIO Codification

Table 1: Codification standards used in GHS in Cyprus[18]

It is very difficult to know what types of systems are used in the private sector since anyone can use anything to cover the needs of the patients. This lack of standardization and transparency complicates the integration of care between public and private providers, making it challenging to assess the overall quality and accessibility of healthcare services in Cyprus. Without a cohesive framework, patients may face

---

[16] ICD-10-CY,V1.0 is the ICD-10 codification with additional codes exclusively for the Cyprus healthcare system.

[17] CMP-CY,V1.0 is ICD9CM with additional codes exclusively for the Cyprus healthcare system. The format is numerical and up to 5.

[18] https://www.gesy.org.cy/sites/Sites?d=Desktop&locale=en_US&lookuphost=/en-us/&lookuppage=hiocodificationproviders

inconsistencies in care, especially when there is a need to transition between the national health system and private providers. This situation underscores the need for more comprehensive guidelines and interoperable systems to ensure seamless care across all healthcare sectors.

Greece

In Greece there are managed a variety of data formats, from **medical imaging data** stored in DICOM, NIfTI, and raw data formats, to **clinical data** using the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), often collected through Excel and Word files. Specialised datasets like **dosimetry ionising data** for radiation therapy and **chronic disease data** from oncology, dermatology, neurology, and other fields are integrated with legacy EHR systems to improve clinical care. Additional data sources include **user engagement data** from mobile apps to track patient behaviour, **psycho emotional monitoring data** focused on breast cancer patients, and **genomic data** collected for haematological cancers. **Anonymized cancer patient data** helps reduce recall bias, gathered via questionnaires to understand clinical, financial, and survival factors. Plans are underway to upload **Quality of Life (QOL) data** from cancer patients using EORTC QOL questionnaires.

Data Collection and Storage systems vary, including SSD NAS, hard drives, cloud infrastructure like Zoho's data centre, and AWS-hosted PostgreSQL databases for metadata. Imaging data is managed using PACS, and some patient data is collected anonymously through QR code-enabled Zoho forms. By law, electronic health records must be retained for over 20 years.

In terms of software and platforms, Greece uses PACS and DICOM stores for imaging, relational and NoSQL databases for clinical data, and a cloud infrastructure hosted within the EU. Laravel/PHP web applications integrate Zoho Forms for patient data collection, with metadata and logs managed through PostgreSQL. Data is exported through Excel, and analysis tools like **PyRadiomics** and **Pytorch** process health data, while **R** is used for statistical analysis. Data is primarily stored and processed on AWS cloud services, with additional local PCs and smart devices handling survey data collection.

Maintenance, Access, and Security measures are stringent, ensuring compliance with GDPR and HIPAA regulations. Role-based permissions control access, with data regularly backed up, encrypted, and anonymized. Healthcare providers, researchers, and pharmaceutical companies access data for clinical care and research, while statisticians and developers handle metadata and logs. External parties must request permission for access, and security teams manage system maintenance to ensure the highest levels of data protection.

Greece uses the data particularly in developing AI models for clinical applications like chemotherapy response, tumour identification, and public health policy evaluation. AI tools, Decision Support Systems (DSS), and predictive models are being trained on this data, offering insights into patient outcomes and health trends.

Current Needs and Challenges for the VELES initiative include the need for improved data processing capabilities, enhanced analytics tools, and continuous regulatory guidance to comply with GDPR, HL7, and HIPAA standards. Participants called for a centralised database where clinics and hospitals could anonymously contribute medical data, as well as strategic partnerships with larger healthcare entities and tech companies. There is also a pressing need for AI developers with clinical expertise, as well as resources like digital health specialists and statisticians. Interoperability standards and a clear business model for the secondary use of health data are also critical.

Greece faces some data processing struggles that arise from issues like scanner variance, the reliability of expert annotations, and the heterogeneity of data formats. Large datasets require substantial computational resources, making uploads and downloads time-consuming. Privacy concerns, data silos, and missing data complicate unified analysis, while vendor lock-in and bureaucratic hurdles hinder data sharing.

Looking ahead, foreseen changes in the field include the introduction of the EU AI Act, which may add regulatory constraints and third-party evaluations, increasing costs and complexity. Advancements in AI and machine learning will improve data analysis, but evolving privacy laws will require careful adaptation. Large-scale European initiatives to establish accessible medical databases and the digitalization of past paper-based data through RRF funding will also shape the future of health data in Greece, enhancing both primary and secondary uses in national health systems.

Romania

At the national level, Romania utilises a variety of data types, including medical imaging, clinical data, laboratory analyses, and personal data (e.g., height, age, weight). Efforts are underway to standardise genomic data and collect life quality data covering demographic, social, and environmental factors. Additionally, data on individual and family behaviours, such as dietary habits and healthcare expenditures, are increasingly being considered.

Medical imaging data is managed through **PACS** (Picture Archiving and Communication Systems) using the **DICOM** format, ensuring compatibility across hospitals. However, this system is not yet universally adopted, with patients often receiving their imaging data on CDs. Clinical data is recorded in systems like **Hipocrate**[19] and **Medicai**[20], but standards for newer data types like social factors are lacking, with issues in data quality and standardisation.

Hospitals typically store data digitally, though there is no system for data exchange between institutions. This results in patients leaving hospitals with printed documents or CDs, and often needing repeated procedures due to incompatibility between hospital systems. There is no infrastructure for conducting comprehensive analyses of patient data over time, and data remains stored internally within each hospital.

The infrastructure for eventual Regional Smart Health Data Space (RSHDS) lacks high-performance computing but aims to incorporate it in the future. A data centre operated by the Technical University of Iași supports the storage needs of the "Nicolae Oblu" Emergency Hospital, but sustained investment and human resources are needed to make the infrastructure fully operational.

Health data in Romania serves two primary functions: managing patient records and reporting to health authorities for reimbursement and national health statistics. Patient consent is required for data sharing, and approval from ethics committees is needed for secondary uses. Data security is a concern due to limited resources and infrastructure, and some hospitals choose to remain disconnected from the internet to prevent cyberattacks.

National and country health insurance houses, as well as public health directorates, have access to health data for reimbursement and reporting purposes. Hospitals store patient data in secured systems, but this data is generally only accessible within the hospital where it was collected. Patients have limited access to their data, usually receiving hard copies of documents upon discharge. The place-based ecosystem in Romania will rely on the "Nicolae Oblu" Emergency Hospital as the primary data provider, with data stored securely in a virtual machine, though access is restricted to the hospital itself.

Romania's health data space concept faces several challenges, including a lack of communication between hospitals, limited infrastructure for data sharing, and issues with interoperability. There is also a need for a unified protocol for storing both clinical

---

[19] http://rsc.showmineit.ro/ro/Hipocrate/

[20] https://www.medicai.io/ro

and imaging data to improve consistency and reliability. The absence of real-time access to patient data hinders diagnostic processes and secondary analysis, and there is a pressing need for continued investment and regulatory support to develop a sustainable health data infrastructure in the country.

Similarities between countries

Romania, Greece, Bulgaria, and Cyprus share several similarities in their RSHDS Ecosystems, particularly in their management and challenges related to interoperability, data storage, and security:

Diverse Data Types and Formats: All four countries handle various types of health data, including personal patient data, clinical data, medical imaging, and laboratory results. Standard formats like DICOM for imaging data are widely used in each country, although formats for other types of data can vary, causing interoperability challenges. For instance, Romania uses DICOM for imaging, and similar formats like HL7 are seen in Bulgaria. In Cyprus's private sector, healthcare providers may adopt different formats based on their specific needs, further complicating standardization efforts.

Interoperability Challenges: A common issue in all four countries is the difficulty in achieving seamless data exchange between different healthcare systems. In Bulgaria, Romania, and Greece, hospital systems tend to rely on incompatible or proprietary platforms, leading to fragmented data that hinders patient care and secondary uses, such as research. Similarly, Cyprus faces challenges with data integration, even with plans to use national frameworks like OpenNCP.

Mixed Infrastructure: The technological infrastructure in each country is a mix of local digital storage, cloud solutions, and physical servers. Bulgaria and Romania, in particular, face issues with outdated systems and a reliance on analogue methods alongside digital platforms. Cyprus, while having a legal framework eHealth Law, still struggles with integrating older formats because the law has not yet been enforced.

Data Access and Security: GDPR compliance and stringent data protection measures are enforced across the board, with all four countries emphasizing role-based access controls and encryption. However, challenges persist, especially in Romania and Bulgaria, where security infrastructure remains underdeveloped, and hospitals sometimes opt to disconnect from the internet for fear of cyberattacks. Cyprus and Greece have more established measures, but access to data for secondary purposes remains limited.

Regulatory and Ethical Constraints: Research access to health data is limited in all countries due to regulatory complexities. Bulgaria and Greece both experience bottlenecks in secondary data usage due to a lack of clear guidelines, while Cyprus enforces strict patient consent policies for secondary use. Romania also requires ethics committee approval for research purposes.

While each country has a unique way to optimise its healthcare data system, they share common challenges such as data fragmentation, limited interoperability, and the need for regulatory improvements in order to leverage health data for both patient care and research purposes.

Differences between countries

The health data ecosystems in Bulgaria, Cyprus, Greece, and Romania share similarities but also have differences in how they handle data collection, infrastructures and secondary use:

1. Data Types and Formats:

- **Bulgaria**: Handles a variety of data formats, including diagnostic data, imaging records, and outpatient sheets, stored across a mix of analogue and digital systems. Formats vary widely, and while international standards like **HL7** are used, consistency is lacking.
- **Cyprus**: The formats used vary between the public and private sectors. In the public sector, the formats listed in Figure 1 are used. In contrast, the private sector lacks standardization guidelines, allowing healthcare providers to use any system they prefer, including non-digital methods such as paper records.
- **Greece**: Manages data in DICOM and other specialized formats like **OMOP CDM** and **NIfTI**, with a focus on AI applications in healthcare. Clinical and imaging data are stored in both local and cloud-based systems.
- **Romania**: Primarily uses **PACS** for imaging in **DICOM** format, but lacks universal adoption across hospitals. Clinical data is stored locally without a system for data exchange, leading to inefficiencies.

2. Infrastructure and Platforms:

- **Bulgaria**: Uses both proprietary and state-owned platforms, with electronic medical records stored in systems like **NHIS** and **NHIF**. Data is archived but often difficult to access for secondary use.

- **Cyprus**: The primary platform used in the public sector is the HIO's system, which serves as a reimbursement platform rather than a comprehensive electronic patient record.

- **Greece**: Relies on a mix of cloud-based and local storage solutions, such as **AWS** for clinical data and **PACS** for imaging. Hospitals use AI models and tools like PyRadiomics for clinical research.

- **Romania**: Medical imaging data is managed through **PACS** but lacks centralized infrastructure, with hospitals storing data internally using systems like **Hipocrate** and **Medicai**.

3. Data Access and Secondary Use:

- **Bulgaria**: Data access for secondary purposes, such as research, is **restricted due to unclear regulations**. Financial control often takes precedence over patient care.

- **Cyprus**: **Allows secondary use** of anonymized data for research, in compliance with GDPR.

- **Greece**: Data is **used for developing AI models** and decision support systems. There's a growing focus on secondary data use for research, particularly in cancer care and public health.

- **Romania**: **Data access is limited**, with patient data primarily used for reimbursement and national statistics. There is no real-time access to patient data, and secondary use is hampered by a lack of infrastructure and regulatory support.

Maturity and Integration assessment

In this section, we assess the maturity and integration of health data spaces in the four widening countries, focusing on their respective national and local specificities. The evaluation covers key factors such as the degree of interoperability, the obstacles encountered in data access and sharing, and the standardisation challenges each country faces. The collaboration level between different stakeholders reveal the willingness and the level of coordination within each health data ecosystem.

Additionally, this section explores best practices and the scalability and development potential of the local and national platforms and data spaces, hence we gain valuable insights into how each country is progressing towards a more integrated health data ecosystem, as well as the challenges that should be addressed, in order to achieve successful collaborations and mature and effective health data spaces.

National and local repositories and platforms

Bulgaria has two key repositories: the National Health Insurance Fund (NHIF)[21] and the National Health Information System (NHIS)[22] and a minor one: the National Centre for Public Health and Analyses.

In **Cyprus** there are local data repositories, such as Biobank[23], the Drug List from the Pharmaceutical Services of Cyprus[24] and various registries managed by the Ministry of Health, through the Health Information System. They also rely on various European open access databases and sources.

Greece uses a variety of medical data repositories at both national and European level, where they contribute by providing patient data, participating in research and clinical trials and developing AI and imaging algorithms (e.g. HECKTOR, ProCancer-I, TCIA, etc.).

At a national level, Greece relies on the E-health Records System (IDIKA)[25] for centralised e-prescription, the Greek Biobank and specialised registries for molecular oncology,

---

[21] https://www.nhif.bg/en

[22] https://www.opengovpartnership.org/members/bulgaria/commitments/BG0011/

[23] https://biobank.cy

[24] https://koef.org.cy/

[25] https://www.gov.gr/en/upourgeia/upourgeio-psephiakes-diakuberneses/elektronike-diakubernese-koinonikes-asphalises-edika-ae

inherited cardiovascular and neurodegenerative diseases and several databases managed by universities and research institutions.

Romania's digital health system is still in the development stage, consisting of the Unique Integrated Information System[26] (SIUI), the Electronic Health Record System[27] (DES), the Electronic Prescription[28], the Electronic Health Insurance Card[29] (CEAS) and the Integrated Health Insurance Platform[30] (PIAS).

Data access, sharing, standardisation and integration issues

All four widening countries face similar data access, sharing and integration problems. The most obvious one is the utilisation of **various data formats**, which are often standardised neither at the national level, nor between the four countries. Other common issues are **storage issues**, since they are dealing with sizable data, technical difficulties and failures, challenges concerning the data accuracy, leakage and other types of **security threats.**

Operating and accessing such a sensitive data setup also requires professionals and well-trained staff, so that they should relieve both the bureaucratic and technical burden from the medical staff. **Human resources** rank high in the issues top, since connecting with external sources and verifying data accuracy calls for expertise and effort and all countries have mentioned that they encounter limited personnel or technical proficiency issues in data management and analysis. Having that in mind, skilled human resources also demand funds for both training and retaining the valuable ones.

The legal aspect is also of utmost importance since compliance with GDPR can often be strenuous and demanding and lead to delays or access and sharing restrictions and limitations.

Accessing medical datasets typically requires membership or **collaboration** within broad consortia or research networks and can be time consuming and resource intensive.

---

[26] http://siui.casan.ro/cnas/despre_siui

[27] https://cnas.ro/2021/12/22/comunicat-dosarul-electronic-de-sanatate-a-redevenit-functional/

[28] https://tinyurl.com/3v8hn3k9

[29] https://cnas.ro/cardul-national-de-asigurari-de-sanatate/

[30] https://www.ms.ro/ro/centrul-de-presa/ministerul-s%C4%83n%C4%83t%C4%83%C8%9Bii-a-aprobat-finan%C8%9Barea-pentru-digitalizarea-cnas-pias/

Whereas in **Bulgaria**, in terms of secondary use, no one has access to the two major databases (NHIF and NHIS), except for patients and they also do not contain imaging data, in **Cyprus**, several research organisations have access to multiple databases for secondary use. Different organisations have their own policies where the data owner (clinics), the data production officer, the top administrators (board of directors) or heads of departments determine with whom the data could be shared, after getting patients' consent and the internal **bioethics committees' approval**.

Patients also hold a significant role in consenting with whom their healthcare data can be shared, especially in the situation external entities, beyond their healthcare institutions, are involved. Some organisations share anonymized data without patient consent after following specific procedures within the organisation and signing Data Processing Agreements.

Stakeholders in **Romania** have declared the need for the existence of **national data centres**, which could simplify data access. At this moment there is no concrete objective for creating data centres, nor do hospitals own data centres (as some Western European countries do) or have well-rooted practices for collecting, storing and processing health data.

In **Romania** there is access to data related to costs and spendings, which are available for the health insurance houses and public health directorates, in order to account for the expanses. There is no other type of data systematically and unitarily collected, other than the data required by the National Health Insurance House and there is neither leverage or motivation for the medical units to expand their data collection practices, nor any long-term planning on how to use data in a smart way.

In a nutshell, the ecosystem integration pace is still low since many healthcare institutions use paper-based documentation, there is a lack of skilled or trained personnel, bureaucratic inefficiencies, outdated IT systems, proprietary software limitations, cyber threats or connectivity gaps. There is also an environment resistant to change and new technologies and refractory to the need of a wholesome cultural shift.

Fragmentation and lack of standardisation (e.g. inconsistent data formats) and integration is the overview of future health data spaces within the four widening countries, since information seems to be scattered across various platforms.

The issues related to aiming for unitary data types are language hindrances, data encoding, staff digital illiteracy and the lack of legal practice that does not motivate or convince patients to consent to having their data processed and shared. There have been some standardisation efforts in **Bulgaria**, but very scarce since the National Health Strategy 2030 was drafted. **Greece** is a member in working groups, within the EHDS, concerning the OMOP-CDM (Observational Medical Outcomes Partnership - Common Data Model) and FHIR (Fast Healthcare Interoperability Resources) frameworks. They aim to adopt the HL7/FHIR standards and specific vocabularies.

As for the **systems integration**, the general headline is that interoperability between datasets and platforms varies across the four widening countries, and across systems and projects at the national level. All four need tools for data harmonisation, categorisation, unique processing protocols and standardised APIs. Their healthcare institutions face resource shortage, have varying levels of technological infrastructure and comply with different laws, policies and regulations.

They all use DICOM (Digital Imaging and Communications in Medicine) for imaging data in hospitals, healthcare facilities and research projects for sharing medical imaging and use imaging equipment (CT, MRI, X-ray machines) that comply with DICOM standards.

In **Greece**, some datasets are shared primarily through company and project websites or cloud resources. Integration with local health information systems and national platforms such as the H-Cloud of the Greek NHS, EOPYY (National Organization for the Provision of Health Services)[31] registries - which is the public health insurance organisation - and proprietary datasets from health tech companies are in place.

Moreover, their national legislation is aligned to EU laws and regulations, including data protection and usage and it is progressing towards adopting EHDS standards. Their Health Insurance Organisation[32] embraces the internationally recognised standards (e.g. ICD-10, CPT, LOINC and ICPC II). Additionally, it also uses its own codification system tailored to local healthcare needs and integrates the Anatomical Therapeutic Chemical (ATC) classification system alongside unique identifiers, ensuring accurate tracking and monitoring of pharmaceutical usage across healthcare facilities.

In **Romania**, as previously mentioned, there is a fragmented digital ecosystem characterised by inconsistent implementation, limited digital literacy, insufficient or poorly used funding and data privacy and security concerns.

Collaboration between key actors

---

[31] https://eu-healthcare.eopyy.gov.gr/en/

[32] https://www.gesy.org.cy/sites/Sites?d=Desktop&locale=en_US&lookuphost=/en-us/&lookuppage=home-en

The four widening countries have different approaches and perceptions towards collaboration between key actors that would lead to a functional health data ecosystem.

In **Bulgaria**, major data repositories lack the willingness to collaborate and give access to data, the main argument being compliance to GDPR provisions.

Romania also experiences a lack of desire to collaborate from providers operating in public hospitals (especially those hospitals that do not engage in research activities). Partnerships are easier to build and collaboration works better in/with smaller or private medical units.

In **Greece**, there is a readiness to work together, however, technical issues, regulatory barriers and outdated practices represent a serious hindrance. But the acknowledgment for the need for better integration and standardisation of digital tools and data systems does prevail. Organisations are willing to work together, provided there is suitable infrastructure, transparent usage protocols and sustainable pricing models.

Collaborative efforts are crucial for optimizing the EU Patient Summary and ePrescription services. In **Cyprus**, this requires strong cooperation among various national and local healthcare units, including academic institutions, research entities, and state hospitals. On the other hand, due to the fact that hospitals have limited resources and expertise, they might refrain from collaborations. Budgetary constraints, staff shortage and technological gaps interfere with extensive data-sharing initiatives.

There is a general view that, even though collaboration is obviously scattered and mostly isolated, the development of the EHDS would promote partnerships and integration.

Maturity, scalability and development potentials

All the ongoing databases, registries, platforms and health data spaces in the four widening countries are foreseen to be scalable in the future.

Bulgaria mentioned that they are using certain databases (e.g., SQL) which can handle increasing amounts of data and adapt to growing system demands without requiring a lot of effort and changes.

Also, the IT standardisation packages they work with (IHE - Integrating the Healthcare Enterprise, OMOP - Observational Medical Outcomes Partnership, FHIR - Fast Healthcare Interoperability Resources, openEHR - Open Electronic Health Record) provide standards for interoperability and easily support scalability. They also mentioned the IT Tech Framework for Labs as a potential future toolkit which would include laboratory data within the standardisation endeavours.

Based on the Digital Decade eHealth Indicator study[33] **Cyprus** had an overall eHealth maturity score of 68% in 2023, characterised as "follower". There is a national and centralised database for medical images and hospital discharge reports and the amount of data collected from patients varies from one organisation to the other, but there are plans to integrate more patient collected data through mobile health apps and remote monitoring devices.

Greek patient centred platforms support a future expansion in terms of data structure and complexity, traffic and integration and are hosted either in central cloud repositories or local data nodes.

They also allow the integration with other databases storing patient data and are designed to be aligned with international practices, since using the DICOM format for medical imaging. Data storage also meets secure cloud standards and future compliance is planned to include ISO 27001, internationally recognized standard for managing information security, for information safety reasons. However, integration with international standards such as OHDSI (Observational Health Data Sciences and Informatics), which is a collaborative network aiming at creating large-scale health data analytics, is still limited and would require state support.

In **Romania** most databases and infrastructures are sustainable and scalable so that they could operate an increased volume of data. However, at the moment there is no enhanced storage and processing capacity, skilled human resources or a national data centre that would support scalability efforts.

It is difficult to assess the institutional performance and the data spaces maturity level since, as aforementioned, data spaces are incipient, data volume is low and their functionalities are limited. The institutional impact can only be evaluated when the respective projects reach a higher level of maturity.

In a nutshell, all four widening countries strive to use standardised frameworks that would help make the healthcare data systems more flexible and scalable, thus allowing them to manage increasing amounts of data and users, avoiding technical flaws and security threats.

---

[33] https://digital-strategy.ec.europa.eu/en/library/digital-decade-2024-ehealth-indicator-study

Successful initiatives

According to the stakeholders, a solution for creating robust data species is taking part and promoting broad partnerships (even outside the national boundaries) and consortium with diverse key actors (e.g. medical units, hospitals, technical universities, companies, etc.) that would assume different roles, tasks and responsibilities, thus leading to the development of big data sets, IT solutions, apps, algorithms and processing and sharing protocols.

All four widening countries have successfully launched initiatives and fostered partnerships aimed at creating resilient health data spaces.

In Bulgaria, the Bulgarian Association for Personalised Medicine vouches to create the **HiMSS** (Health Information Management System for Personalised Medicine) community. There are also joint activities between the two major health clusters (Health and Life Sciences Cluster and the Digital Health and Innovation Cluster). There are also limited initiatives in the area of cancer treatment.

The **EUCAIM project** (European Cancer Imaging Initiative)[34] in Greece, is part of the European Commission's Cancer Mission aimed at improving cancer prevention, diagnosis, and treatment through the use of advanced imaging technologies and data sharing. It proves that steps towards integrations are being taken. Datasets are hosted on-premises or in a central repository, common data models, a meta-data catalogue for dataset search and access requests and a future pricing model are also part of this initiative.

The **ProCancer-I project**[35] is another example where integration is achieved through the utilisation of the DICOM format for imaging data and OMOP-CDM for clinical data.

There are also integration efforts between the local health information system and national platforms (mentioned above).

In **Romania,** we could mention the **ROGEN project,** carried on by the University of Medicine and Pharmacy" Carol Davila" which aims at creating the Institute of Research and Development in Genomics. Several other universities and medical institutions have joined the initiative to build the National Network for Genomic Medicine.

---

[34] https://www.egi.eu/project/eucaim/

[35] https://www.procancer-i.eu/

The Centre for Innovation in Medicine is the Romanian representative in the **ECHoS project**[36], to build a national hub and a network for cancer hubs. At a regional level, there is a cancer registry within the **Competence Centre for Cancer in Cluj-Napoca**, administered by a vast consortium of universities, research institutions and private IT and medical services companies.

The **MEDIMAG-IA project** - The Regional Centre for Excellence in Personalised Diagnosis and Artificial Intelligence in Medicine and Imaging[37] - represents a successful collaboration between an emergency hospital and a technical university to achieve the collection/uploading/storing/using of medical data on an infrastructure provided by the university.

In the private realm, there is a data collection platform for oncology developed by **Oncochain** that organises and curates data provided by doctors and sends back structured information to the hospitals for secondary use.

As for international initiatives, Romania activates in the **REVERT project**[38]**,** for identifying pathological mechanisms in some forms of cancer with the support of AI models and an integrated database between several biobanks.

These efforts do reflect a commitment to collaboration between public and private sectors, involving healthcare providers, research institutions, academia, companies and governmental bodies, at regional, national and international levels.

In conclusion, the maturity and scalability of health data spaces across the four countries show promising progress, with notable advancements in standardisation and interoperability. Fostering partnerships and aligning strategies between stakeholders should be an ongoing objective to collectively attain a better quality of healthcare services and research results.

---

[36] https://cancermissionhubs.eu/

[37] https://www.imago-mol.ro/centrul-regional-de-excelenta-pentru-diagnostic-personalizat-si-inteligenta-artificiala-in-medicina-si-imagistica-medimag-ia/

[38] https://www.revert-project.eu/

Strategic insights (swot analysis)

This section presents a comparative SWOT analysis of the Regional Smart Health Data Space (RSHDS) ecosystems across the 4 widening countries. By examining these dimensions in each country's health data landscape, we can gain strategic insights into the regional challenges and potential or opportunity for development. The analysis below highlights common trends as well as country-specific factors that influence the readiness and capacity for implementing an integrated health data system.

Strengths

Category	**Romania**	**Greece**	**Cyprus**	**Bulgaria**
Collaborative Projects and EU initiatives	● Involvement in collaborative projects like **ROGEN** (genomic medicine), **ECHoS** (cancer hubs), and **MEDIMAG-IA** (AI in diagnosis), ● participation in European initiatives: **Cancer Mission, Europe's Beating Cancer Plan**, and **the Genomic Data Infrastructure** (GDI) for secure access to genomic data across the EU. ● alignment with the **1+**	● Participation in European projects like **epSOS** and **JAseHN**, focusing on healthcare data interoperability and regional integration. ● Initiatives like **EUCAIM and ProCAncer-I** focusing on imaging data for improving cancer management.	● Participation in initiatives like **MyHealth@EU[39],** enhancing cross-border healthcare services and facilitating better healthcare delivery for EU citizens.	● The **Health and Life Sciences Cluster Bulgaria** and **Digital Health and Innovation Cluster** are conducting joint efforts in cancer treatment, pushing for broader collaboration between medical institutions and research centers .

---

[39] https://op.europa.eu/en/publication-detail/-/publication/3e983ee5-fed7-11ea-b44f-01aa75ed71a1/language-en

	Million Genomes initiative, promoting access to shared genomic resources.			
Existing Functional Systems & Technological Infrastructure	• Use of digital platforms like the **Radiology Information System** (RIS), **Picture Archiving and Communication Systems** (PACS) for medical data management.	• **ESYNet** and **ePrescription** are in place for healthcare data management, but integration challenges persist. • High-performance computers (**HPC**), **AI** servers, and dedicated **bioinformatic** servers offer infrastructure support	• Cyprus currently lacks a comprehensive EHR system for its citizens, with the primary system in use being the HIO's reimbursement platform. •	• **NHIF** & **NHIS** serve as core systems for national health data. Databases support **SQL** and **IHE**, **OMOP**, **FHIR**, **openEHR** standards. • **Mobile applications** for administrative tasks like appointment scheduling
Public Investment	• Substantial investment, through the **Recovery and Resilience Plan** (PNRR), in digitalizing the national health system, with a focus on interoperability and infrastructure development.	• **N/A**	• National eHealth Law[40] 2019 initiated public investment into EHRs and telemedicine	• Investment through the national operational programmes for development of national Health Data Space in the next 2 years.
Data Repositories	• **DATA.GOV.RO** is the central gateway for open data sets, collected and delivered by	• **HECKTOR, ACRIN, ProstateNET, TCIA, MIMIC, EUCAIM**: are	• **Biobank** and **National Health Information System** store a wide	• **NHIS** • **NHIF**

---

[40] http://www.cylaw.org/nomoi/enop/non-ind/2019_1_59/full.html

	public authorities and institutions - Other registries such as the **Cancer Registry,** the **Rare diseases Registry** and the **Vaccination Registry** are disease specific data repositories. - **GDI** Repository for genomic data, aligned with the **1+ Million Genomes** initiative.	specialised imaging and medical data repositories, critical for areas like cancer treatment and imaging data. - **Greek Biobank (BBMRI.gr)** repository of biobank data, for genetic and molecular research - **H-Cloud, EOPYY registries, Harmoni repository** are platforms that manage large-scale health data for Greece's National Health Service	range of medical data, including clinical, genetic, and research data.	- **Information system of the Ministry of Health** - **Cancer disease register** - **Hospitals and clinics** - **Outpatient care providers** - **Pharmacies** - **Laboratories**
Data Analytics	- **OncoChain** leverages cloud storage and implements **Natural Language Processing** (NLP) for scalability and advanced data analysis.	- use of AI and ML for data analysis	- **N/A**	- Utilization of advanced tools for statistical reporting via commercial viewers, service cost calculations, and specialized healthcare software (e.g. for imaging data processing).
Legal framework	- **N/A**	- The National laws align with GDPR guiding data management and protection.	- The enactment of the **National eHealth Law** in 2019 established a framework for using eHealth solutions like EHRs and telemedicine,	- The National laws and regulations (e.g., GDPR, health law, health insurance law) provide a structured approach to

			enhancing healthcare delivery	data management and protection.

Weaknesses

Category	**Romania**	**Greece**	**Cyprus**	**Bulgaria**
Digital Infrastructure and Interoperability	• Fragmented digital Infrastructure: The various systems in use (DES, SIUI, PIAS etc) are not integrated and experience technical issues at times.	• Issues with data fragmentation across regions and healthcare providers, leading to inefficiencies and gaps in patient data.	• Varying data formats and standards complicate data exchange and integration, leading to delays and errors in patient care.	• Lack of uniform integration across different levels of the ecosystem, despite some adherence to international standards like HL7
Standardisation	• Data formats and protocols are not standardised, especially for the newer types of data which includes social factors and genomic data.	• Inconsistent data formats and privacy concerns complicate data sharing across the system.	• Inconsistent data entry practices and outdated systems often result in incomplete or inaccurate patient data	• This issue is recognized as an international one regarding, for example, symptoms description, disease classification, data pseudonymization.
Data Access and Governance Challenges	• In the absence of a clear governance framework, hospitals are reluctant or unable to share data for primary or secondary use	• While there are projects allowing patient data access, the overall system lacks comprehensive online access for patients to view their health	• Inconsistent data entries, reliance on paper -based documentation and outdated hardware/ software platforms.	• Limited to no access to NHIF and NHIS databases for healthcare providers, restricting patient care • Hospitals use proprietary platforms, which may

		records.		hinder seamless data integration and sharing.
Storage and Retention Capabilities	- limited no. of dedicated national data centers for health data, and many hospitals do not have the capacity to develop their own data centers - The data collected is, so far, not enough for creating big data centers or for significant secondary use	- **N/A**	- Redundant processes and lack of streamlined workflows hinder efficient data management and integration	- Data typically available for only one month before archiving, complicating long-term data analysis.
Human Resources	- With few exceptions, most stakeholders experience a shortage in skilled human resources to manage and maintain digital systems	- Cultural resistance in change	- Limited access to specialized human resources in data science, bioinformatics, and cybersecurity hampers progress.	- Shortage of experts in the public sector to maintain complex data systems and digital assets.
Stakeholder Collaboration	- Although there is desire among stakeholders to collaborate, this action is limited by the fragmented infrastructure	- Collaboration among healthcare specialists is hindered by the lack of standardised digital systems	- **N/A**	- Limited collaboration among healthcare entities, with major data repositories reluctant to share data.

Opportunities

Category	**Romania**	**Greece**	**Cyprus**	**Bulgaria**
Scalable Infrastructure	● Projects like MEDIMAG-IA, supported by the Technical University of Iași, and Oncochain show scalability potential. These infrastructures can be expanded to support larger data volumes	● Building a scalable cloud infrastructure to enhance data storage, analysis, and advanced analytics capabilities, with a focus on secure, patient-centric solutions.	● **N/A**	● Standardization packages like IHE, OMOP, FHIR, openEHR offer potential for scaling up health data systems and facilitating integration.
EHDS alignment	● EHDS offers the opportunity to standardize data sharing and enhance interoperability, supporting the creation of unified data centers	● The European Health Data Space (EHDS) provides an opportunity to standardise secure data sharing across Europe.	● Collaboration with European initiatives like EHDS and FAIR principles will improve data interoperability and reusability.	● EHDS implementation offers a clear path to standardization and integration, providing opportunities for collaborative growth.

Funding and Support	● Increased public investment for system interoperability and the creation of data spaces, further enhanced by EU funding	● National funding for health and interoperability problems along with EU open calls.	● Potential for increased funding and support from European Union initiatives to enhance digital health infrastructure and capabilities	● **Incoming public investment in health data space through one of the National operational** programmes**.**
Policy Frameworks	● Development of the National Strategy on Digital Health aligned with European funding and strategies, paving the way for coordinated digital health efforts.	● Better alignment with open access initiatives for secondary usage of health data.	● **N/A**	● The development of a national genome database can provide a rich source of data for research and personalized medicine.
Advanced Technology Adoption	● Increasing use of AI and NLP for data analysis and personalised healthcare solutions	● Increasing the penetration of IT and AI services and analytics in healthcare.	● Increasing use of AI and machine learning for data analysis	● Adoption of technologies such as telemedicine, digital medical examinations, and traceability of therapy effects.

Threats

Category	**Romania**	**Greece**	**Cyprus**	**Bulgaria**

GDPR	• Future regulatory pressure from GDPR may make hospitals even more reluctant to share data, especially with the rise of AI and big data analytics.	• Privacy concerns, particularly around data anonymization and transferability, create challenges for sharing medical data	• Compliance with regulations like GDPR may delay or restrict access to important datasets	• GDPR concerns complicate data sharing and integration efforts.
Cultural Resistance & Awareness	• Low awareness among stakeholders about data spaces and their benefits; • hospitals show little interest in data-sharing initiatives.	• Cultural resistance to adopting new technologies and digital transformation poses a significant threat to data integration efforts.	• General resistance among healthcare staff to adopting new digital systems and processes slows digital transformation efforts.	• Stakeholder resistance, particularly among larger organizations, may impede the creation of a unified health data space.
Resource Limitations	• **N/A**	• Insufficient funding and reluctance to invest in better infrastructure may slow down data integration progress	• Budgetary constraints and lack of specialized personnel may limit the ability to implement and sustain new technologies	• Continuous shortage of data experts in the public health sector may limit the adoption of new technologies and concepts.
Security Risks	• **N/A**	• **N/A**	• Increased digitization poses risks to data security, requiring robust measures to protect from cyber attack	• Inconsistent maintenance and security practices, as they are managed by the data owners or the State.

The comparative SWOT analysis reveals that while each country faces unique challenges, there are shared obstacles, particularly regarding infrastructure, interoperability, and regulatory compliance. However, the commitment to European initiatives like the

EHDS, ongoing public investments, and advancements in AI and data analytics present significant opportunities for growth. Addressing the common weaknesses and leveraging the strengths can facilitate the development of sustainable and integrated health data spaces across the region. Collaboration, standardisation, and continued investment will be critical in overcoming the identified threats and achieving long-term success.

Case studies & Best practice analysis

Germany

Germany is actively participating in the European Health Data Space (EHDS) program, aiming to create a unified framework for managing and sharing health data across Europe. Here's a brief overview of how Germany is implementing Data Spaces in the health domain:

- **Data Spaces Concept**: In the context of EHDS, Data Spaces refer to secure, interoperable environments where data providers (e.g., hospitals, research institutions) and data consumers (e.g., healthcare professionals, researchers, policymakers) can access and share health data. The goal is to improve healthcare delivery, facilitate research, and enhance public health while ensuring data protection and privacy.

- **Regulatory Framework**: Germany aligns its national regulations with the EHDS guidelines to ensure compliance with EU-wide data protection standards, particularly the General Data Protection Regulation (GDPR) and the proposed EHDS Regulation. This includes ensuring data security, patient consent, and data sovereignty.

- **Technical Infrastructure**: Germany is developing and implementing technical infrastructures that support the EHDS framework. This includes creating interoperable health data platforms, standards for data exchange, and secure data storage solutions. The German government supports different initiatives which aim to facilitate the integration of health data across different systems and organizations.

- **Stakeholder Involvement**: Germany collaborates with various stakeholders, including healthcare providers, technology companies, and research institutions, to develop and refine the Data Spaces such as, for example, the International Data Spaces Association (IDSA).

IDSA plays a crucial role in enabling secure and trusted data sharing in the German national ecosystem. Here are some prominent examples of projects that implement best practices for health data spaces based on the IDSA standard: Health-X DataLOFT, GAIA-X for Health.

Health-X DataLOFT focuses on developing a trusted data-sharing infrastructure that enables the secure exchange of health data among various stakeholders, including hospitals, researchers, and patients. The project utilizes the IDSA architecture to ensure secure data sharing across different organizations. Health-X DataLOFT leverages IDS connectors, which enable standardized, controlled access to health data while maintaining data sovereignty for data providers. By adhering to IDSA principles, Health-X DataLOFT provides a decentralized, secure, and GDPR-compliant data space that empowers patients with control over their data.

GAIA-X for Health is a part of the bigger European initiative - GAIA-X, aims to create a federated data infrastructure, with a specific focus on the health sector. It seeks to establish a secure and sovereign cloud infrastructure for health data sharing across Europe. Within GAIA-X for Health, the IDSA standard is used to ensure that data exchanges are secure, decentralized, and compliant with European regulations.

Additionally to that, it worth to mention some other German health related initiatives that aim to align on the national regulations within the EHDS guidelines: MII (Medical Informatics Initiative), Smart-MD (Smart Medical Data Platform), Phellow, MIDATA Cooperation, HiGHmed.

The Medical Informatics Initiative (MII) is a flagship project in Germany aimed at improving healthcare and research through the integration of clinical data. It brings together university hospitals, research institutions, and private-sector partners to create interoperable data platforms.

The Smart-MD project focuses on creating a secure and standardized data-sharing platform for medical data. The platform aims to facilitate the exchange of health data for research and clinical purposes while ensuring data protection and compliance with regulations.

Phellow aims to create a health data platform that enables patients to control and share their health data securely. The platform focuses on integrating data from various sources, including electronic health records (EHRs) and wearable devices, into a single, patient-centric ecosystem.

MIDATA is a cooperative platform that allows citizens to store and manage their health data securely. The initiative focuses on patient data sovereignty and transparency, enabling users to decide how their data is shared and used.

HiGHmed is a consortium within the Medical Informatics Initiative (MII) that focuses on developing innovative solutions for healthcare through data integration and interoperability. The project aims to create a data-sharing infrastructure across university hospitals for improved patient care and research.

Spain

In **Spain**, the National Health System (SNS) ensures that citizens can move between different autonomous communities (i.e., regions) and receive medical care and prescriptions for medicines or medical devices in any region of the country. To facilitate this process, healthcare professionals have access to an infrastructure that allows them to consult clinical information for healthcare provision (primary use) regardless of where it was generated. This means that despite the decentralisation of health services, which are managed by the 17 autonomous communities, continuity of care is guaranteed at national level.

Currently, each Spanish Autonomous Community has its own physical infrastructure for storing and processing data, and interoperability between them exists thanks to coordinated efforts between the different regions and the central government. This collaboration, led by the Ministry of Health, has made it possible to create a nationwide interoperable health information system that benefits both citizens and professionals. Key services such as the Individual Health Card (TSI)[41], the Electronic Prescription (RESNS)[42] and the Digital Health Record (HCDSNS)[43] are examples of the progress made in this area.

Regarding the presence of formal, structured collaboration frameworks between various types of stakeholders (e.g. hospitals, academia, research organizations, etc.) that allow further uses of health data (secondary use), we highlight the **BIGAN** initiative.

BIGAN[44] (Big Data in Healthcare, Aragon) is a key project in the autonomous region of Aragon (Spain), which has developed a data lake to integrate large volumes of health and health-related data that can now be accessed upon application for research, public health planning and quality management purposes. The ultimate goal is to improve the healthcare system and the health of residents in Aragon through data observation.

---

[41] https://www.sanidad.gob.es/en/areas/saludDigital/tarjetaSanitariaSNS/home.htm

[42] https://www.sanidad.gob.es/en/areas/saludDigital/recetaElectronicaSNS/home.htm

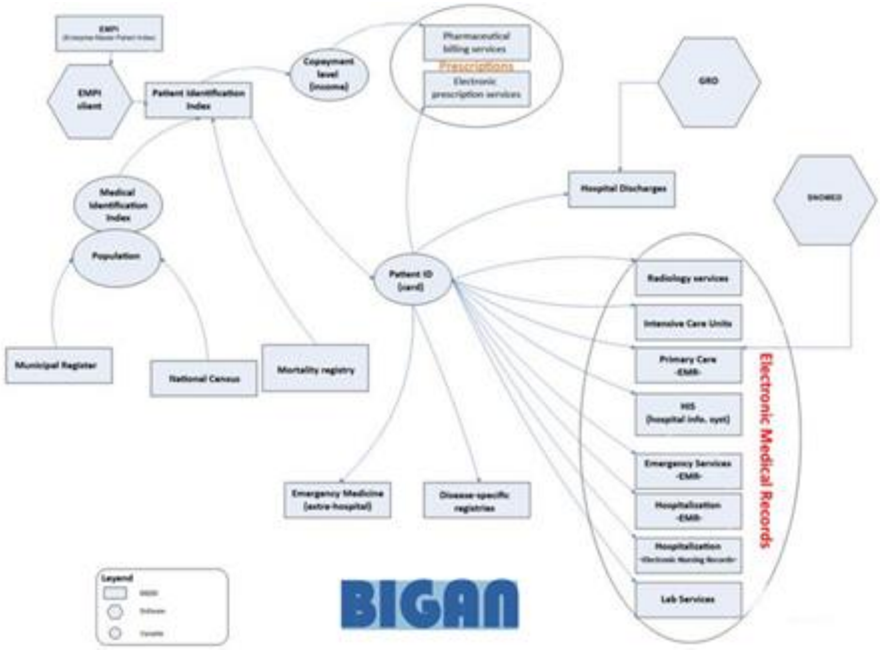
[43] https://www.sanidad.gob.es/en/areas/saludDigital/historiaClinicaSNS/home.htm

[44] BIGAN (Big Data in Healthcare, Aragon) : https://bigan.iacs.es/

To achieve this, collection, analysis, and sharing of information between all involved stakeholders is vital.

Over the past seven years, the Instituto Aragonés de Ciencias de la Salud (IACS)[45] has led the creation of this technological infrastructure gathering individual population and patient data from the regional health service and health related information systems from Aragón. Data from these sources are updated according to their specific generation dynamics, in most cases daily. In BIGAN, patients are able to view and change their data opt-out choice at any time (and without any justification needed).

The development of the BIGAN platform was largely facilitated by the introduction of a Single Health Identifier for each citizen in Aragón, as well as by a 15- year process of connecting and integrating the information systems within the public health service, including primary care, specialised care, hospitalisations, ER episodes, drug prescription, drug reimbursement, image diagnosis, laboratory analytical determinations, diagnostics, vaccination, anamnesis and demographics, across the entire territory. The holistic approach gathering not only health data but also health related data (social, environmental, geographical) provides cross-fertilisation from various research areas which in turn might provide insight to future research policies.



---

[45] A public independent entity within the Health System in Aragón responsible for overseeing, promoting and managing biomedical research and innovation and producing evidence-based guidance on health technology, health policy assessment, and medical practice guidelines

Figure 5. BIGAN, Integration of Information Systems

Specifically, for secondary use, BIGAN has put together healthcare data from 1.3 million lives (Aragón population), more than 800 million records in a data lake of pseudonymised patient data and renders it accessible to the scientific community as a one-stop shop service. The platform supports about 50 research projects each year, and its experience has been studied by the Joint Action TEHDAS[46] and allowed the development of recommendations on how to build and manage a federated data lake for Europe.

Additional governance and legal information[47]:

BIGAN was created as a new subsystem within the existing health information system in Aragón. Executive order (SAN/1355/2018) established the Aragón Regional Health Authority BIGAN platform. As an element of the health information system in Aragón, BIGAN platform is governed by the Health Law of Aragón (Law 6/2002), the Decree on social and healthcare information system (Decree 164/2000) and the Law on Research and Innovation in Aragón (Law 17/2018). Furthermore, BIGAN research complies with Law 41/2002 Governing Patient Autonomy and Law 14/2007, on biomedical research, and with national and European data protection legislation.

BIGAN Oversight Committee controls and follows up BIGAN development according to its goals while IACS is in charge of the day-to-day operations. The Ethics Committee for Research in Aragón (CEICA) is responsible for ensuring the correct application of the methodological, ethical and legal principles in BIGAN activities including the assessment of the implications for individual and civil rights, distributive justice, health and safety and quality of life. BIGAN data controllers are the Aragón Regional Health Authority (Department of Health) and the Aragón Health Service (SALUD).

According to the Protocol approved by the BIGAN Oversight Committee (December 2019), within the context of a research project, the pseudonymised data is accessible, directly to researchers within the “R&D Aragonese system” (as defined by regional law 17/2018); and indirectly accessible by other researchers (either public or private), when an agent of the R&D Aragonese system actively participates. Accessing BIGAN health research infrastructure includes a transparent approval process for health research projects which favours trust and accountability and fosters public-private partnerships

---

[46] Jendrossek, M., Xayakhom-Dauvergne, O., & Zidi, I. (2022). Description of steps in accessing individual-level data for national and EU researchers in a selection of centralised systems and decentralised systems. Joint Action TEHDAS.

[47] Commission Staff Working Document Impact Assessment Report *Accompanying the document* PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL *on the European Health Data Space*

and collaboration between public and private researchers, always under the assumption of the societal benefit of this collaboration.

Regarding foreign data users, favouring a seamless health data exchange in the European Research Area is an important objective of BIGAN research infrastructure and multi-country projects funded by national or European institutions are able to access to BIGAN research platform. Within the context of cross-border research projects, pseudonymised data is accessible by researchers (either public or private), when an agent of the R&D Aragonese system actively participates in the project. Non-R&D Aragonese agents can have granted direct access to the data although it requires a specific access by the BIGAN Oversight Committee in the light of the criteria of relevance, security and social interest.

The BIGAN data lake contains already externally pseudonymised data only. Re Identification of data at origin may take place only when, in the course of a research using pseudonymised data, it becomes apparent that there is a real and specific danger to the safety or health of a person or a specific group of people, or a serious threat to their rights, or that it is necessary to ensure proper health care.

Sweden

Sweden has a clear strategy for health data which have been described in the document Vision eHealth 2025[48] which sets the strategic vision for 2025:

"In 2025, Sweden will be best in the world at using the opportunities offered by digitalisation and eHealth to make it easier for people to achieve good and equal health and welfare, and to develop and strengthen their own resources for increased independence and participation in the life of society"

The following are examples of good practices that can be transferred to other countries and illustrates the strategic vision of Sweden to be the frontrunner in terms of digitalisation end eHealth:

National quality registries: Sweden has a long history of national quality registries and was also the first country to have a unique identifier (person nummer) for all its citizens. 14 registries, some which have been in operation for more than 70 years, are legally

---

[48] https://ehalsa2025.se/english/

mandated and augmented with national mortality, morbidity, medical and healthcare services data. The registries are built on different platforms, but they have been integrated in the workflow of healthcare professionals in the hospitals, meaning that each hospital department knows how to interact with the relevant registry they are using. Each registry is developed and maintained by an organisation of healthcare professionals and patient representatives, ensuring that they stay relevant and up to date. The registries support research and data can be accessed by researchers once they have the necessary permit from the national ethical review board. The quality of the registries has shown repeatedly to contribute to the good outcomes of the Swedish healthcare system by providing clear data on which treatments contribute with the best outcomes. Furthermore, they contribute to eHealth services, patient-centred approaches and decision support, IT development, and integration.

Recently, the Swedish eHealth agency presented proposals to the government on how the registries can be combined into a new national platform for quality registries[49]. Discussions are ongoing as to how this proposed harmonised infrastructure and governance could be extended to meet aspirations such as the EHDS vision, and what additional design considerations should be incorporated to go beyond.

1177: 1177[50] started as a phone number to call for medical advice, but today it is a complete and widely used eHealth platform. 1177 became an eHealth platform in 2010 and already then offered online consultations, appointment booking, prescription renewal, and access to medical records, all authenticated with BankID, the national digital ID which was introduced in 2003. 1177 has since then been complemented by an app and additional features such as direct contact between the patient and care team, and an overview over appointments. 1177 also contains curated information from healthcare professionals about different diseases and conditions which is accurate and up to date, with details on when to seek medical attention. Furthermore, it contains self-help tools for living a healthy life and information to patients for how to manage chronic conditions.

Centre for Health Data Stockholm: The centre[51] for health data was created to provide researchers a centralised location to retrieve data which might be stored in various locations. The centre also offers services such as assistance with ethical approvals and research plans. This ensures that the research is carried out in accordance with ethical

---

[49] https://www.ehalsomyndigheten.se/globalassets/ehm/3_om-oss/rapporter/rapporter_regeringsuppdrag/forstudie-digital-nationell-infrastruktur-nationella-kvalitetsregister-slutrapport.pdf

[50] https://www.1177.se/en/other-languages/other-languages/

[51] https://www.regionstockholm.se/forskning-innovation/halsodata/

and regulatory guidelines. The centre also provides a one-stop-shop for sharing health data between researchers which facilitates collaboration, and that data is shared in a coordinated and secure manner. The centre does not host its own databases, but instead uses a federated solution to release data. Data is only released following a confidentiality examination which guarantees that the recipient can uphold confidentiality and security. This currently limits the centre's activities to universities, but industrial partners can access data through a university partnership. Like the national registries, an application to the national ethics review board is required for data access which includes details on the variables of interest. In the case of third-party collaborations, a data transfer agreement is also required. Currently, the centre offers its services for a base rate of 5,000 SEK (~500€), except in the cases where external contractors must be involved.

Conclusions

The desk research and stakeholder interviews indicated that the topics that require attention are common in the four widening countries: fragmented health data infrastructures, different data formats and collecting/sharing procedures and protocols, issues concerning standardisation, data privacy and technical issues, reduced storage capabilities, limited resources (human resources, funding, etc.), the lack of structured and formalised collaborations between stakeholders at a national or international level and the absence of a clear policy strategy backed by a clear legal framework. Security and safety concerns, especially those related to GDPR, also complicate the data sharing and integration efforts.

Another important setback could be presented as a" soft" issue, namely the cultural resistance and the lack of awareness about the need for digitalisation and interoperability among stakeholders of all kinds - medical units, public and private parties and even citizens as the final beneficiaries of the improved health services. There is a sense of reluctance among these key actors when it comes to data sharing, but concrete issues do prevail when compared to outdated mentalities, since the most usual data" format" is still paper-based.

For example, Romania struggles with the absence of a national data space or a network of interconnected data spaces, even though some registries have been developed at a local level and act as decentralised initiatives. However, the region has presented a series of positive aspects when it comes to national or international collaborative projects. There are examples of joint efforts and initiatives focusing on healthcare data interoperability and regional integration. A series of platforms and data repositories are functional in each country or even private data analytics endeavours, even if challenges do exist.

Among the analysed countries, Cyprus seems to have a relatively more enhanced level of digitalisation and a more developed strategic framework for health data management and interoperability.

The EHDS launch is strongly awaited and perceived as an opportunity and a boost in data sharing and access, hence the reluctance of developing something prior to the EHDS that might not be aligned with the European framework. Another encouraging perspective is that all platforms, registries and incipient data spaces are designed to be scalable and to store big data sets. Moreover, funding opportunities are available and steps have been taken for the development of policy frameworks. Another opportunity is represented by the innovative technological environment; thus, the four countries can benefit from the increased use of AI and advanced technologies.

In a nutshell, the digital health landscape is similar in all four widening countries, namely a mix of advancements, challenges and shortages, but with a growing commitment to improve data interoperability and integration.

Recommendations

The most prevalent recommendation is the adoption of **common data standards** (e.g. HL7/FHIR etc.), to address the issues of interoperability and standardisation This should be further complemented by **upgrading the existing infrastructure and platforms** for enhanced storage and management capabilities. Additionally, providing support for multi-layered partnerships including (1) public-private collaborations and (2) national-international initiatives is paramount for driving these improvements forward.

National data centres are perceived as a better storage option as opposed to private clouds (e.g., Amazon etc.). Achieving this goal would further require forming a broad consortium consisting of a variety of actors with unique skills and needs, each acting as a small puzzle piece, thus, collectively contributing to forming a cohesive and unified outcome, namely a national data centre.

Improving digital literacy through **targeted training** for healthcare staff and IT professionals is also a significant desirable action since it contributes to the development of a digital culture and environment within the four widening countries. Moreover, increased patient **access** to their health data through user friendly online portals would encourage both patients and the medical staff to participate more actively in data sharing efforts.

The success of these initiatives could be ensured through the development of a clear **policy and legal framework.** This framework should be backed by **application norms** that are easy for stakeholders to understand and implement. The clarity of the roles, responsibilities and benefits associated with the digital transformation, would help instil a **digital mindset** across the healthcare ecosystem.

Finally, the importance of implementing **the European Health Data Space (EHDS)** and adhering to **FAIR principles** was highlighted as a means for enhancing data interoperability, ensuring seamless data exchange, and promoting efficient and transparent use of health data across borders.

List of acronyms

AI - Artificial Intelligence

ATC - Anatomical Therapeutic Chemical

AWS - Amazon Web Services

CDM - Common Data Model

CEAS - Electronic Health Insurance Card

CPT - Current Procedural Terminology.

CSV - Comma-Separated Values

CT - Computed Tomography

DES - Electronic Health Record System

DICOM - Digital Imaging and Communications in Medicine

DSS - Decision Support Systems

EHDS - European Health Data Space

EHDSR - European Health Data Space Regulation

EHRs - Electronic Health Records

EORTC - European Organisation for Research and Treatment of Cancer

EU - European Union

EUCAIM - European Cancer Imaging Initiative

FAIR - Findable, Accessible, Interoperable, and Reusable

FHIR - Fast Healthcare Interoperability Resources

GDPR - General Data Protection Regulation

GP - General Practitioner

HiMSS - Health Information Management System for Personalised Medicine

HIPAA - Health Insurance Portability and Accountability Act

HL7 - Health Level 7

HL7 CDA - Health Level 7 Clinical Document Architecture

ICD-10 - International Classification of Diseases, 10th Revision.

ICPC II - International Classification of Primary Care, Second Edition

LOINC - Logical Observation Identifiers Names and Codes

MEDIMAG-IA - The Regional Centre for Excellence in Personalized Diagnosis and Artificial Intelligence in Medicine and Imaging

ML - Machine Learning

MRI - Magnetic Resonance Imaging

NHIF - National Health Insurance Fund

NHIS - National Health Information System

OMOP - Observational Medical Outcomes Partnership

OpenEHR - Open Electronic Health Record

PACS - Picture Archiving and Communication Systems

PET - Positron Emission Tomography.

PIAS - Integrated Health Insurance Platform

PRO - Patient Reported Outcomes

RBAC - Role-Based Access Control

RIS - Radiology Information System

RSHDS - Regional Smart Health Data Space

SIUI - Unique Integrated Information System

SNOMED CT - Systematized Nomenclature of Medicine—Clinical Terms

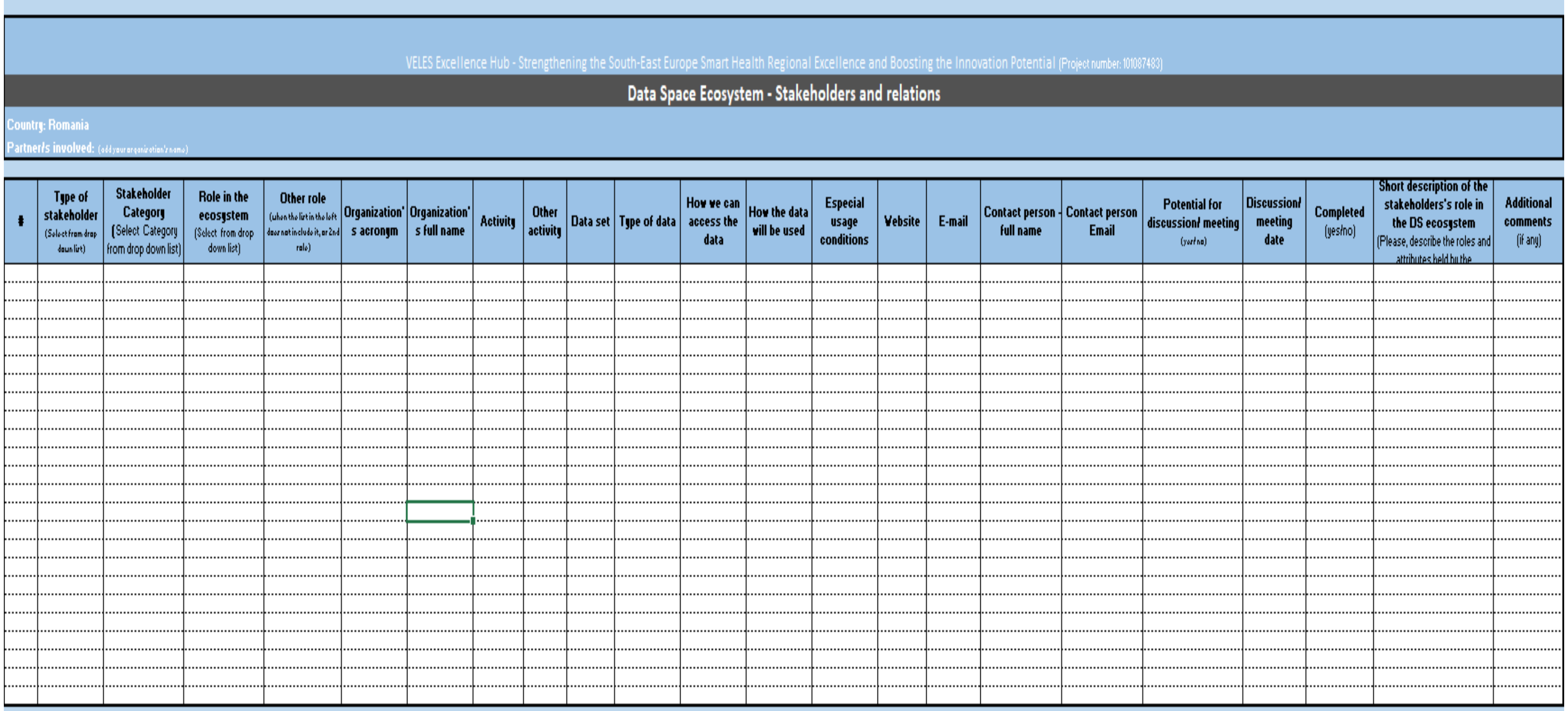
SQL - Structured Query Language (database)

SWOT - Strengths, weaknesses, opportunities and threats

XML - Extensible Markup Language

Annexes

Annex 1 Stakeholder mapping



VELES Excellence Hub - Strengthening the South-East Europe Smart Health Regional Excellence and Boosting the Innovation Potential (Project number: 101087483)

Data Space Ecosystem - Stakeholders and relations

Country: Romania

Partner/s involved: (add your organization's name)

#	Type of stakeholder (Select from drop down list)	Stakeholder Category (Select Category from drop down list)	Role in the ecosystem (Select from drop down list)	Other role (when the list in the left does not include it, or 2nd role)	Organization's acronym	Organization's full name	Activity	Other activity	Data set	Type of data	How we can access the data	How the data will be used	Especial usage conditions	Website	E-mail	Contact person - full name	Contact person Email	Potential for discussion/ meeting (yes/ no)	Discussion/ meeting date	Completed (yes/no)	Short description of the stakeholders's role in the DS ecosystem (Please, describe the roles and attributes held by the	Additional comments (if any)

Annex 2 Interview guidelines and questionnaire

The Smart Health Data Space in SE Europe

VELES Excellence Hub - STRENGTHENING THE SOUTH-EAST EUROPE SMART HEALTH REGIONAL EXCELLENCE AND BOOSTING THE INNOVATION POTENTIAL

HORIZON-WIDERA-2022-ACCESS-04-01

Guidelines for T3.1. - RSHDS enablement and ecosystem's stakeholders engagement

[WP3 - Regional Smart Health Data Space boosting the R&I potential in South East Europe]

Lead: UEFISCDI, Contr.: GATE, HDHC, INSO, JOIST, IDSA, BIOBG, UEFISCDI, CYENS, AMEN, 3EaHealth

Funded by
the European Union

Introduction

The following guideline is developed in the context of *WP3 – "Regional Smart Health Data Space boosting the R&I potential in South East Europe"*, Task 3.1 of the **"VELES Excellence Hub - Strengthening the South-East Europe Smart Health Regional Excellence and Boosting the Innovation Potential"** project (Pr. No: 101087483).

WP3 contributes the project through the execution of the following activities:

- Fostering a sustainable ecosystem around the Regional Smart Health Data Space;
- Setting the groundwork by progressing standardized infrastructure, architecture, and technologies to ensure data quality, security, and interoperability.
- Establishing a strong ethical and lawful data governance and rules for secure and safe data exchange;
- Facilitating data monetization via business models centred around data sharing and innovations driven by data.
- Ensuring smooth integration and interoperability within the Regional Health Data Space and its alignment with the EU Health Data Space.

The current document constitutes the guidelines for the partners to collect the necessary data in order to help the consortium to the development of *D3.1 Regional Smart Health Data Space ecosystem.*

Methodology

Task 3.1 RSHDS enablement and ecosystem's stakeholders' engagement aims to facilitate the establishment of national and regional self-sustainable ecosystems around the Smart Health Data Space through supporting supply and demand-side e.g., the data sharing and the value-adding utilization of data in the pilots, to be designed in WP4.

Task 3.1 is led by UEFISCDI and the following Contributors: GATE, HDHC, INSO, JOIST, IDSA, BIOBG, UEFISCDI, CYENS, AMEN, 3EaHealth.

With the current methodology, we aim to describe the ecosystem around the Data Space at different levels and according to the stakeholders and their roles in the 4 widening countries (Bulgaria, Greece, Cyprus, Romania).

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

Funded by
the European Union

Step 1. Stakeholder’s mapping

Based on the findings conducted in WP2 – Task 2.1, the partners will complete the *Task 3.1 Ecosystem Stakeholders Map (Annex 3)* integrating the actors in the new sheet according to the new roles, explain their roles and the ways in which they interact.

Step 2. Guided discussions with stakeholders

The partners will conduct min. 5 – 7 semi-structured interviews per country or focus group/group interviews with key stakeholders from their respective national ecosystems - Alzheimer (Bulgaria), Cancer treatment (Greece), Dementia (Cyprus), Cerebral tumours (Romania). The interviews can be conducted either online or face-to-face and they will have a duration of around 60’. The interviewing partners should follow the Interview guide.

The interviewers should choose the interviewees also based on their pilot use cases, planned to be developed in WP4. That said, some of the questions in the interview are referring also to the work to be done in WP4.

Step 3. Illustrating ecosystem dynamics

Each country partner will create a report on the findings using the template provided by the task leader. The report will also include an illustration to exemplify stakeholder relationships and their roles and responsibilities within the data space ecosystem for pilot topics.

Timeline overview

- Desk research (step 1) – stage 1 – 15th of March / stage 2 – ongoing activity during the field research
- Field research (step 2) - April - May*
- Dl. country reports for Bulgaria, Greece, Cyprus, Romania – 15th of June*
- Dl. draft deliverable D3.1 (Lead - UEFISCDI) - 15th of July
- Dl. internal revision – 30th of July
- Dl. final deliverable – 10th of August

UEFISCDI will provide the report template in due time

The internal organisation is up to the partner as long as they meet the country report deadline

Interview guide

Before conducting the interviews, the participants will need to sign the consent form of the interview (Annex 4).

Preamble

Dear expert,

Thank you for agreeing to participate in this interview.

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.

Through this interview, we hope to achieve several key objectives:

1. **Ecosystem Mapping** - identifying the key actors and their roles in the ecosystem
2. **Understanding relationships** - actors interaction within the ecosystem
3. **Assess the level of institutional digitalisation** and the alignment with EU strategic goals and data compliance standards
4. **Identify opportunities and challenges** for further digitalisation and integration of medical data

The interview will last approximately 1 hour. It will take place online or face–to–face based on your availability and it 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 (attached to this interview guide) which informs you about the data regulation procedures and how they will be used, in compliance with GDPR regulation.

Thank you in advance.

The VELES team.

Funded by
the European Union

I. CATEGORY OF RESPONDENTS

A.
Hospital - clinic - diagnostic centre - analyses laboratory - pathology laboratory (hospital or independent)

Public Administration

Other: academia/research, pharmacy/pharmaceutical company, medical/professional association, medical insurance organisation, NGO, equipment supplier

B.
Physician, biologist, IT specialist, technician, bioinformatician, researcher, administrator, manager, etc. ....

Name ....
Position +/ profession..
Organisation ....
City ....

C.
Data owner, Data provider, Infrastructure provider, Technology provider, Components provider, Service provider, Broker service provider, Clearing House, DaaS/ Application provider, Data consumer, Data user, DaaS/ Application user, Apps store provider, Regulatory bodies, Standards development organization/ SDO (see Annex 2).

***Legend* >> fact || awareness (fact-check needed) || perception || opinion // instructions for the interviewer**

II. DATA HANDLED

D1. What medical data are you working with in your current activities?
Please describe: [compile list of datasets if appropriate]

a. Type (discriminate between medical imaging and (patient) data)
b. Data Format
c. Volume (total or monthly - or appropriate - estimate; in data storage units in possible)
d. Collection and storage practice/procedures and infrastructure (discriminate between local digital, physical (such as CDs), and online.
e. Storage period and archiving
f. Software and platforms employed (discriminate between PC, machine computer, local network server, organisational Electronic Medical Record system, cloud, regional or national database)
g. Maintenance and data security
h. Access (what type, for which users, for what/which of the data) - especially remote

i. Data analytics (general discussion or go into details of software, algorithms, reporting, etc., if appropriate)
j. Data usage (what is the data used for)

D2. What are your current needs (in terms of resources, support and maybe strategic coherence) related to your work with medical data?

D3. What problems or issues are you facing during the processing of the data? What could be improved?
Please elaborate, even in the form of an exploratory exercise [take notes on empty pages]

D4. Are you aware of any potential upcoming major changes in the field or in your organisation that could significantly impact your work with medical data?
If so, please provide details and discuss their potential implications

D5. What other (significant) medical data are used/produced/collected at your organization?
Please indicate and describe to the best of your knowledge

D5.1. Who else has access? For what purpose?

III. DATA ECOSYSTEM'S MATURITY

III-1. RESPONDENT - ECOSYSTEM REACH

E1. What major medical data repositories, sources, and collection practices at national or local level are you familiar with?
Please indicate and briefly describe if you have any additional information

E1.2. Do you have or would benefit from access to those datasets (or sources)? If would benefit >>>

E1.3. What are the obstacles to access?
Please elaborate

E2. How could the data you are working with be integrated into a significant flow (namely both for primary and secondary use)? - including through efforts related to access, procedures and management, collaborative arrangements, technological upgrades, extended digitalisation
Please elaborate, if any suggestions or needs

E3. In your opinion, are the various organisations in the national or local healthcare system (in general or in regards to the data you are working with) able and/or willing to work together towards strengthening a collaborative medical data ecosystem? (if possible, discriminate between perception on national and local system and between organisations' skill and will)
YES/NO >>> Please elaborate on your assumptions or if any suggestions

E4. With which organisations are you collaborating in terms of data sharing?

III-2. INTEROPERABILITY AND DATA COMPLIANCE

F1. Is the data you are working with integrated with other datasets or platforms - at **organisational** or **inter-organisational level**?
YES/NO >>> If YES, please describe/If NO, how do you share the data with other organisations?

Funded by the European Union

F1.1. Are the databases you are working with scalable? (for example, in terms of structure, data complexities, traffic, integration, performance - with queries and content loading, etc. Also, in terms of the possibility to replicate or build on existing databases framework.)
YES/NO >>> If YES, please describe

F2. Do any of the following apply or could apply either (1) in respect to the data you are working with or (2) in your organisation in general? (emphasise both apply and could apply, especially discuss potential)
(1) alignment with international practices,
(2) compliance to international standards,
(3) complementarity to- or integration with public datasets, such as the (soon to be revised[52]) EHIS[53].
YES/NO >>>Please elaborate

F3. Do you know or could you think of any standardisation endeavours that would enhance the datasets that you are working with, their utilisation and impact, or your work with them?
Please elaborate, especially on potential

F4. In your opinion, does the Romania/Bulgaria/Greece/Cyprus healthcare system exhibit standardisation in terms of medical data? In which areas and to what extent?
YES/NO >>>Please elaborate, either the YES or NO

III-3. EU STRATEGIC ALIGNMENT + “Data Space” FEASIBILITY

G1. [Context: Our project aims to develop an integrated medical data ecosystem comprising regional data ecosystems in participating Member States.]
Are you aware of any past (recent) or ongoing efforts of this kind in Romania/Bulgaria/Greece/Cyprus, at the regional/local level, or within your field? - even if marginal.
YES/NO >>> If YES, please indicate and describe if you have any additional information

G1.1. What are or could be some main obstacles to such an initiative?

G1.2. Could you describe key features of such an ecosystem? - either pertaining to your work or in considering the Romanian/Greek/Bulgarian/Cyprus healthcare system general.
Please elaborate

IV. INSTITUTIONAL PERFORMANCE, DIGITALISATION LEVEL, AND DATA INTENSITY

H1. Assess maturity level - based on the Electronic Medical Record Adoption Model (EMRAM) and Adoption Model for Analytics Maturity (AMAM) models

H1.1. Identify major weak points: patient admissions, paper-based documentation, administration, culture, specialised expertise, digital infrastructure, interoperability, network access, data security.

H2. What proportion of patient-collected data is integrated into your systems?

H3. Do patients have online access to their data through an integrated management system? Do they provide consent for processing of their data?

---

[52] (See the CE Communication with the plans for 2025)

[53] (European health interview survey. See the survey and its variables)

Funded by
the European Union

H4. Are there any applications (possibly mobile ones, what type) for medical purposes (such as scheduling appointments)? Who are these applications intended for?

H5. Are there any data or digital systems in place for interdisciplinary diagnosis or for inter-institutional teams of specialists to collaborate?

H6. Who determines with whom the data could be shared?

ANNEXES. FURTHER REFERENCES FOR DISCUSSIONS:

Annex 1. If discussing the details of interoperability, you can refer to:

Four Levels of Interoperability[54]:

- Foundational (Level 1): Establishes the inter-connectivity requirements needed for one system or application to securely communicate data to and receive data from another
- Structural (Level 2): Defines the format, syntax and organization of data exchange including at the data field level for interpretation
- Semantic (Level 3): Provides for common underlying models and codification of the data including the use of data elements with standardized definitions from publicly available value sets and coding vocabularies, providing shared understanding and meaning to the user
- Organizational (Level 4): Includes governance, policy, social, legal and organizational considerations to facilitate the secure, seamless and timely communication and use of data both within and between organizations, entities and individuals. These components enable shared consent, trust and integrated end-user processes and workflows

Annex 2. Roles and definitions:

Roles	Definition
Data owner	A data owner is an entity or individual that has legal and administrative control over a dataset. They are responsible for determining how the data is collected, stored, shared, and used.
Data provider	A data provider is an organization or entity that offers access to datasets. They may collect, curate, and maintain datasets, making them available to other parties within the ecosystem.
Infrastructure provider	An infrastructure provider supplies the technical resources and facilities needed for data storage, processing, and distribution within the data ecosystem. This can include cloud service providers, data centers, and network providers.
Technology provider	A technology provider offers the software, hardware, and tools necessary for data management, analytics, and processing.
Components provider	A components provider furnishes specific software or hardware components that are integrated into larger data-related systems, such as data analytics platforms.
Service provider	A service provider delivers services related to data management, analytics, or processing, as part of the broader data ecosystem.
Broker service provider	A broker service provider acts as an intermediary that facilitates data transactions between data providers and data consumers, often providing matchmaking, negotiation, and mediation services.
Clearing House	A clearing house serves as a central hub for managing and coordinating data transactions, ensuring data quality, and handling contractual and financial aspects of data exchanges within the ecosystem.

---

[54] (Source)

Funded by the European Union

Application provider/ DaaS	A DaaS or application provider offers data-driven applications or services that leverage the data available within the ecosystem, providing valuable insights or functionality to users.
Data consumer	A data consumer is an entity or individual that accesses and uses data from data providers or DaaS/application providers for various purposes, such as analysis, decision-making, or application development.
Data user	A data user refers to an individual or organization that actively engages with data, often as part of their job or research, to extract insights, make informed decisions, or create value.
DaaS/ Application user	A DaaS/application user is an entity or individual that utilizes data-driven applications or services provided by DaaS/application providers to meet specific needs or goals.
Apps store provider	An apps store provider operates a platform or marketplace where users can discover, acquire, and install data-related applications and services, often acting as a distribution channel.
Regulatory bodies	Regulatory bodies are governmental or industry-specific entities responsible for creating and enforcing rules, regulations, and standards governing data usage, privacy, and security within the ecosystem.
Standards development organization/ SDO	A standards development organization is an entity that defines and maintains industry-specific standards, protocols, and specifications to ensure interoperability, data quality, and consistency within the ecosystem.