PRECISEU

DELIVERABLE 4.1

PRECISEU readiness framework (Readiness/maturity assessment framework)

BIOPRO, ART-ER, FORTH & Clust-ER Health

30/09/2025

Co-funded by the European Union

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Project information	
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EU Project officer	Christina Nanou
Project coordinator	Montse Daban (Biocat)
Project manager	María Cejas (Biocat)

Table 1 Project information

Deliverable information	
Deliverable n.	D4.1
Work package n.	4
Deliverable title	PRECISEU readiness framework
Lead beneficiary	BIOPRO
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*Legend = **R –** Report // **DEM –** Demonstrator, pilot, prototype, plan designs // **DEC –** Websites, patents filing, press & media actions, videos, etc. // **DMP –** Data management plan // **OTHER –** Software, technical diagram, algorithms, models, etc.	

Table 2 Deliverable information

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Task 4.1 CONSORTIUM PARTNERS

	Name of the Entity	Acronym	Role	Country	ORG Type
1	BIOPRO Baden-Württemberg GmbH	BIOPRO Baden-Württemberg GmbH	B	Germany	
2	ART-ER-SOCIETA CONSORTILE PER AZIONI	ART-ER	B	Italy	
3	CLUST ER INDUSTRIE DELLA SALUTE E DEL BENESSERE	Clust-ER Health	B	Italy	
4	IDRYMA TECHNOLOGIAS KAI EREVNAS	FORTH	B	Greece	
5	Biocat la Fundació BioRegió de Catalunya	BIOCAT	C	Spain	
*Legend = Role in the Project: C – Coordinator // B – Beneficiary // AP – Associated Partner					

Table 3 Task 4.1 PRECISEU consortium

CONSORTIUM PARTNERS

	Name of the Entity	Acronym	Role	Country
1	Biocat LA FUNDACIO BIOREGIO DE CATALUNYA	Biocat	COO	ES
2	DEPARTAMENT DE SALUT - GENERALITAT DE CATALUNYA	SALUT	BEN	ES
3	BARCELONA SUPERCOMPUTING CENTER CENTRO NACIONAL DE SUPERCOMPUTACION	BSC-CNS	BEN	ES
4	BIORN CLUSTER MANAGEMENT GMBH	BIORN	BEN	DE
5	BIOPRO BADEN-WUERTTEMBERG GMBH	BIOPRO	BEN	DE
6	AGENTIA PENTRU DEZVOLTARE REGIONALA NORD-EST	NE RDA	BEN	RO
7	ASOCIATIA DIGITAL INNOVATION ZONE ZONA DE INOVARE DIGITALA	DIZNE	BEN	RO
8	CLUSTERUL REGIONAL INOVATIV DE IMAGISTICA MOLECULARA SI STRUCTURALA NORD-EST (IMAGO-MOL)	IMAGO-MOL	BEN	RO

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9	BIOTEHNOLOGICHEN I ZDRAVEN KLASTER	HLSCB	BEN	BG
10	STOLICHNA OBSHTINSKA AGENTSIA ZA PRIVATIZATSIA I INVESTITSII	SIA	BEN	BG
11	CLUST ER INDUSTRIE DELLA SALUTE E DEL BENESSERE	CLUST-ER HEALTH	BEN	IT
12	REGIONE EMILIA ROMAGNA	RER	BEN	IT
13	ART-ER-SOCIETA CONSORTILE PER AZIONI	ART-ER	BEN	IT
14	VLAAMSE GEWEST	EWI	BEN	BE
15	MEDVIA	MEDVIA	BEN	BE
16	VIESOJI ISTAIGA INOVACIJU AGENTURA	IA LITHUANIA	BEN	LT
17	BRG, BUSINESS REGION GOTEBORG AB	BRG	BEN	SE
18	EATRIS ERIC	EATRIS	BEN	NL
19	PLATAFORMA DE ORGANIZACIONES DE PACIENTES	POP	BEN	ES
20	AGENCIA PER A LA COMPETITIVITAT DE LA EMPRESA	ACCIO	BEN	ES
21	IDRYMA TECHNOLOGIAS KAI EREVNAS	FORTH-ICS	BEN	EL
22	REGION OF CRETE	CRETE	BEN	EL
23	SAHLGRENSKA SCIENCE PARK AB	SSP	BEN	SE
24	RIVNE INTERREGIONAL MEDICAL CLUSTER	RIVNE	BEN	UA
25	ASTRAZENECA FARMACEUTICA SPAIN S.A.	ASTRA ZENECA	BEN	ES

Table 4 Consortium partners

WORK PACKAGES AND LEADERS

Work Packages Name		WP Leader
WP 1	Project Management and Coordination	Biocat
WP 2	Communication and Dissemination	NE RDA
WP 3	Interregional Collaboration and Partnership Bridging	IA Lithuania
WP 4	Use of Health Data	ART-ER
WP 5	Multistakeholder infrastructure to enable access to ATMP on large scale	BIO PRO
WP 6	Market and Patient Access	SSP
WP 7	Training and Cultural Change	HLSCB
WP 8	Adoption of PM innovations in the HealthCare System	SALUT
WP 9	Innovation Support Program	Biocat

Table 5 PRECISEU'S Work Packages and Leaders

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LIST OF ACRONYMS AND ABBREVIATIONS

Abbreviation	Description
ACN	Agenzia per la Cybersicurezza Nazionale (Italy)
AEPD	Agencia Española de Protección de Datos
AGENAS	Agenzia nazionale per i servizi sanitari regionali
AGID	Agenzia per l'Italia Digitale
AHTI	Amsterdam Health & Technology Institute
AI	Artificial Intelligence
AP	Autoriteit Persoonsgegevens
API	Application Programming Interface
ART-ER	ART-ER Società Consortile per Azioni
ATLAS	National Health Care & Insurance Capacity Registry - Greece
AQuAS	Agency for Health Quality and Assessment of Catalonia
BIGAN	Big Data Project, Aragon
BIFI	Biocomputation and Physics of Complex Systems Institute
BIOCAT	Fundació BioRegió de Catalunya
BIOPRO	BIOPRO Baden-Württemberg GmbH
BSC	Barcelona Supercomputing Center
CBS	Centraal Bureau voor de Statistiek
CD	Compact Disc
CDA2	Clinical Document Architecture Release 2
CIBG	No information available in document
CIE	Carta d'Identità Elettronica (Italy)
CLUST-ER	Clust-ER Health (Italy)
CNAS	Casa Nationala de Asigurari de Sanatate (Romania)
CNP	Cod Numeric Personal (Romania)
COR	National Nomenclature of Occupations (Romania)
CPDP	Commission for Personal Data Protection
CRO	Contract Research Organisation
D4.1	Deliverable 4.1
DAAMS	Data aanvraag applicatie
DICOM	Digital Imaging and Communications in Medicine

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DigiG	Digital Health Act (Germany)
DES	Digital Electronic Record
DGIA	Dutch GDPR Implementation Act
DNIe	Documento Nacional de Identidad electrónico (Spain)
DPA	Data Protection Authority
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
DRG	Diagnosis Related Group
DSP	County Public Health Department
EATRIS	European infrastructure for translational medicine
ECl@ve	Electronic Identity for Administrations (Spain)
EDS	Ecosistema Dati Nazionali (Italy)
EHDEN	European Health Data and Evidence Network
EHDS	European Health Data Space
EHDS2	Secondary use of EHDS
EHR	Electronic Health Record
eID	Electronic Identification
eIDAS	electronic Identification, Authentication and trust Service
ELIXIR	Research infrastructure for life-science data
EMR	Electronic Medical Record
ENSALUD	No information available in document
ePrescriptions	Greek electronic prescriptions portal
ERDF	European Regional Development Fund
ESPBI IS	State Electronic Health Services and Cooperation Infrastructure Information System
EU	European Union
EUCAIM	European Federation for Cancer Images
FHIR	Fast Healthcare Interoperability Resources
FIS	Fondo italiano per la scienza
FIRST	Fondo di Investimento per la Ricerca Scientifica e Tecnologica
FNUASS	Fondul Unic de Asigurari Sociale de Sanatate (Romania)
FORTH	Foundation for Research and Technology – Hellas
FSE	Fascicolo Sanitario Elettronico (Italy)
FWO	Fonds Wetenschappelijk Onderzoek (Belgium)
GARR	Italian ultra-broadband network
GDI	Genomics Data Infrastructure

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GDNG	Gesundheitsdatennutzungsgesetz (Germany)
GDPR	General Data Protection Regulation
GHGA	German Human Genome-Phenome Archive
HBD	Health Big Data (Italy)
HDA	Health Data Agency
HDAB	Health Data Access Body/Bodies
HL7	Health Level 7
HPC	High Performance Computing
HTA	Health Technology Assessment
ICD-10	International Classification of Diseases, 10th Revision
ICD-11	International Classification of Diseases, 11th Revision
ICTU	ICT Uitvoeringsorganisatie (Netherlands)
IDIKA	Greek e-Government Center for Social Security
INI	National Infrastructure for Interoperability (Italy)
IoT	Internet of Things
IT	Information Technology
IT4LIA	Italy for AI
JIP	Joint Interregional Projects
LEPIDA	Regional IT company (Italy)
LOINC	Logical Observation Identifiers Names and Codes
LOPDGDD	Organic Law on Data Protection and Guarantee of Digital Rights
LSH	Life Science and Health
MDR	Medical Device Regulation
MII	Medical Informatics Initiative (Germany)
MGM	Maturity Grid Model
MTA	Material Transfer Agreement
NCPeH-NL	National Contact Point for eHealth Netherlands
NEN	Netherlands Standardization Institute
NHIF	National Health Insurance Fund
NHIS	National Health Information System
NHS	National Health Service
NHSU	National Health Service of Ukraine
Nictiz	National centre for standardisation and eHealth
NSIS	National centre for standardisation and eHealth

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NWO	Nederlandse Organisatie voor Wetenschappelijk Onderzoek
OECD	Organisation for Economic Cooperation and Development
OMOP CDM	Observational Medical Outcomes Partnership Common Data Model
OHDSI	Observational Health Data Sciences and Informatics
ONDS	National Health Data Observatory
PACS	Picture Archiving and Communication System
PADRIS	Program for the reuse of healthcare data in Catalonia
PDPA	Personal Data Protection Act
PhD	Philosophiae Doctor
PIAS	Integrated Health Insurance Platform
PGO	Personal health environments
PNRR	Piano Nazionale di Ripresa e Resilienza (Italy)
PRECISEU	PeRsonalised medicine Empowerment Connecting Innovation ecoSystems across EUrope
PRIN	Progetti di Rilevante Interesse Nazionale (Italy)
R&D	Research and Development
RDI	Research, Development and Innovation
RHC	Regional Healthcare
RIVM	Rijksinstituut voor Volksgezondheid en Milieu
RNBB	Spanish National Biobank Network
RRF	Recovery and Resilience Facility
SaMD	Software as a Medical Device
SENASH	Swedish Health Data
SFMI	Swedish Federation for Medical Informatics
SIPE	National Electronic Prescription System
SIUI	Single Integrated Information System (Romania)
SME	Small and medium-sized enterprises
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SOLE	Sanità OnLinE (Italy)
SPID	Sistema Pubblico di Identità Digitale (Italy)
STEP	Emilia-Romagna Region innovation strategy
SymbIASIS	Greek healthcare innovation accelerator funded by EIT Health

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TEHDAS	Joint Action Towards the European Health Data Space
TTP	Trusted Third Party
UAVG	Uitvoeringswet Algemene verordening gegevensbescherming (Netherlands)
UDI	Unique Device Identification
VWS	Ministerie van Volksgezondheid, Welzijn en Sport (Netherlands)
Wegiz	Electronic Data Exchange in Healthcare Act (Netherlands)
WGBO	Medical Treatment Contracts Act (Netherlands)
WP	Work Package

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EXECUTIVE SUMMARY

The report of **Task 4.1, "Assessing Readiness to EHDS"**, presents a systematic approach for evaluating the technological, regulatory, organisational, and societal **readiness of health data information ecosystems across PRECISEU-countries in Europe** for integration into the **European Health Data Space (EHDS)**, as part of the **PRECISEU** project's **Work Package 4 "Use of Health Data"**.

To achieve this, the consortium developed the **Maturity Grid Model (MGM), a standardised assessment tool with three levels of EHDS readiness that collects and compares essential EHDS requirements such as governance, technical infrastructure, health data readiness, resources, societal readiness, data privacy and security, access and control, unified market to EHR systems and innovation capacity**. The assessment process is based on desk research and the analysis of existing reports and policy papers from the respective PRECISEU countries or regions, with all results transferred to the MGM and visualised in abridged versions in clear **factsheets** for each participating country or region.

This readiness framework provides a transparent and harmonised baseline for identifying strengths and gaps in EHDS implementation at the European level. The results serve as a foundation for further project activities, such as **developing targeted recommendations for policymakers, informing joint interregional projects, supporting the design of interoperable health data infrastructures, and guiding capacity-building measures to enhance cross-border data sharing and the adoption of personalised medicine**. Ultimately, Task 4.1 and the PRECISEU framework support the sustainable and effective realisation of the EHDS vision, enabling secure, innovative, and patient-centred healthcare across Europe.

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1. INTRODUCTION

The **EHDS** is a flagship initiative of the European Union to create a secure and harmonised digital environment for health data across Europe. The health sector is the first area in which the EU is implementing such a comprehensive data space regulation, which emphasises both the importance and the pioneering role of the health sector in shaping the European data strategy. As the first EU-wide data space for the health sector, the EHDS is a cornerstone of the European Health Union and part of the wider European strategy for data. It establishes common rules, standards and infrastructures that enable individuals to access, control and share their electronic health data, both at national level and across borders within the EU.
The EHDS has **two central aims**. **First**, it **empowers citizens by providing immediate, free, and secure access to their personal health data** – such as medical records, prescriptions, and test results – and enables them to share this data with healthcare professionals anywhere in the EU. **Second**, it **facilitates the secondary use of health data** for research, innovation, public health, and policymaking, always in compliance with strict data protection and cybersecurity standards.

By harmonising legal and technical frameworks for electronic health records and ensuring interoperability between national health systems, the EHDS is designed to boost innovation, support the development of digital health services, and improve patient care across Europe. The **regulation** entered into force in **March 2025** and will be implemented gradually, marking a significant step toward high-quality, accessible, and sustainable healthcare in the EU.
Importantly, the EHDS also lays the foundation for advancing **personalised medicine**. By facilitating secure access to and sharing of large, diverse datasets, it empowers researchers and clinicians to develop personalised treatments, moving beyond the traditional "one-size-fits-all" model of conventional medicine.
The **Horizon Europe funded project** PRECISEU demonstrates how the EHDS can accelerate the implementation of personalised healthcare by connecting innovation ecosystems, sharing best practices, and scaling up deep-tech healthcare solutions across Europe.

Work Package 4 (WP4) "Use of Health Data" focuses on enabling the effective and secure use of health-related data, with a particular focus on supporting the **EHDS** and **advancing personalised medicine**.
The **objectives of WP4** are to **design and implement a robust framework** for evaluating the readiness and maturity of health information systems and infrastructures at national, regional, and local levels, with particular emphasis on enabling the secondary use of health data within the diverse ecosystems and use cases represented in PRECISEU. In this project, the following countries and regions are intended: Germany (Baden-Württemberg), Spain (Catalonia), Belgium (Flanders/Vlaamse Gewest), Bulgaria (Sofia), Romania (Nord-Est Region), Italy (Emilia-Romagna), Lithuania, Sweden (Västra Götaland/Gothenburg), the Netherlands (Noord-Holland/Amsterdam), Greece (Crete), and Ukraine (Rivne).
In addition, WP4 aims to **define key requirements, gaps, and cost factors** associated with hosting, curation, and processing of health data, considering both its primary application in

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healthcare and its secondary roles in policy-making and research. The work package also seeks to **develop a reference framework and guidelines** to promote the interoperability of health data across borders. Finally, WP4 **contributes to the design and monitoring of PRECISEU's Joint Interregional Projects (JIP)** in personalised medicine from the use of data perspective.

WP4 is closely linked to other work packages within PRECISEU, deepening the data-specific aspects outlined in WP3, providing essential input for the development and evaluation of Advanced Therapy Medicinal Products in WP5, and supporting the creation of market access models and capacity-building activities in WP6 and WP7. The guidelines and assessment results from WP4 also support the selection of innovation projects within the Innovation Support Programme in WP9.

Central to WP4 is **Task 4.1 "Assessing Readiness to EHDS"** which evaluates the readiness and maturity of the national, regional and local health data information systems and infrastructures in multiple domains/requirements across the participating PRECISEU countries. Partners involved in Task 4.1 include the task lead organisations **BIOPRO** from **Baden-Württemberg in Germany, ART-ER and Clust-ER Health** from **Emilia-Romagna in Italy**, and **FORTH** from **Crete in Greece**. They worked together in this task from **July 2024 to September 2025**, aiming to ensure a comprehensive and representative assessment to support the future of personalised medicine in Europe.

The main output of **Task 4.1 is Deliverable 4.1 (D4.1), the "PRECISEU Readiness Framework"**. This deliverable sets out a structured method for assessing the readiness and maturity of health data systems across several requirements, based on recommendations from the TEHDAS project regarding cross-border collaboration between Health Data Access Bodies (HDABs). These requirements including technological, clinical, regulatory, organisational, and societal readiness. The assessment will also consider the sustainability of the EHDS by evaluating data curation costs (see Deviation) in different countries, including the costs of health data collection, preparation, quality management, standardisation, pseudonymisation, and processing.

To achieve this, the PRECISE partners pf Task 4.1 developed the **Maturity Grid Model (MGM)**, a comprehensive, standardised **assessment tool** that organises and compares critical requirements of EHDS, while also evaluating the readiness of the EHDS. The requirements were categorised with a **color code into three levels of EHDS readiness**: green indicated that actions for EHDS implementation are already in place, yellow signified that actions are currently in progress, and red showed that no actions have yet been initiated. The information on each requirement is based on desk research and policy reviews. To ensure clear and concise presentation, **region-specific factsheets** were created, summarising the MGM's assessment of each requirement for EHDS readiness.

A key feature of Task 4.1 is its emphasis on ensuring the long-term sustainability of the EHDS. This task covers the entire process – from secondary research, including the collection of data regarding the requirements of EHDS from regional and national publications on the EHDS of the PRECISEU-countries, to the assessment of each PRECISEU-EU-country's level of readiness

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for the EHDS, as well as the status of health data infrastructure in Ukraine, which, as a non-EU country, is also involved in the project. It further includes an analysis of the current state of the requirements of the EHDS and culminates in the development of recommendations for policymakers. These efforts aim to foster interregional collaboration in personalised medicine. In addition, the results will support an ex-post evaluation of progress made in EHDS readiness.

1.1. Deviation

In connection with Task 4.1 and Deliverable 4.1 (D4.1), the "PRECISEU Readiness Framework," we have a **deviation from the project proposal** regarding the **treatment of costs**. The assessment of data curation costs in connection with the European Health Data Space (EHDS) – including the costs of collecting, preparing, quality management, standardization, pseudonymization, and processing health data – could not be included in our analysis. This exclusion is due to a lack of expertise in this context within the consortium to reliably assess the cost dimensions specifically related to EHDS readiness in the different countries. Given the complexity and variability of national cost structures and the methodological requirements of comparative cost benchmarking, including this factor at this stage would have risked introducing uncertainties and compromising the reliability of the readiness assessment.

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2. METHODOLOGY

2.1. Approach

Task 4.1 employs a multidimensional and collaborative methodology to assess the readiness of national and regional health information systems for the EHDS across all PRECISEU partner countries and regions. The approach is based on comprehensive literature and document reviews, systematically capturing the technological, regulatory, organisational, and societal aspects of EHDS readiness. These findings are consolidated in the standardised assessment tool – the Maturity Grid Model (MGM) – which provides a harmonised and comparable readiness assessment with a colour coding system. This enables the identification of strengths and gaps across PRECISEU countries and regions. The results inform targeted policy recommendations.

The process is coordinated by the project partner organisations **BIOPRO (Germany), with ART-ER and Clust-ER Health (Italy) and FORTH (Greece)** as core partners. With the help of the country representatives of PRECISEU the information of each country and region was finalised. The **timeline for Task 4.1** runs from **July 2024 to September 2025**.

All PRECISEU partners participated by reviewing EHDS-relevant reports for their respective regions or countries and uploading these documents to a dedicated PRECISEU SharePoint directory. Since only Germany, Greece and Italy were covered by the Task 4.1 partners, we asked the country representatives to help us with this Task. Each country representative completed the MGM Excel template with extracted information from their country or region, referenced all sources, and provided additional context where necessary.

2.2. Maturity Grid Model, Factsheet construction and country requirements

The **Maturity Grid Model (MGM)** is a central tool for the systematic assessment of country requirements related to EHDS readiness (see 3. Country Requirements of EHDS). It includes key requirements like Governance, Technical infrastructure, Health data readiness, Resources, Societal readiness, Data privacy and security, Access and control, Unified market for EHR systems and Promoting innovation. Each aspect is further divided into subcategories, such as National, Regional and Legal and regulatory aspects in Governance (additional subcategories see in 2.2.1 Template of the Maturity Grid Model (MGM)).

A **color-code** was used within the MGM to visualise the status of EHDS readiness:

- **Green:** Set Actions for EHDS readiness.
- **Yellow:** Actions in process for EHDS readiness.
- **Red:** Not set actions for EHDS readiness.

All sources were referenced in the MGM and detailed in a dedicated “Sources” sheet in the same excel document. Partners had the opportunity to provide additional explanations or context in the fields labeled “Important Additional Remarks” and “Comments”.

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Once all individual country-specific MGMs were completed, the results were consolidated into a single, comprehensive MGM covering all PRECISEU countries. To facilitate reporting and visualisation, a **Factsheet** template (see Annex) has been developed that summarises the MGM findings for each country in a concise and clearer format. This ensures that all key requirements of EHDS readiness are clearly presented for stakeholders.

2.2.1 Template of the Maturity Grid Model (MGM)

This excel template presents a comprehensive overview of key requirements and subcategories of the EHDS. The excel template is in fact a single table, but for clarity and better readability, it has been divided into two sections.

Section 1: This section covers the requirements Governance, Technical infrastructure, Health data readiness, Resources, and Societal readiness, along with their respective subcategories and descriptions. Under these rows there is a row that contains General remarks, while the subsequent rows list the countries participating in PRECISEU. The color code indicates each country's and region´s level of readiness regarding the requirements of the EHDS (see Figure 1).

Country and Region	Governance			Technical infrastructure	Health data readiness				Resources		Societal readiness
Description	All member states must designate authorities (and have already done so in some cases) to ensure that the conditions for the EHDS are coordinated and created and that the rights of citizens are respected in the process. These authorities are also obliged to participate in the concrete development of the cross-border digital infrastructure and to support			Technological framework and tools enabling secure, standardized, and interoperable exchange, storage, and access to health data across the EU.	Ability to securely manage, share, and use health data effectively, ensuring interoperability, compliance, and support for care, research, and innovation within the EHDS.				Tools, infrastructure, data repositories, technologies, and expertise needed to enable secure, interoperable, and efficient health data sharing and use across Europe.		Public's acceptance, trust, and preparedness to engage with and benefit from health data sharing, ensuring ethical use, transparency, and alignment with societal values.
Subcategories	**National**	**Regional**	**Legal and regulatory aspects**		**General state of health data**	**Secondary use of health data (EHDS2) Research and innovation** Promote the use of health data for scientific studies and technological developments. **Policy making and regulation** Provide data for evidence-based policy decisions and regulatory activities.	**Interoperability of data** Member states are responsible for ensuring data interoperability; e.g. electronic patient records, medication data, images and laboratory results must be issued in a common European format	**Data quality / Standardisation of data**	**Resources and funding**	**Human Resources**	
General remarks											
Country A											
Country B											

Section 2: This section covers the requirements Data privacy and security, Access and control, Unified market for EHR systems, and Promoting innovation along with their respective subcategories and descriptions. In the last two columns – Important additional remarks and comments – the country representatives added extra information or explanations. Under these

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rows there is a row that contains General remarks, while the subsequent rows list the countries participating in PRECISEU. The color code indicates each country's and region´s level of readiness regarding the requirements of the EHDS (see Figure 1).

Data privacy and security			Access and control		Unified market for EHR systems	Promoting innovation		Important additional remarks	Comments
Ensuring that personal health data is processed securely and lawfully, protecting individuals' rights through strict access controls, transparency, data minimization, and compliance with GDPR and EHDS-specific regulations.			Guaranteeing that individuals and authorized entities can access health data appropriately, while ensuring that citizens retain control over who accesses their data and for what purpose.		Establishing a common European framework that ensures interoperability, certification, and compliance of Electronic Health Record (EHR) systems to enable seamless and secure cross-border data exchange.	Enabling secure and ethical use of health data for research, policy-making, and innovation to improve healthcare delivery and foster digital health solutions across the EU.		Key supplementary points or considerations, such as ethical implications, regulatory nuances, or practical challenges critical to the framework's implementation and success.	
General Data Protection Regulation (GDPR) Strict adherence to the General Data Protection Regulation (GDPR).	**Data protection provisions** Data protection provisions to safeguard privacy.	**Health Data Access Bodies (HDABs)** Establishment of Health Data Access Bodies (HDABs) to oversee data access requests and grant data access approvals.	**Access rights** Defining access rights for patients and authorized users.	**Transparency** Ensuring transparency in the use of health data.	**Harmonisation of standards** Support a unified market for electronic health record systems (EHR), medical devices, and high-risk AI systems.	**Technology-based solutions** Supporting technology-based solutions in healthcare.	**Research and development** Encouraging research and development based on health data.		

Figure 1 Maturity Grid Model (MGM) with color code (Green: Set actions for EHDS readiness, Yellow: Actions in process for EHDS readiness and Red: Not set actions for EHDS readiness).

2.3 Requirement Analysis

The Requirement Analysis (see 4. Requirement Analysis) assessed the **status quo of EHDS readiness in the PRECISEU participant** countries, rather than across the entire European Union (EU), as PRECISEU does not include all EU member states and the EHDS belongs to the EU. Ukraine could not be included in the Requirement Analysis as it is not yet a member of the EU and does not have the EHDS in force. The information on Ukraine is contained in 2. Country Requirements. The readiness was evaluated against the EHDS requirements using the MGM (see 2. Country Requirements), which consolidates country-specific information for the assessment. To visualise the findings, a bar chart was produced following the MGM color code. This was determined by totaling the information marked green, yellow and red for each requirement across all countries. In this bar chart, information marked red highlights the gaps that still exist overall in the PRECISEU countries' readiness for the EHDS.

To address the identified gaps, we developed **recommendations for policy-makers** for **PRECISEU EU-countries** based on the gaps (red marked information) identified in the MGM and the overall Requirement Analysis. These recommendations were then validated with the help of EHDS and health data experts from the PRECISEU partner countries as well as part of our Advisory Board, and suggestions for improvement or further recommendations were made to

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ensure that they reflect a clear and concise expert perspective. We also asked experts which recommendations they would make for Ukraine, as their health data infrastructure is supposed to meet the EHDS but does not include it right now.
The recommendations were intended for inclusion in the conclusions of the report, with the aim of supporting decision-making at the EU level regarding EHDS readiness. As part of the validation process, the experts systematically reviewed the recommendations, focusing on several key criteria: Clarity and comprehensibility of formulation, feasibility and relevance for policymakers, and sufficient concreteness to enable effective implementation. Furthermore, the experts identified and added important elements where they considered aspects to be missing, thereby enhancing the overall quality and applicability of the recommendations.

3. COUNTRY REQUIREMENTS OF EHDS

3.1 Germany

Governance

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National

The German Health Data Use Act (GDNG) provides for the establishment of a Health Data Lab at the Federal Institute for Drugs and Medical Devices. This centre will make anonymised and pseudonymised billing data from statutory health insurance, as well as data from the German electronic health record (EHR) system and national and regional cancer registries, available for research purposes (EIT Health Think Tank, 2024).
According to the EHDS regulation, Germany must designate one or more digital health authorities responsible for implementing and monitoring EHDS requirements (European Union, 2025) Art. 19). In addition, Germany is required to set up a national contact point for digital health, which will be linked to the EU-wide MyHealth@EU infrastructure and will enable the secure cross-border exchange of health data (European Union, 2025) Art. 23).

As the EHDS regulation is still under negotiation, it remains unclear which data holders will ultimately fall under its scope. The Health Data Use Act provides for the creation of a Health Data Lab at the Federal Institute for Drugs and Medical Devices, which will make pseudonymised health data – including billing data from statutory health insurance, German EHR data, and national cancer registry data – available for research purposes. The Act also anticipates that further data holders may be included in the future, although the exact details have not yet been defined (EIT Health Think Tank, 2024).

Regional

Germany's healthcare data management is decentralised, reflecting its federal political structure. Data is organised and managed mainly at the regional level, leading to varied practices and systems across federal states (EIT Health Think Tank, 2024).

Legal and regulatory aspects

In 2024, Germany introduced several new laws to advance digitalisation and health data use, including the Digital Health Act (DigiG), the GDNG, and the Hospital Transparency Act. These laws aim to create a decentralised health data infrastructure, promote transparency, and digitalise healthcare. While these are important steps towards the EHDS, further measures are needed, especially to ensure interoperability of electronic health records across the EU (EIT Health Think Tank, 2024).

Technical infrastructure

Germany is also reportedly still lacking the necessary infrastructure and tools to enable data collection and sharing for both primary and secondary uses (EIT Health Think Tank, 2024).

Health data readiness

General state of health data

The health data landscape is often characterised by highly fragmented digital systems (EIT Health Think Tank, 2024).

Secondary use of health data (EHDS2)

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Research and innovation & policy making and regulation

German research institutions and companies will be able to access health data through the EHDS infrastructure to foster innovation. This access is granted under stringent data protection and security requirements (European Union, 2025) Art. 53 & 73).
German citizens have the right to access, transfer, and restrict the use of their electronic health data. They can also review information regarding who has accessed their data and have the right to refuse the use of their data for secondary purposes (European Union, 2025) Art. 3-10 & 71).

Germany has begun integrating digital and data-driven solutions into clinical and patient pathways, supported by established assessment procedures and reimbursement schemes for digital medical devices (EIT Health Think Tank, 2024).

There is a lack of a data-sharing culture and persistent concerns about data misuse among healthcare professionals in Germany, particularly regarding the release of what is often viewed as their own data – rather than the patient's – for secondary use, from which they perceive no direct benefit (EIT Health Think Tank, 2024)

Interoperability of data

Germany is required to ensure that electronic health data can be stored and exchanged in a standardised European format, known as the European EHR Exchange Format. This standardisation facilitates the seamless cross-border exchange of health data, for example, when individuals travel or receive medical treatment in other EU countries (European Union, 2025) Art. 15 & 23).

The GDNG and DigiG proposals represent only initial steps that should be sustained in future initiatives. However, they are not a reason to slow down progress; a swift follow-up will be necessary to implement the EHDS, particularly with respect to ensuring interoperability of EHR systems between member states. To achieve EHDS interoperability, it will be essential to establish a common language, a unified (logical) data model, shared semantics, and a standardized set of technical specifications (EIT Health Think Tank, 2023).

Data quality / Standardisation of data

The implementation of a nationwide EHR system has been underway for more than a decade. However, as of 2023, patient adoption remains critically low (EIT Health Think Tank, 2024). The effective secondary use of health data fundamentally relies on the quality of data collection in primary care settings. Currently, technical standards, data semantics, and data quality are insufficient to enable seamless secondary use of this data. Several panelists pointed out that Germany lacks accessible and reliably structured hospital data. Data silos are prevalent, with limited interoperability between systems. Paper-based documentation is still widespread, as is the manual transfer of information between systems. These challenges are particularly pronounced in smaller, less well-equipped, and understaffed healthcare providers, who often lack the capacity and time for comprehensive reporting (EIT Health Think Tank, 2023).

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Current practices for updating the EHR have led to it becoming a repository of PDFs rather than structured, usable data. For instance, many records consist of scanned printouts from individual institutions' Electronical Medical Record (EMRs), often including handwritten annotations. There is little standardisation in the data itself, with semantic inconsistencies and syntactic differences – for example, in how patients are asked about pain levels – as well as significant variation in how metadata is recorded. These issues make it difficult to share and compare data across existing systems. Since most medical care in Germany is still delivered in isolated silos – and the country ranks low in integrated care among Organisation for Economic Cooperation and Development (OECD) nations – there is little long-term vision or incentive for most healthcare providers to improve their data collection practices, whether for primary or secondary data use (EIT Health Think Tank, 2024).

Resources

Resources and funding

The federal government remains primarily responsible for EHDS funding. In BadenWürttemberg, the Forum Health Region – BadenWürttemberg illustrates how regional funding streams can advance – healthdata use: over 60 projects have been supported across three rounds, with the current 2023–2026 round piloting -healthdata use and preparing for Germany's Health Data Use Act and the EHDS. The Land's positions- emphasise interoperability, robust anonymisation or pseudonymisation, and the creation of test and training datasets, including instruments suitable for Small and medium-sized enterprises (SME). For SMEs, BW provides access to digital and innovation funding calls via Wirtschaft.Digital BW and BIOPRO Baden-Württemberg, which regularly curate relevant programmes and Invest BW opportunities. While Baden-Württemberg does not have a direct analogue to Bavaria's "digiOnko", university hospitals engage through MII infrastructures and service models for data provision, complemented by coordinated digitalisation initiatives in the public health service (ÖGD BW) (Forum Gesundheitsstandort Baden-Württemberg, 2025), (BIOPRO Baden-Württemberg GmbH, 2025).

Human resources

Regional funding for hospital digitalisation exists across Germany, but disparities remain. Smaller providers in less developed areas often lack not only financial means and technical equipment, but also sufficient human resources and IT expertise needed for EHDS implementation, making them particularly vulnerable to new digitalisation requirements. The Bavarian State Ministry of Health and Care warns that an opt-out system for secondary data use may disproportionately affect patients with limited digital literacy or internet access, such as the elderly and disabled. Small and medium-sized providers may also struggle to meet EHDS technical demands. Enhancing digital literacy among both individuals and professionals is essential. Successful healthcare digitalisation requires more than funding; organisational reform and, crucially, the recruitment of skilled personnel are also needed. Investments should focus on process improvement and resource management. Without additional human resources, financial support and reforms will not achieve their intended impact (EIT Health Think Tank, 2023).

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Societal readiness

Recent survey data indicate high willingness in Germany to share anonymised health data for research (82.4%), but lower readiness to share own non-anonymised data (53.5 %). Acceptance varies by recipient: public/clinical institutions 83.8%, health insurers 49.1%, pharma 30.7%, Big Tech 4.4%. Focus on anonymisation, strict purpose limitation, robust security/governance, and trusted public infrastructures to strengthen societal readiness (Deutsches Ärzteblatt, 2024).

Data privacy and security

General Data Protection Regulation (GDPR)

The processing of personal health data must adhere to the requirements of the GDPR, particularly the principles of data minimisation, purpose limitation, and security (European Union, 2025) Art. 66 & 74). Wherever possible, health data should be anonymised or pseudonymised to safeguard the identity of data subjects (European Union, 2025) Art. 66).

Data protection provisions

Health data may only be processed within secure environments that meet stringent technical and organisational security standards. These measures include access logging, pseudonymisation, and safeguards against unauthorised access (European Union, 2025) Art. 73).

Health Data Access Bodies (HDABs)

In Germany, data protection authorities are responsible for overseeing compliance with data protection regulations. They collaborate with digital health authorities, who are tasked with implementing the EHDS (European Union, 2025) Art. 19 & 65). Clear and timely communication to the public is essential regarding which datasets are used, for what purposes, and with what outcomes (EIT Health Think Tank, 2024). Especially on sensitive or polarising issues, communication should not be limited to the EU and national ministries responsible for implementation. Instead, non-political actors - such as health data access bodies, statutory health insurers, physicians, and IT service providers or software manufacturers - should also play a prominent role. Public awareness campaigns should ensure universal access to information by incorporating non-digital channels, such as telephone hotlines and information desks. Once data permitting and secondary use activities commence, regular and transparent updates from health data access bodies - detailing which datasets have been used, by whom, for what purposes, and ideally with what results - can help to foster and maintain citizens' trust and engagement over time (EIT Health Think Tank, 2024).

Access and control

Access rights

Citizens have the right to access, correct, transfer, and restrict the use of their health data (European Union, 2025) Art. 3-10). They may also object to the secondary use of their health data through an opt-out mechanism (European Union, 2025) Art. 71).

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Transparency

Establishing common rules, principles, and transparency requirements for setting data access fees would help ensure a clear understanding of the system and prevent negative user experiences that could result from significant fragmentation in national approaches (EIT Health Think Tank, 2024). To support appropriate secondary research and policymaking, it is essential to provide users with transparency and guidance regarding which types of questions and research methodologies are best suited to specific datasets (EIT Health Think Tank, 2024). At both national and regional levels, communication should highlight the life-saving potential of data sharing for citizens, while also ensuring transparency about data collection, storage, use, and the privacy safeguards in place to protect personal data (EIT Health Think Tank, 2024).

Unified market for EHR standards

Harmonisation of standards

Germany is pursuing a federated model for EHRs, which means health data is stored and managed in a decentralized way while still ensuring interoperability between different systems. This approach supports the EHDS's objective of harmonizing legal and technical frameworks for EHRs, thereby fostering both interoperability and innovation (European Commission, 2024), (European Union, 2025). Germany has introduced the electronic patient record (ePA), enabling patients to digitally store and manage their health data. Although uptake has been gradual, the ePA remains a cornerstone of Germany's strategy to improve data interoperability and aligns with the EHDS's aims of empowering individuals with access to and control over their electronic health information (European Commission, 2024).

Promoting innovation

Technology-based solutions

Germany is advancing personalised medicine through a range of technology-driven initiatives. Secure genomic data platforms such as genomDE and the German Human Genome-Phenome Archive (GHGA) provide robust infrastructures for integrating and accessing genomic and health data, enabling more precise diagnoses and targeted therapies (Bundesministerium für Gesundheit, 2025), (GHGA, 2025). Research centers like Helmholtz Munich and the Max Delbrück Center are at the forefront of developing artificial intelligence and machine learning models, as well as single-cell analysis techniques, to tailor medical treatments to the needs of individual patients (Helmholtz Munich, 2024), (MDC Berlin , 2024). Innovative sensor technologies are also playing a key role: projects such as QSens and nanodiag BW are developing ultrasensitive quantum sensors and nanopore technologies that improve diagnostics and allow for personalised monitoring of therapies (Gesundheitsindustrie BW, 2024), (NanoDiag, 2024). Furthermore, the Medical Informatics Initiative (MII) is enhancing data integration by securely linking clinical and research data. This is supported by the Health Data Utilization Act (GDNG), which provides the legal framework for innovative and responsible use of health data in personalised medicine (Medizininformatik-Initiative, 2024), (Bundesministerium für Gesundheit, 2025).

Research and development

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Germany fosters innovation in research and development (R&D) for personalised medicine through a comprehensive strategy that brings together advanced technologies, robust data infrastructures, and collaborative networks. With the national genomDE initiative, Germany is integrating genomic medicine into routine healthcare by enabling access to genomic data for both research and clinical applications. This supports the development of innovative diagnostics and therapies. The German Human Genome-Phenome Archive (GHGA) further strengthens this approach by providing a secure platform for sharing omics data, facilitating large-scale research collaborations (Bundesministerium für Gesundheit, 2025), (GHGA, 2025). Leading research institutions such as Helmholtz Munich and the Max Delbrück Center are developing AI-driven models and bioinformatics tools to analyze complex biological datasets. These advances support personalized treatment approaches and accelerate drug discovery (Helmholtz Munich, 2024), (MDC Berlin , 2024). Projects like QSens and nanodiag BW are pioneering the development of quantum sensors and nanopore technologies. These innovations enable precise, real-time monitoring of patients, which is essential for personalized therapeutic interventions (Gesundheitsindustrie BW, 2024), (NanoDiag, 2024). The Medical Informatics Initiative (MII) promotes interoperability by linking clinical and research data across multiple institutions. The Health Data Utilization Act (GDNG) provides a secure and ethical legal framework for the use of health data in research and innovation (Medizininformatik-Initiative, 2024), (Bundesministerium für Gesundheit, 2025).

3.2 Spain

Governance

National

SPAIN

Spain has established robust governance frameworks to enhance EHDS readiness, with particular emphasis on health data standardisation and security. Well-defined protocols for data sharing and interoperability are in place, facilitating more efficient information exchange between regional and national systems. The country's strategic commitment to digital transformation – across both public and private sectors – has been articulated through comprehensive national initiatives such as Digital Spain 2026, which makes use of funding from the European Union's Next Generation EU stimulus package. Furthermore, Spain's existing infrastructures, including centralised health data repositories and advanced digital health systems, provide a solid foundation for future alignment with EHDS requirements (Digital Spain, 2025).

Mechanisms to ensure meaningful patient involvement in the governance and use of health data are currently lacking. To foster trust and promote equitable access within the EHDS framework, it is essential to empower patients by providing education, implementing transparent consent processes, and creating opportunities for active participation in decision-making related to their health data (EIT Health, 2024).

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The Spanish federal government has launched a project for the implementation of the EHDS under the auspices of the Ministries of Health, Science and the Economy (EIT Health Community, 2024). Since 2020 there has been a significative progress in Spain towards EHDS, with the creation of specific Government units for digital health, launching of funds and instruments like the "Vanguard Health" PERTE (special strategic projects of interest) and the proposal for a creation of a Spanish Data Lake. Next Generation funds are used to transform the health system, not losing the opportunity for modernisation and facilitating the adoption of EHDS (EDAH project, 2023).

Regulatory hurdles: Insufficient harmonisation between the EHDS regulation and national laws and acts poses significant challenges to effective implementation (PredictBy, 2024), (EIT Health, 2024).

Regional

SPAIN

Spain is actively implementing regional pilot projects to refine health data governance models and align them with EHDS standards. At the national level, policies are being harmonised with EU regulations to ensure full compliance. Additionally, targeted efforts are underway to enhance collaboration between public and private stakeholders. Together, these measures are designed to establish an interoperable ecosystem in which governance and technical standards are consistently applied across regions and sectors (EIT Health, 2024).

CATALONIA

The Agency for Health Quality and Assessment of Catalonia (AQuAS) coordinates the PADRIS program, which was born in 2017 as a program promoted by the Catalan Health Department. Its mission is to facilitate the reuse of healthcare-related data of the Catalan Health System. PADRIS has access to the following data sources or types: "ü Catalan Central Registry of Insured Individuals ü Hospitals and primary care EMR ü Pharmacy prescription and dispensing ü Laboratory tests ü Mortality, biobank, and health surveys data ü Specific registries and ü Medical images" (AQUAS – Agència de Qualitat i Avaluació Sanitàries de Catalunya, 2017), (EDAH project, 2023).

Current data governance structures and practices in Spain reflect the decentralised organisation and management of healthcare at the regional level. Each of the 17 autonomous regions operates its own public health system, establishing distinct infrastructures and processes that enable the secondary use of residents' health data for research and public policy purposes. However, comprehensive top-down coordination of these regional initiatives at the national level has so far been lacking (EDAH project, 2023).

Access to health data remains excessively restricted to certain entities, and multiple interpretations of the GDPR (EU 2016/679) coexist among stakeholders at the regional level in Catalonia (EIT Health, 2024).

Legal and regulatory aspects

SPAIN

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Spain is preparing for the implementation of the EHDS through its national digital health initiatives, building on the existing data protection framework established by the LOPDGDD and the GDPR (datos.gob.es, 2025).

Despite progress, several critical governance measures remain absent. Spain lacks comprehensive national legislation fully aligned with EHDS principles. The Spanish Government is working on a unified National Strategy to address key challenges such as resource allocation, workforce training, and ethical data use (Estrategia Española de Saud Global 2025-2030). Additionally, mechanisms ensuring equitable access and governance of health data at both, national and EU levels, are yet to be developed, posing a barrier to full EHDS implementation (EIT Health, 2024).

CATALONIA

A strategic political focus on the digital transformation of the public and private sectors and wider society has been expressed through comprehensive national policies such as Digital Spain 2026, which leverages the funding provided through Europe's Next Generation EU stimulus package and includes a specific `National Artificial Intelligence Strategy`. Framework in place: `The Department (Ministry) of Health` as a strategic planning, `CatSalut` as an operational planning body, `AQUAS`, given its experience with `PADRIS` and technology assessment, TIC Salut Social`, given its functions related to AI, and `BIOCAT`, for its role as a strategic agent and catalyst (Generalitat de Catalunya, 2017), (AQuAS, 2021).

Efforts to fully harness the potential of health data are currently constrained by the strict application of the GDPR in the country, as well as by the absence of supplementary legal frameworks governing its use (EIT Health, 2024).

Technical infrastructure

SPAIN

Spain has developed a foundational technical infrastructure, including various regional EHR systems, which support data exchange within local healthcare networks. These systems are aligned with certain interoperability standards, allowing for sharing health data among healthcare providers within specific regions, contributing to the overarching goal of seamless data sharing under the EHDS. Furthermore, there are digital platforms for patient access to their health data (EIT Health, 2024).

Spain is currently working to improve interoperability across its regions by scaling up existing regional EHR systems to the national level. Efforts are also underway to enhance data security measures in line with EHDS requirements and to prepare for cross-border data exchanges within the EU framework. These initiatives aim to align Spain's health data systems with EU-wide standards and best practices. While Spain participates in some EU health data exchange services through the `eHealth Digital Service Infrastructure`, it has not yet fully implemented all services required by the EHDS, particularly those related to the secondary use of health data (EIT Health, 2024).

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Although progress has been made, Spain still lacks a fully integrated nationwide EHR system that ensures consistent interoperability across all regions. Additionally, advanced tools for data analysis, real-time monitoring, and patient consent management are not yet sufficiently developed, which are crucial for both, secondary data uses and ensuring transparency and trust in the system (EIT Health, 2024).

CATALONIA

The `Spanish Biobank Network` is linking 39 individual biobanks. several autonomous regions have built data lakes making the health data of all their residents accessible for public health and research purposes, and public research infrastructure such as the `Barcelona Supercomputing Centre (BSC)` or the `University of Zaragoza's Institute for Biocomputation and Physics of Complex Systems (BIFI)` provide a robust basis to support secondary use projects. The regional health authority of the autonomous region of Aragón has over the last seven years been able to build a data lake with the health data of its 1.3 million residents. 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. Information from hospitalisations, emergency room visits, primary care, laboratory tests, radiology and medical imaging, drug prescriptions, and more, across the entire territory, can now be accessed upon application for research, public health planning and quality management purposes. The platform supports about 50 research projects each year (EIT Health, 2024).

In Catalonia, PADRIS is meant to be the core of ongoing EHDS strategy in the region (EDAH project, 2023).

Health data readiness

General state of health data

SPAIN

Spain has developed regional health data systems that facilitate the collection and utilisation of health data within individual regions. These systems are becoming increasingly interconnected, enabling regional data exchange and supporting foundational interoperability. Furthermore, Spain has established robust frameworks for data privacy and security that comply with both national and EU regulations, providing a strong basis for future EHDS integration. Spain is recognised as a 'fast-tracker' in enabling citizens' access to eHealth data, with a maturity level score that surpasses the EU-27 average (European Union, 2024).

Spain is actively working on harmonising health data standards across regions and connecting data systems more effectively. Efforts include improving data quality and ensuring the systems align with EU interoperability standards. There are also ongoing initiatives to enhance the use of health data for secondary purposes like research, ensuring that data can be used more broadly while maintaining privacy and security (EIT Health, 2024).

Key actions still missing include the development of a cohesive national data strategy that ensures consistent data quality and access across all regions. Further, there is a need for more

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advanced infrastructure to handle complex data types such as genomic or personalised health data. Additionally, mechanisms to ensure wider patient involvement and transparency in how their data is used are yet to be fully established (EIT Health, 2024). Weaknesses included a lack of effective central coordination, variability in regional implementation of financing measures, and insufficient adaptation to digital health needs (EIT Health Spain, 2023).

CATALONIA

High level of digital maturity and extensive experience with the secondary use of health data has been acquired. In Catalonia 8 million people in MyHealth@EU (Ministry of health, 2024). Spain among the top five out of 17 OECD countries with the most advanced digital healthcare systems in the Bertelsmann Foundation's 2019 Digital Health Index. Key strengths were reported to be the implementation of basic standards at regional level, the capacity of regional EHR systems to export data to a national patient summary system, and the country's comprehensive electronic prescription infrastructure (EDAH project, 2023).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

SPAIN

Spain has established frameworks that facilitate the secondary use of health data, with initial efforts focused on creating secure platforms for sharing anonymised data for research and policy analysis. These systems comply with EU privacy regulations, ensuring that health data is used responsibly and ethically. 2021 report by the Open Data Institute (Open Data Institute, 2025) included Spain in the group of leading countries for policy and implementation especially in the subcategory of infrastructure, with progress similar to known role model countries like Denmark or Finland. Examples of Spain's extensive experience with and infrastructure for the use of federated data for health research include the `Spanish Biobank Network´, which links data from 39 biobanks for the benefit of the wider research community. In addition, in the area of supercomputing, which may be needed for specific projects such as developing AI-based prediction models from the analysis of thousands of medical images, the existing public research infrastructure like the Barcelona Supercomputing Centre or the University of Zaragoza's Institute for Biocomputation and Physics of Complex Systems would offer sufficient capabilities (EIT Health, 2024).

Ongoing efforts include improving data quality and harmonising standards to allow for more extensive secondary uses, such as research and innovation. Spain is working on enhancing data governance to ensure that it is both accessible and secure for secondary purposes, including for public health planning (EIT Health, 2024).

The main capacity gap Spain will likely face pertains to gathering and enabling secondary use of the primary data generated during healthcare provision. Although this data is being recorded electronically in hospitals and in many other facilities, it is generally not standardised even within single institutions. Another key missing action is the need for comprehensive infrastructure to support advanced secondary data uses, such as real-time analytics and personalised medicine. Additionally, mechanisms for transparent patient consent and broader stakeholder involvement in secondary data use are not fully developed (EIT Health, 2024).

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CATALONIA

One of the globally leading hubs for clinical trials, large community of clinicians already accustomed to participating in research as an important asset for driving cultural change in the profession. Catalonia's bioregion BIOCAT is working on a fast-track for the adoption of new technologies, including for digital health, to help them reach the market and become eligible for reimbursement based on a defined health benefit. Spain in the group of leading countries for policy and implementation especially in the subcategory of infrastructure extensive experience with infrastructure for the use of federated data for research (ex. Spanish National Biobank Network (RNBB)) (EIT Health, 2024).

Lack of a data sharing culture and fears surrounding the risk of data misuse within the country's healthcare workforces, especially when it comes to releasing what many still perceive as their data (rather than the patient's) for secondary use purposes from which they receive no direct benefit (EIT Health, 2024).

Interoperability of data

SPAIN

Spain has implemented regional interoperability frameworks for data exchange, ensuring that health data can be shared within specific regions. These systems use standardised protocols to facilitate communication among healthcare providers. Public healthcare providers in Spain are digitally connected, improving interoperability in data access, use and sharing (EIT Health, 2024).

Spain is working to align its regional systems with EU-wide interoperability standards, focusing on enhancing data quality and ensuring data can be securely shared across borders. Current projects aim to improve these frameworks to support national and EU integration (EIT Health, 2024).

A critical gap is the lack of a fully integrated national interoperability system. Moreover, Spain needs to enhance its data governance to ensure seamless, secure access across diverse healthcare stakeholders and address challenges related to complex data types (EIT Health, 2024).

CATALONIA

Medical records are charged between the different levels of health care (primary care, hospital, specialised centres).

Need to increase interoperability of medical records between the different levels of health care and the almost non-existent level with the socio-sanitary level, home care and community pharmacy. This strategy is on the table (EDAH project, 2023).

Data quality / Standardisation of data

SPAIN

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Spain is in a good position to implement a framework for the quality and interoperability of data shared within the EHDS, based on its extensive experience with the use of data standards in both clinical care and throughout its health research ecosystem (EIT Health, 2024).

As the autonomous regions are not all equally advanced in the process of implementing quality improvement measures for their health data, a `General Secretariate for Digital Health`, information and innovation in the healthcare system was recently to support and coordinate their efforts at national level, including with EU funding. The different Spanish regions used to work separately, sometimes even competing for leadership. Now there is collaboration for a common purpose, which is going to make Spain unique as a country and places it in a very privileged position to move forward on the EHDS (EIT Health, 2024).

Although Spain's public health system has evolved significantly over the last few decades, the data stored in its now ubiquitous EHR systems is still overwhelmingly made up of free text which is difficult to use for secondary purposes in its unstructured form. There is technology to help structure all this information, but it will take time because we must move carefully when it comes to health (EIT Health, 2024).

CATALONIA

Although challenges related to data fragmentation and lack of interoperability equally affect Spain's healthcare institutions, the region is considered a leader in the use of data standards throughout its health research ecosystem and even in clinical care (EDAH project, 2023). Among other things, this has allowed the scientific validation of EHR datasets from the country's primary care setting, including diagnoses of chronic diseases such as diabetes, hypertension and atrial fibrillation, for use in research. With the leadership of regions like Catalonia, Andalucía, Aragon, Basque Country, Valencia and Madrid, Spain is one of the main providers of data in the European Health Data & Evidence Network (EHDEN) (EIT Health, 2024). Spain has a very high degree of digitalisation of the health system, at the level of the most advanced countries in Europe, such as Estonia, Denmark, Finland and Sweden. Some of the autonomous communities are leaders in Europe (Catalonia, Basque Country, Andalusia) (EDAH project, 2023).

Resources

Resources and funding

SPAIN

Spain has set up various digital health infrastructures, including regional EHR systems, that support secure data sharing within the country. These EHR systems comply with data privacy and security standards, ensuring that sensitive health data is protected and accessible. The country's existing data repositories are built to handle health data in a structured and interoperable way, laying the foundation for broader integration with the EHDS. Spain has used available funding, including EU and national resources, to develop these infrastructures and support ongoing projects aimed at EHDS readiness (EIT Health, 2024).
The Spanish national government has so far allocated €100 million from both, national and EU funding sources, specifically to the implementation process, €28 million of which have been distributed equally across the 17 autonomous regions to develop local services for the EHDS.

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The rest is serving to build a national data repository and computing infrastructure on the premises of the Ministry of the Economy, a choice called into question by some who argue that the federated data storage and computing capabilities already present throughout the country should have allowed investments to focus on the human capacities, skills and services needed to operate the national data space

Spain is currently enhancing its digital infrastructure and expanding data repositories to support cross-border data sharing. Efforts are underway to improve the technical interoperability of Spain's health data systems with EU standards, which includes adopting common data exchange protocols. Spain is also advancing its cybersecurity measures to ensure that health data is securely exchanged and protected in line with the EHDS framework. Funding from EU programs plays a critical role in supporting these initiatives, though challenges remain in securing sufficient resources for large-scale technical upgrades and expertise development. Spain has improved the implementation of data access technologies, like the secure electronic ID (European Commission, 2025) as per the eIDAS (Electronic Identification, Authentication and Trust Services) regulation, but still some areas require more steps to achieve the objectives from Digital Decade 2030 (EIT Health, 2024).

A fully integrated national health data infrastructure with seamless interoperability across regions and EU member states is still under development. More investments are needed in advanced data analytics technologies, cloud infrastructure, and expertise to process and utilise health data for secondary uses like research, innovation, and policymaking. The country will also need targeted funding to address gaps in expertise and to support complex data types, including genomic data (EIT Health, 2024).

Human resources

SPAIN

Spain has already built a foundation of skilled professionals in healthcare and technology fields, ensuring a basic level of human resource capacity for EHDS readiness. These professionals support existing health data systems and contribute to regional interoperability efforts. Additionally, Spain has benefited from EU funding programs that assist in training healthcare professionals, helping to bridge gaps in health data expertise (EIT Health, 2024).

Spain is currently working on improving human resources through targeted educational programs and collaborations with universities, aiming to enhance the skills of professionals in health data management and digital health technologies. Additionally, efforts are focused on fostering partnerships to upskill the workforce to meet the growing demands of EHDS-related projects (EIT Health, 2024).

There is a need for a comprehensive workforce strategy that addresses the shortage of specialised skills, particularly in areas such as data science, cybersecurity, and health informatics. To ensure the successful implementation of EHDS, Spain must invest in further training, create attractive career pathways in digital health, and recruit more experts capable of managing complex health data systems (EIT Health, 2024).

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CATALONIA

The talent pool is in the field of data analytics and digital health and the Health/AI Programme begins the 'Artificial Intelligence in Health' training (Ministry of health, 2025).

Societal readiness

SPAIN

Public engagement efforts, including awareness campaigns, have been initiated to build trust in health data sharing. These actions foster a foundation of public acceptance for the sharing and use of health data (EIT Health, 2024).

Spain is working to increase transparency around health data usage by enhancing communication with citizens about how their data will be used and the benefits of sharing it. Ongoing efforts aim to improve public participation in decision-making processes regarding health data, aiming to build greater trust and acceptance (EIT Health, 2024).

More resources are needed to ensure the public is continuously informed and confident about the safeguarding of their health data, particularly for secondary uses such as research (EIT Health, 2024).

CATALONIA

High overall rates of digital literacy and use of mobile applications, including for health and wellness, have contributed to shifting the culture in healthcare, but gaps in health literacy, understanding of the health system, and communication with healthcare professionals tend to leave patients disconnected from their own care (Ministry of health, 2017).

Spain in particular stood out in an international comparison for its citizens' reticence to share their data for a variety of secondary use purposes, including scientific research and public health planning (EIT Health, 2024).

Data privacy and security

General Data Protection Regulation (GDPR)

SPAIN

Spain has a strict adherence to GDPR, which complements with national laws - Organic Law on Data Protection and Guarantee of Digital Rights (LOPDGDD) (Agencia Estatal Boletín Oficial de Estado, 2018). The Spanish interpretation of GDPR is one of the most restrictive within Europe. The Spanish Agency of Data Protection (AEPD), the body in charge of overseeing and accomplish GDPR in Spain, has published specific guidelines regarding health data under a strict application (e.g. "APROXIMACIÓN A LOS ESPACIOS DE DATOS DESDE LA PERSPECTIVA DEL RGPD") (agencia espanola protección datos, 2025).

Spain acknowledges the need for a harmonised interpretation of GDPR between member states to guarantee a high and unified data protection environment (EIT Health, 2024).

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Despite its adherence to GDPR, there is a lack of a legal framework in terms of data governance. Linked to the Spanish restrictive vision of GDPR, this provides uncertainty regarding data sharing. Also, there is a lack of coordination between regional and national layers. There are also some issues regarding practical implementation (regional differences, gaps in data collection, consent, etc.) that need to be addressed (EIT Health, 2024).

Data protection provisions

SPAIN

Spain has set up different systems complying with data privacy and security standards, (e.g EHR). There also exist regional infrastructures, such as the (Aragón) `BIGAN platform` (BIGAN, 2025), a secure data lake with pseudonymised data on 1.3 million citizens that allows for secure processing and privacy. BIGAN (Big Data project of the Department of Health of the Government of Aragon) collaborates with the TEHDAS project (Joint Action Towards the European Health Data Space) in recommendations for EHDS and could serve as model for other regions within Spain (EIT Health, 2024).

Spain acknowledges the need to step from a privacy model (negative obligations) to a data protection model (positive and negative obligations). Also, clear communication measures are key to guarantee data protection and privacy measures, including penalties, to all actors.
There is still a widespread perception among Spanish citizens of the risk of personal data being stolen and therefore misused. No clear, accessible, and reversible opt-out mechanism has been announced for the secondary use of electronic health data, which is a requirement for the EHDS (EIT Health, 2024).

Health Data Access Bodies (HDABs)

SPAIN

Spain is working on the `Spain National Health Data Space` (ENSALUD) (datos.gob.es, 2025), a national infrastructure to share and reuse health data, where the access to data will be made from regions to a national level. ENSALUD will be aligned with EHDS. The idea is to have a federated repository where each region manages their data. When more than one region is involved, access will be managed at central (coordination) level. This national node will act as the main contact point with EHDS (EIT Health, 2024).

Spain acknowledges the need of regional data access bodies in addition to the national contact point required by the EHDS. At the moment there is no specific entity designed as HDAB in Spain. There is a need to stablish on a national level which bodies would assume the responsibilities within the EHDS, specifying their roles at regional and national level with respect to governance. Actually there is a cross-over between the roles of data users, holders and access bodies. This needs to be clarified as the EHDS stablishes that HDAB should go separately from the other two roles. There is a need to invest in skills and new professionals for those services needed but unavailable today in terms of data access: national /European data catalogue, public single point of access for data users, etc. It is necessary to create a public interface that will act as a one-stop shop for users to obtain access to data (EIT Health, 2024).

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Access and control

Access rights

SPAIN

Spain holds an advanced position within Europe regarding the digitalisation of EHR and patients in most regions can access them and the information they contain. They can also control/consent on sharing their data, under both national (41/2002) and EU (GDPR) laws. Access to different types of health data is over the EU average for Spain, with the exception of some items such as medical imaging reports, procedures/operations or medical devices/implants. Data on items such as e-prescription and e-dispensation is available to citizens for all regions in Spain. Same for laboratory results and hospital discharges. Spain offers digital identity solutions (Electronic ID - DNIe, Electronic Identity for Administrations - Cl@ve) and citizen portals that enable secure access to e-health services, laying a solid foundation for the 'electronic health data access services' required by the EHDS regulation (EIT Health, 2024).

Spain is working to align national laws regarding patient data rights (Law 41/2002, Law 3/2018) that grants patients the right to access their medical records or control their health data with the EHDS (EIT Health, 2024).

There is a lack of culture in terms of data. Spain has a low implication of patients in data – related bodies. The 'data donation' concept does not acknowledge properly the data-sharing culture as a matter of public interest. There is strong reticence among healthcare professionals to share data collected in clinical routine for secondary use. Spanish citizens are reticent to share their personal data for secondary use, special with other stakeholders (e.g. pharma, insurance companies), which will end up in challenges towards the EHDS. Efforts to further improve Spain's infrastructural readiness for secondary use of health data under the EHDS should focus mainly on creating the paths and the capacities to collect, aggregate, access, and reuse the data generated within healthcare (EIT Health, 2024).

Transparency

SPAIN

Some regional efforts have been made towards transparency in health data. For example, the 'Transparency in the Health Service' project (regional government Castilla y León) born from the Covid-19 pandemic (EIT Health, 2024).

In Spain there is a need for transparency at all levels in explaining to patients how their data are used and how can they be actively engaged in data collection and sharing. There is also acknowledged the need for patients to have different levels of privacy and control over their health data with much more transparency than nowadays. Spain needs better communication and understanding with patients and healthcare providers to understand their needs and concerns. There is a need for clarity to patients on how data will be accessed and used (EIT Health, 2024).

Unified market for EHR standards

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Harmonisation of standards

SPAIN

There is a strategic focus at national level on digital transformation, showed in comprehensive national policies such as Digital Spain 2026 (Espana digital, 2025). Spain has technology to harmonise EHR and is in good position to implement a quality and interoperability framework through the national Secretariat of Digital Health, Information and Innovation, given the widespread use of standards both in clinical practice and research. Spain is one of the main data providers for the European Health Data and Evidence Net project (EHDEN) (EHDEN, 2025) an initiative to create a federated data net from millions of anonymised and harmonised data registries compliant with GDPR (EIT Health, 2024).

Spain has a good position regarding digitalisation of clinical data (e.g. EHR). However, there is still a high variability in quality and implementation of health data between centres and regions, which leads to fragmentation (silos). Regional administrations are in the process of developing a proper framework for interoperability (EIT Health Community, 2024). A national body (Secretariat of Digital Health) acts as coordinator using EU funding to reduce this variability and enhance collaboration between regions. Actions are being made by different companies and public-private associations to develop a common terminology that helps interoperability (EIT Health, 2024).

Despite Spain's advantage regarding the implementation of EHR and the widespread use of standards, differences arise in the quality and implementation between regions. A significant proportion of EHR are still composed by free text. Despite having the normative and infrastructures, more implication and time from staff is needed. In term of reporting data in a timely manner, Spain decreases its score with respect to other countries due to more granular reporting at the regional level. Reporting data on medical devices and implants happens in less than half the regions (European Union, 2024).

Promoting innovation

Technology-based solutions

SPAIN

Spain invested €982 million in public funding for the adoption of technology and precision medicine in the NHS. Although there exist regional differences, Spanish health system is one of the most mature towards digital health, amongst the 5 top in OECD. There is a wide capacity in terms of EHR in regions and an integral infrastructure of e-prescription. Spain is leader in implementation, specifically regarding infrastructures compared to the European countries. There exists robust infrastructure that will help data collection, storing and processing, making possible the interaction between the primary and secondary use of data, which is an advantage towards the EHDS. Spain has a wide implementation of infrastructures at regional levels, even for supercomputing (federated data, AI, etc.). As an example: Biobank Spanish Net. Spain has also been included in the group of leading countries for policy and implementation, specifically in the subcategory of infrastructure, with progress similar to known role model countries like Denmark or Finland (EIT Health Community, 2024).

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Infrastructures have developed open solutions and work is being carried out using them for a federated space at a national scale for an efficient implementation. Spain has also started the transformation towards prediction/prevention models (e.g. IA) into routine clinical practice. However, the process needs time. BIOCAT is working on a speed way for the adoption of new technologies (including digital health) to help these reach the market and be eligible for reimbursement if these demonstrate benefits for health (EIT Health, 2024).

Efforts are needed in creating an adequate strategical approach in terms of investment at a regional and national scale. There is still uncertainty regarding how the long-term sustainability of the infrastructure will be done, as well as the connection between these infrastructures and the EHDS. There is also a need to update infrastructures, specifically regarding open systems (EIT Health, 2024).

Research and development

SPAIN

Millions in funding have already been provided by Spain for its specific implementation of EHDS. There are different initiatives promoting the data curation and processing for secondary use, in line with European guidelines (EIT Health, 2024).

The need to further investment in skills and capabilities in Spain, as in other member states, could endanger its ability to implement the EHDS in a practical way. Also, Spain faces important cultural barriers regarding the use of data and specifically the sharing and reuse of data, specifically among healthcare providers. This will pose challenges towards innovation derived from secondary use of data and it is mainly related to lack of confidence and uncertainty on how these processes will be done in a secure and efficient way. Spain deals with barriers regarding the collection and secondary use of data collected in routine clinical practice. There is a great variability in data collection and a lack of involvement from patients and healthcare providers. Also, Spain faces an hetereogenity of actors involved at the same time (EIT Health, 2024).

Important additional remarks

CATALONIA

Catalonia hosts a dynamic digital health ecosystem with nearly 400 companies, according to reports by ACCIÓ and Biocat, fostering innovation in areas such as telemedicine, AI in healthcare, digital biomarkers, and wearable devices (EDAH project, 2023).
the infrastructure managed by the Catalan Health Service encompasses data from eight million citizens. With more than two decades of continuous investment in IT, Catalonia's healthcare system has built one of the continent's most comprehensive clinical data ecosystems. Various healthcare organizations, some dating back to the 18th century, have quickly embraced digitalisation, although the landscape remains fragmented.
To address this fragmentation, since the late 1990s, the Catalan Health Service has progressively integrated data and connected hundreds of health centers – including primary care, mental health and long-term care facilities, and hospital services – through a unified patient identification system. This effort has enabled clinical follow-up, optimized healthcare management, and facilitated research.

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The jewel in the crown and a benchmark for many health systems is the Shared Clinical History of Catalonia (HC3). HC3 integrates information from 30 different systems, holding hundreds of millions of clinical documents, medical reports, diagnostic images, laboratory results, immunization records, and clinical parameters. These data are accessible to all authorized professionals within the public healthcare network.
Another notable example is the Electronic Prescription System, operational since 2006, processing over 130 million prescriptions annually through the region's 3,200 community pharmacies. This system not only facilitates patient access but also enables continuous, detailed monitoring of medication usage across the population.
Despite significant progress, there still coexist numerous clinical record systems developed by European providers as well as internally by healthcare organizations. To advance interoperability, CatSalut plans to deploy centralized solutions based on the OpenEHR standard. Recently, IBM Group was awarded a tender by CTTI (Catalan Government) and, together with other consortium partners, will provide a comprehensive and homogeneous clinical data platform across the entire region (Biocat, 2025).

3.3 Belgium

Governance

National

In Belgium's national governance of health data is in transition, centered on the newly created **Health Data Agency (HDA)**, which coordinates secure and transparent access to health data, particularly for secondary uses like research and policy. It works alongside **Sciensano's Healthdata.be** platform and federal institutions such as NIHDI and FPS Health. The system is shaped by the **GDPR**, Belgium's Privacy Act, and the 2023 law establishing the HDA, while also preparing for the EU's **European Health Data Space (EHDS)**. Key initiatives like **HeDERA** aim to streamline requests and reuse across fragmented registries (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023), (HDA Health data agency, 2023), (sciensano, 2024).

Belgium could strengthen its national health data governance by improving **interoperability and reducing fragmentation** between federal, regional, and institutional data systems, which currently hinder efficient reuse and cross-border exchange. Clearer, faster **procedures for data access** – with consistent standards for anonymisation and secondary use – would also increase trust and usability for research and innovation. Furthermore, enhancing **public communication and transparency** about how health data is reused could help address privacy concerns and boost citizen confidence. These steps would better align Belgium with the ambitions of the **European Health Data Space (EHDS)** and maximise the value of health data for both care and research (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023), (HDA Health data agency, 2023), (sciensano, 2024).

Regional

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The Flemish government (Dep. of Care, together with Dep. of Science and Innovation and Dep. Digitalisation) has started a feasibility study and impact analysis (mapping of the field, identifying needs, bottlenecks, opportunities). A project about the implementation of a Flemish health data space is being developed. Through the state-of-the-art developed within this project, it will become possible to use healthcare data most optimal for secondary use (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Legal and regulatory aspects

A feasibility study and impact analysis has started to identify the bottlenecks, including for the legal aspects/readiness for EHD (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Technical infrastructure

Information from legal and regulatory aspects applies (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Health data readiness

General state of health data

In Belgium, efforts have been made to regulate accessing and sharing of health data for primary use. These strategies combine processes and rules on therapeutic relations, informed consent for sharing health data, and an 'access matrix' that defines which groups of health care providers have access to which types of health data (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

There are two initiatives, 'We Are' and 'FAQIR', using SOLID technology to collect health information in patients' personal pods, giving patients more ownership in their health data governance. The aim of both projects is to stimulate secondary use of health(-related) data, by researchers, industry or policy making, but keeping the individual in the driving seat (We Are Health, 2025).

There is a lack of a data-sharing culture and considerable concern about the risk of data misuse within the country's healthcare workforce. This is particularly evident when it comes to releasing data that many professionals still regard as their own, rather than the patient's, for secondary use purposes from which they themselves receive no direct benefit (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Interoperability of data

Vitalink is the digital platform of the Flemish government to securely exchange and consult data on care and welfare. Every care provider can easily access correct, up-to-date and complete patient information via Vitalink (Vlaamse overheid , 2025).

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Electronic patient records are mandatory for all hospitals and healthcare providers, but different systems exist which causes interoperability issues. Medication prescriptions are also digitally available via eID. Belgium is partner in the Genomics Data Infrastructure (GDI) project, that enables access to genomic and related phenotypic and clinical data across Europe. Nevertheless, there is still a lack of a data-sharing culture and fears surrounding the risk of data misuse within the country's healthcare workforce, especially when releasing what many still perceive as their data (rather than the patient's) for secondary use purposes, from which they receive no direct benefit (Sciensano, 2025).

Vitalink data is often in pdf format, making it not easily searchable or in a form for future analytics. data is often incomplete because the system is not used by all types of healthcare providers (e.g., general practitioners, outside hospitals) (Vlaamse overheid , 2025).

Data quality / Standardisation of data

EHR are used in all hospitals in Belgium, as well as in most GPs. Different systems are being used, which can cause interoperability issues (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Resources

Resources and funding

Vitalink, HDA set up (see other fields for more information) (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Human Resources

The human resources available are those needed to run Vitalink and HDA. Sciensano, the national public health institute of Belgium, has workforce for GDI and other activities (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Societal readiness

King Baudouin Foundation in Belgium asked citizens how they think about health data. 89% of respondents were willing to share their data with a health professional, 76% to share their data with hospitals and scientific research centres and 74% with their health insurance company (mutuelle) for calculating and adapt reimbursement of healthcare. Overall, respondents in Flanders, those who were digitised and those in good health appeared to be more open to such use of their data. On the other hand, respondents were more reticent about sharing their data with the pharmaceutical industry and even more unwilling to share their data with government and (general) insurance companies. 70% of respondents refused to share their health data with private sector companies for use in marketing (King Baudouin Foundation, 2025).

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Data privacy and security

General Data Protection Regulation (GDPR)

As an EU member state, Belgium adheres to the GDPR, which sets comprehensive rules for processing personal data, including health information. The GDPR mandates lawful, fair, and transparent data processing, emphasizing data minimization and the rights of individuals over their data. The GDPR has been integrated in Belgium through a few laws. The 'Data Protection Act' of July 30, 2018 provides for the implementation of some of the GDPR provisions open to further definition, derogation or additional requirements. The Data Protection Act was amended several times in 2024 to update the rules for the authorities outside the scope of EU law. The Belgian Data Protection Authority, the successor of the Belgian Privacy Commission, was established by the Belgian Federal Chamber of Representatives by the Act of December 3, 2017 ("DPA Act"). Several other laws have also been adapted to align them with the GDPR (e.g. Video Surveillance Act). The DPA Act was amended by the Act of 7 September 20234 and the Act of 25 December 20235, to strengthen the functioning, the independence, the pragmatic approach and sectoral expertise of the Belgian Data Protection Authority. The legislative reforms included changes regarding the composition of the Data Protection Authority and the rules of procedure for cases before the Data Protection Authority. As a result, several provisions were transferred from the DPA Act to the Internal Rules of Procedure of the Data Protection Authority (DLA Piper, 2025).

Data protection provisions

Information from interoperability of data applies (Vlaamse overheid , 2025).

Health Data Access Bodies (HDABs)

In Belgium, the federal Health Data Agency (HDA), setup in 2023, is developing and implementing a policy strategy and framework for the secondary use of health data, aligns well with the responsibilities set out for HDABs. The Belgian HDA pursues the central objectives of facilitating the availability of health (related) data, developing and implementing a policy strategy concerning health (related) data, and stimulating innovation as well as scientific and policy-supporting research. To facilitate the secondary use of health data, the HDA aims, among other things, to function as preferred point of contact regarding secondary use, develop a governance model, provide a data catalogue, facilitate health data access requests, and support the communication between data holders and data users. Other tasks include giving advice regarding the standardisation, “FAIRification”, and quality of data, and establishing a Health Data Academy providing training. Also, initiatives such as creating citizen trust concerning the correct use of their health (related) data are anticipated
(Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Belgium HDA will not act as trusted third party (TTP), other institutions are authorised as TTP (e.g., eHealthplatform, the Crossroads Bank for Social Security, and Statbel. Belgium HDA doesn't hold or process data themselves (except for metadata and anonymised datasets). It

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also gives the role of issuing data permits to other federal or regional institutions (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Access and control

Access rights

Several platforms exist to give patients and individuals access to their own health data (mijngezondheid.be, CoZo, Helena, MyNexuzHealth/VznkuL, Brussels Gezondheidsnetwerk en Réseau Santé Wallon, ...) (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Transparency

We Are and FAQIR project are working on transparency (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Unified market for EHR systems

Harmonisation of standards

Belgium is actively working to adopt the FHIR eHealth standard across its healthcare system. Several implementation guides have been developed and are being shared (eHealth Platform Belgium, 2025).

Nowadays in Belgium several EHR systems are not always easily interoperable. There should be more focus on using standardisation (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Promoting innovation

Technology-based solutions

VLAIO (Agency for Innovation & Entrepreneurship) is the Flemish government's point of contact for all entrepreneurs in Flanders. VLAIO stimulates and supports innovation and entrepreneurship and contributes to a favorable business climate. They stimulate all fields of innovation, including related to health data (VLAIO, 2025). Biovia is an industry-driven membership organisation that fosters health innovation in Flanders. Biovia supports R&D at the intersection of biotechnology, medical technology and digital technologies through funding, services and strategic initiatives (Biovia, 2025).

Limitations exist on which types of innovation can be funded by these mechanisms. For the consortia-based innovation projects funded by VLAIO in collaboration with Biovia only product innovation projects are in scope. Also, the way in which innovation is defined leans more in the direction of invention than innovation, meaning many innovative solutions are not often in scope for this type of funding (VLAIO, 2025).

Research and development

The FWO is the most important funding partner for researchers in Flanders. By offering

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financial support and promoting international cooperation, they create a favorable climate for excellent scientific research. They are responsible for the selection of the best research proposals based on international peer review. The sole criteria is excellence, but FWO often funds research and development on health-related topics (Saelaert, et al., 2023), (Koninklijke Bibliotheek van België, 2022), (Raeymaekers, 2024), (Schmitt, et al., 2023).

Important additional remarks

The Belgium HDA started the 'HDA academy', to contribute to increasing the level of data literacy of the Belgian Health Data Ecosystem by establishing a collective knowledge base and level on data-related skills and leading practices (HDA Belgium, 2025).

3.4 Bulgaria

Governance

National

Bulgaria's approach to establishing a national Health Data Space is set out in its 2030 National Strategy for E-Health and Digitisation of the Healthcare System, adopted in March 2024. This strategy aligns with the European Commission's initiative for a unified European Health Data Space and aims to improve healthcare efficiency and quality through better data management. The main objective is to create an integrated health data space that supports efficient treatment, accurate diagnoses, and informed decision-making for healthcare providers and authorities. The framework focuses on patient-friendly care, enabling access to cross-border healthcare and real-time information for patients. Digitising processes and eliminating paper-based systems is intended to streamline administrative tasks. Uniform rules and standards are introduced to strengthen regulation, foster competition, a, aiming to enhance healthcare efficiency and quality through improved, aiming to enhance healthcare efficiency and quality through improved and improve accountability. The strategy also promotes re-use of health data for research and statistics, ensuring valuable insights are gained from existing information. By increasing transparency and closing reporting gaps, financial performance across healthcare institutions is expected to improve. Building on previous projects, the strategy includes developing a robust National Health Information System as the foundation for data sharing and integration. Bulgaria's framework is designed to be compatible with EU strategies, ensuring interoperability and compliance with health data regulations. Implementation will involve collaboration among stakeholders, including healthcare providers, authorities, and patients (Veles (a), 2024)

Regional

Bulgaria's regional framework for the Health Data Space centres on the VELES Excellence Hub, a collaborative initiative with Greece, Romania, and Cyprus to establish a Regional Smart Health Data Space. The project aims to create a secure and compliant environment for health data sharing, enhancing innovation and interoperability across participating countries.
Key elements include cross-country collaboration to develop smart health ecosystems, and targeted pilot studies addressing specific health issues: Alzheimer's disease in Bulgaria, cancer

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in Greece, cerebral tumours in Romania, and dementia in Cyprus. These studies are intended to generate insights for regional health policy. The framework empowers stakeholders - citizens, healthcare professionals, researchers, and regulators - by granting greater control over health data and improving access to information. The initiative is aligned with EU objectives for an EHDS, supporting cross-border data exchange and improved healthcare accessibility. This approach, led by the VELES Hub, marks a significant advance in healthcare innovation and data interoperability in South-East Europe, contributing to the wider digital transformation of health across the continent (Veles (a), 2024).

Legal and regulatory aspects

Bulgaria's legal framework for the Health Data Space is progressing, shaped by national legislation and EU directives. The GDPR and Bulgaria's Personal Data Protection Law ensure strong protection for health data, requiring explicit consent and compliance from healthcare providers and the National Health Insurance Fund (NHIF). However, there are no specific legal provisions for electronic health records (EHRs) or interoperability between health information systems, which limits the development of a unified digital health infrastructure. The Health Insurance Law provides access to medical records, but current records are mainly financial tools rather than official EHRs. The Electronic Governance Law addresses electronic documents but does not cover health data management in detail. Additional challenges include unclear rules on data retention and anonymisation for research. Future readiness depends on developing EHR-specific legislation, aligning with EU directives for cross-border data exchange, and involving stakeholders such as healthcare providers, patients, and regulators. While existing laws offer a solid foundation for data protection, addressing these gaps through targeted reforms is essential for Bulgaria to establish an effective and compliant Health Data Space in line with European standards (Veles (a), 2024).

Technical infrastructure

Bulgaria is developing a robust technical infrastructure for its Health Data Space, in line with European digital health initiatives. Central to this is the implementation of a National Health Information System featuring electronic health records and prescriptions, designed to improve interoperability and facilitate secure data exchange nationally and internationally.

A Digital Health Platform is being established as a central repository for medical data, integrating patients, healthcare professionals, and regulators. The government is investing in cloud solutions, high-speed networks, and fibre optic connectivity to support efficient health data management. Efforts are also underway to modernise medical infrastructure and integrate existing IT systems within healthcare institutions. Challenges include inadequate internet connectivity, especially in rural areas, and outdated healthcare systems, which complicate the integration of new technologies. A clear regulatory framework is essential to support these developments. Future plans focus on investing in AI and secure data processing, collaborating with European research initiatives, and creating patient-centric solutions. Bulgaria's evolving technical infrastructure aims to deliver a secure, integrated, and efficient Health Data Space, but further investment and modernisation are needed to overcome current obstacles (Veles (a), 2024).

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Health data readiness

General state of health data

Bulgaria is working to digitise and unify its health data, guided by the 2030 National E-Health Strategy and recent legislative reforms. Key developments include the adoption of electronic health records, digital prescriptions, and telemedicine, supported by the National Health Information System to improve data quality and integration. Despite progress, challenges remain: limited health funding, fragmented IT systems, and varying digital literacy among healthcare professionals hinder full modernisation. Bulgaria is addressing these issues by aligning with EHDS regulations, investing in infrastructure, and focusing on improving data quality. Continued efforts and EU support are essential for Bulgaria to realise an effective, unified health data space (Veles (a), 2024).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

The secondary use of health data in Bulgaria is expanding to support public health, research, policy-making, and innovation. Guided by GDPR, Bulgaria is developing frameworks to securely reuse health information beyond its original purpose, with initiatives such as participation in DARWIN EU and the EHDS.
Efforts are underway to improve data quality and management, led by the National Center for Public Health and Analyses, and to build a digital health ecosystem that enables secure exchange of anonymised data among stakeholders. Benefits include better decision-making, resource optimisation, and accelerated innovation.
However, challenges remain, including data privacy concerns, system interoperability issues, and the need for training in data management. Overcoming these barriers will be vital for Bulgaria to fully realise the benefits of secondary health data use (Veles (a), 2024).

Interoperability of data

Interoperability of health data is central to Bulgaria's healthcare modernisation and alignment with European standards. Recent amendments to the Public Health Act mandate electronic health records for all medical activities, improving centralised data management and software compatibility. Bulgaria's participation in the VELES Excellence Hub promotes secure, cross-border data exchange with neighbouring countries. The draft National Interoperability Framework aims to enhance data sharing across public sector organisations, while eHealth solutions from private providers support cross-organisational collaboration. Challenges include fragmented IT systems, data privacy concerns, and varying digital literacy levels. Continued investment in infrastructure, stakeholder engagement, and pilot studies are essential for progress. Bulgaria's efforts in legislative reform, regional collaboration, and technological advancement are laying the groundwork for a cohesive, interoperable health data ecosystem, better serving both healthcare providers and patients (Veles (a), 2024).

Data quality / Standardisation of data

Health data quality in Bulgaria is being improved through legislative reforms, the adoption of electronic health records, and the development of the National Health Information System.

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These measures aim to make health information more accurate, accessible, and reliable. Audits of e-health initiatives help identify barriers and guide improvements.
Challenges remain, including fragmented systems, incomplete or inconsistent data, and limited public awareness of the importance of data quality. Future priorities include standardising data protocols, investing in training for healthcare professionals, and establishing robust monitoring systems. Ongoing efforts are essential to ensure high-quality health data that supports patient care, policy-making, and research (Veles (a), 2024).

Resources

Resources and funding

Health data management in Bulgaria is primarily financed through compulsory health insurance, public spending, and European Union support. Although there have been recent investments in e-health and technological improvements, overall health expenditure remains below the EU average, with citizens facing high out-of-pocket costs. EU funding and COVID-19 emergency funds have contributed to modernisation and better data management. However, limited resources and the absence of sustainable funding models pose challenges for comprehensive health data initiatives. Ongoing investment and reliable funding are vital for Bulgaria to improve the quality and accessibility of health data, ensuring alignment with European standards (Veles (a), 2024).

Human resources

The development of human resources for health data in Bulgaria is key to advancing the healthcare system as it becomes more digital and integrated. Healthcare professionals, researchers, and regulatory bodies are being trained in data management and digital tools, with initiatives such as the VELES Excellence Hub and CPD programmes supporting skill development. Collaboration between healthcare providers, academic institutions, and technology firms is fostering innovation. Challenges include varying levels of digital literacy, retention of skilled staff, and fragmented health information systems. Future priorities are expanding training in digital skills, strengthening partnerships, and regularly assessing workforce needs. By focusing on training and collaboration, Bulgaria can improve health data management and support better patient care and research (Veles (a), 2024).

Societal readiness

Bulgaria is preparing for the Health Data Space by focusing on public awareness, stakeholder engagement, digital literacy, and regulatory frameworks. The 2030 National E-Health Strategy has increased recognition of digital health's benefits, but educational campaigns are needed to build trust and understanding. Low digital skills among healthcare professionals and patients remain a barrier, making training initiatives essential. Stakeholder involvement is helping shape the Health Data Space to meet diverse needs, while ongoing legal reforms and alignment with EU regulations are building public trust in data security. Infrastructure development is also underway to enable effective data exchange. Challenges include fragmented healthcare delivery, resistance to new technologies, and poor internet connectivity in rural areas. Addressing these issues through continued engagement,

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investment, and supportive regulation is vital for Bulgaria's successful adoption of the Health Data Space (Veles (a), 2024).

Data privacy and security

General Data Protection Regulation (GDPR)

Bulgaria fully complies with the GDPR, supported by its own Personal Data Protection Act (PDPA), which addresses national requirements and EU directives. The Commission for Personal Data Protection supervises compliance, conducts audits, and can impose substantial fines for breaches. Health data are treated as sensitive, requiring explicit consent or a clear legal basis for processing, with mandatory breach reporting within 72 hours. All digital health systems, including the National Health Information System, operate under these strict data protection standards, ensuring secure processing, patient consent management, and transparency in accordance with GDPR and EHDS provisions (Veles (a), 2024).

Data protection provisions

Bulgaria enforces strong data protection through its PDPA, most recently amended in 2023, which complements the EU GDPR. The PDPA requires the lawful, fair, and transparent processing of personal data, with explicit consent needed for sensitive information such as health records. Individuals are granted robust rights, including access, rectification, erasure, objection, and data portability. Parental consent is necessary for digital services provided to children under 14. Data controllers must implement technical and organisational measures to ensure data security, and data breaches posing risks must be reported to the Commission for Personal Data Protection (CPDP) within 72 hours, with affected individuals notified if there is a high risk. The CPDP has the authority to investigate, issue binding decisions, and impose fines of up to €20 million or 4% of global turnover. The PDPA also limits public access to personal identification numbers and requires transparency, accountability, and data protection by design and by default, ensuring comprehensive privacy safeguards in line with EU standards (Veles (a), 2024).

Health Data Access Bodies (HDABs)

In accordance with the EHDS Regulation, Bulgaria must establish a HDAB to oversee and regulate secondary use of health data. The HDAB will authorise access for researchers, policymakers, and other approved users, ensuring all requests are processed within set deadlines and data are accessed only in secure environments with strict privacy and cybersecurity standards. It will also maintain a national health metadata catalogue, guaranteeing compliance with GDPR and EHDS safeguards, including transparency and auditability. Bulgaria is actively working with the EU HDABs Community of Practice to harmonise its procedures and finalise the legal and operational framework for its HDAB (Veles (a), 2024).

Access and control

Access rights

Since October 2024, Bulgarian citizens have free and secure access to their electronic health records via the National Health Information System portal and the "еЗдраве" mobile app, using secure identification methods without needing a qualified electronic signature. Individuals aged

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14 and over have independent access, while parents or guardians manage minors' records. Healthcare professionals have restricted, role-based access, generally requiring patient consent except in emergencies. Patients can manage consent electronically, and heirs may access records of deceased relatives with proper verification. This system promotes patient empowerment and transparency, underpinned by strict data protection, although some healthcare professionals have expressed concerns about security and administrative demands (Veles (a), 2024).

Transparency

Bulgaria promotes transparency in health data use through its fully digital National Health Information System (NHIS) and the "eHealth" mobile app, providing citizens with secure, real-time access to their electronic health records via various identification methods. Legal reforms in 2024 have strengthened patient control, consent management, and data security, allowing individuals greater oversight of their data. The NHIS's modular records system supports openness, reduces errors and fraud, and builds trust. National AI and digital strategies further prioritise interoperability, ethical data sharing, and transparency throughout the healthcare sector (Veles (a), 2024).

Unified market for EHR systems

Harmonisation of standards

Bulgaria is aligning with EU standards to create a unified market for electronic health record systems, medical devices, and high-risk AI systems. The NHIS uses HL7 FHIR, SNOMED CT, and DICOM standards to ensure interoperability with EU platforms. Medical device regulation follows the EU MDR framework, overseen by the Bulgarian Drug Agency, requiring CE marking and conformity assessments. For Artifical Intelligence (AI) in healthcare, Bulgaria complies with the EU AI Act, ensuring robust risk management, transparency, and human oversight for high-risk applications (Veles (a), 2024).

Ongoing efforts for AI/system certification (Veles (a), 2024).

Promoting innovation

Technology-based solutions

Bulgaria actively promotes technology-driven healthcare innovation through strategic investments, public-private partnerships, and targeted funding. The Ministry of Health has introduced advanced technologies such as AI diagnostics and robotic surgery in leading hospitals, while collaborations with companies like GE HealthCare accelerate modernisation. In 2025, over EUR 60 million was allocated for research and digital health infrastructure. National strategies and EU funds support e-health reforms, telemedicine, and improved connectivity, with technology transfer programmes helping to reduce regional disparities and further integrate Bulgaria into the European digital health landscape (Veles (a), 2024).

Research and development

Bulgaria is rapidly developing its health data research and development ecosystem through national strategies, EU funding, and international partnerships. The country ranks among the

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global top 20 for clinical trials, supported by strong regulation and skilled professionals. Initiatives like the VELES Excellence Hub are creating a Regional Smart Health Data Space for secure cross-border data exchange and innovative pilot projects. The government's AI Development Concept prioritises data standardisation, system integration, and investment in AI diagnostics and telemedicine. Partnerships with European organisations connect Bulgarian researchers to wider networks and funding. Public investment in Research and Development (R&D is increasing, with health and quality of life as key priorities (Veles (a), 2024).

Important additional remarks

As Bulgaria advances its health data framework, several key considerations remain crucial. Ensuring informed patient consent, robust data privacy, and equitable access to digital health services are essential ethical priorities. The country must also align its regulations with EU standards, involve ethics committees in overseeing data use, and standardise health data protocols for effective interoperability.
Practical challenges include integrating fragmented health information systems, improving digital literacy among healthcare professionals, raising public awareness to build trust, and securing sustainable funding. Addressing these ethical, regulatory, and practical issues is vital for Bulgaria to establish a robust, effective health data system that enhances healthcare outcomes.

3.5 Romania

Governance

National

Romania's governance framework for health data remains in a developmental phase, with ongoing efforts to implement the priorities set out in the National Health Strategy. While the legislative basis for data management is in place, practical implementation is hindered by fragmented approaches at the hospital level and insufficient financial instruments for interoperability initiatives. The draft National Strategy for Digitalisation in Healthcare, which was under public consultation as of December 2024, outlines the creation of two new governance structures: a Digitalisation Unit for Health within the Ministry of Health, and an independent Agency for Digital Health. Although the establishment of the Digitalisation Unit is currently underway and a governance structure is being envisaged, progress towards setting up the independent agency has stalled, and it is currently seen as a difficult objective to realise (Veles (a), 2024), (Romanian Health Ministry, 2024).

Regional

National information applies. In Romania, the healthcare system is centralised, meaning regional healthcare structures operate under the same regulations, policies, and challenges as those at the national level. As a result, regional issues closely mirror national ones, with limited local autonomy in decision-making or resource allocation (IMAGO-MOL, 2025).

Legal and regulatory aspects

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Romania's legal framework for health data is aligned with the GDPR, ensuring a high level of protection for personal data, including health information. National legislation, which comprises Law No. 46/2003 on Patient Rights, Law No. 95/2006 on Healthcare Reform, and Law No. 677/2001 on the Protection of Individuals regarding the Processing of Personal Data, collectively provides the foundation for managing health data, safeguarding patient privacy and ensuring data security. Building on this basis, the National Strategy for Digitalisation in Healthcare recognises the need to further strengthen and adapt the legislative and regulatory landscape to meet emerging digital health requirements. Key focus areas include the development of digital identity (such as the use of the National Personal Identification Number (CNP) and/or other digital identifiers), improved governance and sharing of health data (including open data), enhanced cybersecurity measures, and greater legal clarity around compliance and liability in the context of digital tools like electronic health records, telemedicine, and e-prescriptions. The strategy also emphasises alignment with the EHDS and the introduction of certification mechanisms for digital health applications (Veles (a), 2024), (Romanian Health Ministry, 2024).

Technical infrastructure

Romania's technical infrastructure for health data is centred around the Integrated Health Insurance Platform (PIAS), overseen by the National Health Insurance House (CNAS). PIAS is a complex online platform designed to optimise access to medical services and ensure efficient management of the unique National Health Insurance Fund (FNUASS). It brings together several key components, such as the Single Integrated Information System (SIUI), the National Electronic Prescription System (SIPE), the Electronic Social Health Insurance Card (CEAS), and the Electronic Health Record (EHR – DES-Dosarul Electronic al Pacientului). The system faces significant technical challenges, particularly with the EHR, which has experienced controversies related to security and reliability since its inception. The EHR functioned inconsistently between 2013 and 2015 and continues to operate poorly, suggesting it requires substantial improvements (CNAS, 2021). Moreover, patients encounter difficulties in accessing their records, as this process relies on obtaining login credentials through their family doctor. While numerous digital systems exist for the collection of primary health data, their effectiveness is undermined by a fragmented and underdeveloped technical infrastructure (Veles (a), 2024).

Health data readiness

General state of health data

Romania's health data environment consists of a range of digital health systems that are vital for the collection and management of health data. However, these systems were developed at different times and built on varying technical architectures, resulting in a fragmented landscape. In response, the aforementioned PIAS was established to consolidate key components, including the DEHR. While PIAS has become an indispensable part of Romania's health data infrastructure, it still faces significant limitations in supporting integrated analysis across its components, largely due to the heterogeneity of the underlying systems. The DES, in particular, was developed to provide an integrated and up-to-date view of a patient's medical history and adopts the international HL7 (Health Level 7) collection standard to support interoperability and efficiency in medical data exchange. However, the DES system is currently

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inaccessible and undergoing reconstruction, limiting its utility and further highlighting the challenges in realising a fully integrated and functional digital health environment (Veles (a), 2024).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

Overall, health data in Romania primarily serves two functions: supporting patient care through individual records within hospitals and enabling reporting to health authorities for reimbursement purposes and national health statistics. However, this data is largely confined within individual hospital systems, with no effective national-level exchange, making it difficult to build comprehensive patient histories or enable integrated care.

Although researchers can access hospital data for secondary purposes, this is only permitted with prior approval from ethics committees and is constrained by legal requirements under GDPR and Romanian law. Patients must give informed consent, but this typically covers use within the institution that originally collected the data. Tertiary use (such as sharing data with external entities) is not covered under standard consent procedures and requires separate, explicit patient agreement. Data security remains a key concern due to limited resources and infrastructure. In some cases, hospitals opt to stay offline entirely as a protective measure against cyber threats (Veles (b), 2024).

Interoperability of data

Interoperability of health data in Romania remains a challenge, despite the variety and breadth of data types collected across the healthcare system. Clinical records, laboratory results, medical imaging, and personal data such as height, age, and weight are routinely gathered. Emerging efforts also focus on incorporating genomic data, life quality indicators (including demographic, social, and environmental factors), and individual and family behavioral data such as dietary habits and healthcare expenditures. Medical imaging is managed in many hospitals through Picture Archiving and Communication Systems (PACS) using the Digital Imaging and Communications in Medicine (DICOM _standard, which facilitates compatibility. Nonetheless, this system is not universally implemented, and many patients still receive imaging data on physical media like CDs. In general, hospitals store data digitally, but there is no infrastructure for secure or seamless exchange of information between institutions. This results in a fragmented data environment, where patients must often carry printed records or digital copies themselves, and where redundant procedures are common due to the incompatibility of systems. Moreover, the absence of a national infrastructure for longitudinal data analysis further limits the ability to track patient health over time or to conduct comprehensive research. Health data remains siloed within individual hospitals, impeding continuity of care and restricting the potential of data-driven research (Veles (a), 2024).

Data quality / Standardisation of data

Romania's health data ecosystem suffers from pronounced fragmentation, primarily due to the existence of parallel data flows that often collect identical information in disparate formats. A critical underlying issue is the absence of unified data standards and nomenclatures, and there is no comprehensive practice of centralised data storage or systemic interoperability.

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Hospitals, clinics, and laboratories are the main generators and custodians of medical data, yet they frequently rely on customised IT systems developed by private vendors to meet local operational needs. This decentralised approach has resulted in heterogeneous systems and standards within incompatible platforms. Furthermore, private healthcare providers are generally not required to report data to the County Public Health Departments (DSPs), unless it is necessary for reimbursement from the National Health Insurance House (CNAS). Consequently, patient data generated in private settings is frequently excluded from public health records, leading to substantial data gaps at the national level. In addition, data from clinical studies is collected and governed under separate, highly regulated frameworks. Contract Research Organizations (CROs), for instance, often employ granular consent forms to align with ethical and legal requirements for treatment adherence and research protocols. Although most health data is digitalised, a significant portion remains in unstructured text formats. In some institutions, data sharing and communication still rely on outdated and insecure practices, including printed documents, CDs for medical imaging, or even channels like WhatsApp. These methods not only hinder efficiency but also pose serious risks to data security and patient confidentiality. The overall system is currently in a transitional phase. There are national-level intentions to enhance standardisation and infrastructure, particularly under the auspices of the planned National Data Observatory and investments from the EU-backed National Recovery and Resilience Plan (PNRR) (mfe.gov, 2021), (Veles (a), 2024). Resources

Resources and funding

Romania's healthcare system is governed centrally, with financial control and administrative and policy regulation concentrated at the national level. The Ministry of Health holds overall responsibility for system governance, while the CNAS manages and regulates the FNUASS, which operates under a mandatory social health insurance model. Although a wide range of institutions are involved in the healthcare system, most existing data flows are administrative in nature, focused on upstream processes such as billing, public health reporting, statistics, and international obligations. By contrast, clinical data exchange remains limited (Veles (a), 2024). To address this imbalance and modernise the system, several initiatives are underway. A World Bank–supported project is driving the development of an interoperable health data infrastructure based on government cloud services. This infrastructure aims to facilitate data sharing between CNAS, the Ministry of Health, and healthcare providers. In parallel, the Ministry of Health is establishing the National Health Data Observatory (ONDS) to modernise health data analysis and address the fragmentation of existing national health registries. ONDS is expected to enable:

- Electronic reporting and real-world data collection from various healthcare providers
- Improved access and quality monitoring of healthcare services
- Efficiency and performance assessment of healthcare services
- Data extraction for identifying various diseases
- System to support patient invitations and follow-ups for preventive services
- Monitoring the implementation of regional master plans for healthcare services
- Policy decision-making support through analysis of various types of data
- Metadata storage system

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- Use of anonymised patient data for research purposes (Romanian Health Ministry, 2024).

In addition, the ROGEN project, launched in December 2024 and coordinated by the University of Medicine and Pharmacy "Carol Davila" of Bucharest, marks a major step toward personalised healthcare in Romania. It aims to establish a National Network for Genomic Medicine (Veles (b), 2024)

Human resources

Romania is currently facing a significant shortage of professionals specialised in health data management, despite the growing importance and need of such expertise. There is a recognised lack of technical specialisation across the healthcare workforce. Family doctors, who currently centralise patient records – mainly in paper format – require targeted training. Nurses, community medical assistants, and other doctors also need to improve their digital skills, ideally within a single, easy-to-use system. From an educational perspective, there is a notable disconnection between what is taught in universities and the practical skills needed in clinical settings. Biomedical engineering students, for instance, frequently study without access to up-to-date medical equipment, limiting their readiness for real-world application. Additionally, research is undervalued, and pursuing a PhD is not a priority for most medical staff. To address these challenges, the first proposed step is to update the national nomenclature of occupations (COR) to include roles such as "medical data analyst". A second step involves hiring well-trained, well-paid support staff (such as data stewards, analysts, and security experts) to create a competitive, IT-skilled workforce in healthcare (Veles (a), 2024).

Societal readiness

Effective governance of health data in Romania depends on strong collaboration among diverse stakeholders and close cooperation with authorities to develop supportive policies and legislation. Promoting standards and protocols for safe and ethical data sharing, and fostering partnerships across the public, private, and academic sectors, are key to overcoming technical and legal barriers. A significant challenge is the lack of public trust in the healthcare system and in the use of health data. To address this, it is essential to establish an Ethics Committee composed of trusted individuals and operating transparently. This would help build trust, clarify stakeholder roles and responsibilities, and ensure the health data ecosystem functions ethically and effectively for the benefit of all (Veles (a), 2024).

Data privacy and security

General Data Protection Regulation (GDPR)

Romania's healthcare system complies with the GDPR, particularly regarding the provision of healthcare services. However, significant gaps remain in the regulation of health data for secondary use, specifically for healthcare system management and scientific research. The current legal framework governing digital health services includes Law No. 45/2019, which amends Law 95/2006 to establish the Electronic Health System, alongside Government

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Decision 196/2020 regulating telemedicine, and the Health Minister's Order No. 1584/2023 focused on teleradiology. These laws ensure GDPR compliance in service provision but fall short in enabling broader data use. For healthcare management and system improvement, additional legislation is in place: Government Decision 11/2015 refines the role of the National Agency for Management and Quality in the Healthcare System; Law No. 185/2017 focuses on quality management; Law No. 134/2019 establishes the National Agency for Medicine and Medical Devices; and Order No. 1466/2008 sets out procedures for controlling transmissible diseases. In contrast, data use for scientific research is more restricted. Article 3 of Law No. 190/2018 limits the use of health data strictly to public health purposes. Mechanisms to support research, such as obtaining approval from a research ethics committee or the Data Protection Authority (DPA), are rarely implemented. To enable responsible innovation and data-driven research, comprehensive legislative updates remain urgently needed (Natasa, et al., 2024).

Data protection provisions

Law 362/2018 was adopted by Romania as part of the national transposition of the EU's NIS Directive and establishes a robust legal framework to ensure cybersecurity across all sectors, including healthcare. This law underscores the critical role of cybersecurity in protecting network and information systems, especially those processing personal data. Health institutions are required to carry out rigorous assessments of existing cybersecurity measures, evaluate the potential impact of incidents on service delivery, and report cybersecurity incidents to relevant authorities. In line with GDPR requirements, they must implement both technical and organisational safeguards to protect their networks and systems. These measures are essential for preventing, detecting, and responding to cyber threats efficiently. By mandating strict security and notification obligations, Law 362/2018 reinforces the resilience and integrity of Romania's health information systems, ensuring that personal data is protected through a proactive and comprehensive cybersecurity approach (RO-CCH Romanian Cyber Care Health, 2024).

Health Data Access Bodies (HDABs)

The Ministry of Health is currently in the process of establishing a ONDS to advance the modernisation of health data analysis in Romania. A call for funding for ONDS has been launched and is presently under public consultation, coordinated by the Managing Authority for Public Health. The National Public Health Institute is designated as the sole beneficiary of this initiative (Ministerul Investițiilor și Proiectelor Europene, 2025).

Access and control

Access rights

Patients in Romania are entitled to access their personal health data under both the GDPR and national law. However, the legal framework presents several ambiguities and limitations regarding other key rights. There is no specific legislation addressing the correction of inaccurate data, while the right to data deletion is unclear; certain provisions suggest that health data must be archived and not erased. The Patient's DES was developed to anonymise

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and export patient data, but it remains non-functional in practice. Although the national health card system stores detailed medical histories, the data cannot be exported in internationally standardised formats, which restricts portability, especially for patients needing to transfer records abroad. Some legislative progress has been made: Law No. 21/2023 initiated a pilot project to explore mobile and digital transformation solutions; Ministerial Order No. 1584/2023 introduced privacy and security measures for teleradiology services; and Law No. 351/2023 requires healthcare providers to ensure the secure digital storage of patient data (Natasa, et al., 2024).

Transparency

In Romania, the national health card allows the storage of a patient's full medical history, enabling domestic data portability. However, this data cannot be exported in an internationally standardised format, preventing patients from carrying their complete digital medical records when traveling abroad (Natasa, et al., 2024).

Unified market for EHR systems

Harmonisation of standards

Romania's health system remains deeply fragmented, limiting the full potential of EHRs. Challenges include incomplete data from all providers, lack of dedicated training in data collection, management and analysis, a variety of hospital software systems in place, the restricted number of national registries, and shortages of funding and specialised personnel (Grad & Mureșanu, 2022). The decentralised IT procurement in hospitals, combined with the absence of interoperability standards, impedes service integration and efficient use of digital health investments. Although this fragmentation allows digital health innovators to develop market-driven solutions, it reduces overall value for money. To address these issues, the National Health Insurance House is modernising the PIAS. The project aims to enhance system performance, scalability, interoperability, and availability, strengthen data management across health institutions, and improve both vertical and horizontal integration of healthcare services. It also focuses on accelerating telemedicine adoption, increasing accessibility for vulnerable groups, enabling real-time reporting, ensuring integration with national and EU health systems, and guaranteeing cybersecurity compliance with GDPR and EHDS standards (Casa Națională de Asigurări de Sănătate, 2024).

Promoting innovation

Technology-based solutions

Romania's Strategy for Digitalisation sets several objectives aimed at fostering innovation in healthcare technology. Key goals include creating an environment that accelerates the development and testing of innovative digital solutions and facilitates the exchange of best practices among stakeholders (Romanian Health Ministry, 2024).

Research and development

The Strategy for Digitalisation outlines objectives to stimulate the digital health industry and Research, Development and Innovation (RDI). This includes supporting ecosystem

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organisations and advancing the operationalisation of the National Health Data Observatory. The Observatory is planned to invest in analysing and redefining the health information system, incorporating routine reporting from all healthcare service providers across the country concerning health data, inputs, processes, and health service outcomes (Romanian Health Ministry, 2024).

Important additional remarks

Romania's health data space concept encounters several challenges, such as poor communication between hospitals, limited infrastructure for data sharing, and interoperability issues. There is a clear need for a unified protocol to store both clinical and imaging data to enhance consistency and reliability. Moreover, the lack of real-time access to patient data hampers diagnostic processes and secondary data analysis. Addressing these issues requires ongoing investment and regulatory support to establish a sustainable health data infrastructure in the country (Veles (b), 2024).

3.6 Italy

Governance

National

🟩 The Ecosistema Dati Nazionali (EDS) Decree, issued by the National Health Ministry on 31 December 2024, identifies the Ministry as the data controller for the national health data ecosystem EDS, while AGENAS (Agenzia nazionale per i servizi sanitari regionali- National Agency for Regional Health Services) serves as its operational manager. AGENAS acts as the data processor and facilitates the transfer of data from EHR/Fascicolo Sanitario Elettronico (FSE) and the Tessera Sanitaria (Healthcare card) system to the EDS. Each region or autonomous province hosts its data in dedicated units, which are subsequently shared, to be part of the federated national EDS (ecosistema dati sanitari) (Italian Ministry of Health, 2025).

🟥 Despite the decree, Italy's National Healthcare (NHC) system remains highly fragmented into Regional Healthcare (RHC) systems. To ensure consistent information nationwide, the Ministry of Health must collaborate with regional entities to establish a shared information model for publication on the national EHR/FSE Portal. Moreover, there is a need to formalize the involvement of citizens and patient representatives in EHDS governance, a point widely supported by multiple policy documents but not yet addressed in current drafts (Italian Ministry of Health, 2025), (Italian Ministry of Health, 2023).

Regional

🟩 Moving to the regional level, Emilia-Romagna is already compliant with national interoperability requirements concerning the EHR/FSE 2.0 system (Italian Ministry of Health, 2025).

🟥 However, there is not yet a regional governance framework to coordinate collaboration among the various Local Health Authorities, AUSL (Aziende Sanitarie Locali / Trust-local

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hospitals), AO/AOUni (Az.Ospedaliere e ospedaliero-universitarie / general hospitals), a gap that limits unified regional strategy implementation (Italian Ministry of Health, 2025), (Italian Ministry of Health, 2023).

Legal and regulatory aspects

The EDS Decree (31/12/2024) identifies legal responsibilities and readiness steps. The National Health Ministry is the data owner, while AGENAS manages operations. In fact, AGENAS will provide for the transfer to the EDS of the data conferred to the EHR/FSE by healthcare and socio-medical facilities, National Healthcare bodies, plus the data conferred through the Tessera Sanitaria system (Italian Ministry of Health, 2025).

Concerning the readiness for EHDS, by the end of 2025, 85% of General Practitioners will have to feed the EHR/FSE, while by mid-2026 the Regions and Autonomous Provinces will have to have adopted and fully utilised the EHR/FSE (Italian Ministry of Health, 2025).

According to Article 5 of the GDPR (General Data Protection Regulation), data may only be used for the purposes for which they were collected, except in cases where obtaining consent would require disproportionate effort or render research objectives unattainable. In such instances, consent may be waived following consultation with the Data Protection Authority and approval from the Ethics Committee, although this option has reportedly seen little practical use to date (European Union, 2016).

Technical infrastructure

At national level, Italy's cybersecurity is overseen by the Agenzia per la Cybersicurezza Nazionale – National Agency for Cybersecurity (ACN), while the Italian ultra-broadband network (GARR) provides high-speed data exchange infrastructure with regional nodes, and the National Infrastructure for Interoperability (INI) ensures interoperability. Regionally, LEPIDA, the regional in-house company, manages storage and connectivity, supporting healthcare data exchange via the Sanità OnLinE (SOLE) platform. High-Performance Computing (HPC) capacity is based at Tecnopolo Manifattura in Bologna (MarghERita). The "Alleanza contro il Cancro Health Big Data (HBD) project", funded by the Ministry of Economy and Finance and coordinated by the Ministry of Health, aims to connect health data from various sources across Italy (Italian Ministry of Health, 2023).

In May 2015, the Agenzia per l'Italia Digitale (AgID) published technical specifications to enable interoperability between regional Fascicolo systems, providing a framework and dataset for regions to develop effective FSE services (Italian Presidency of the Council of Ministers, 2018). This followed successful pilot tests in Emilia Romagna, Lombardy, and Veneto, supported by the National Research Council (CNR). Decree No. 178, formalised in September 2015, became the key reference for regional implementation. The 2022 Guidelines further consolidated previous recommendations, laying the foundation for EHR/FSE 2.0 (2022-2026), with aims of standardisation, improved interoperability, and enhanced governance nationwide. However, uneven regional progress and fragmented local telemedicine platforms continue to

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challenge national integration (Italian Ministry of Health, 2025), (Italian Ministry of Health, 2024).

Regional healthcare systems in Italy result in inconsistent approaches to data collection and storage. For successful implementation of the EHDS, it will be crucial to adapt existing infrastructures such as the EHR/FSE and develop new systems under the National Health Ministry within the New Health Information System (NSIS). Achieving effective interoperability will require centralised coordination and the standardisation of data acquisition across the country within a clear timeframe. The diversity of information systems, not only between countries but also among Italian regions, remains a significant challenge. As repeatedly emphasised by stakeholders, establishing a unified national infrastructure is a top priority. Introduced in 2012 (Italian Presidency of the Council of Ministers, 2012), the EHR/FSE supports the management of patients' health data at the regional level. The national EHR/FSE project, now reinforced by investments under Mission 6.2 of the PNRR (Piano Nazionale di Ripresa e Resilienza – Italian Next Generation EU) and new Ministry of Health guidelines adopted in 2023, aims for completion by 2026. This will ensure comprehensive access to health information, enabling more informed and targeted medical care, and align Italy with broader European initiatives (Italian Ministry of Health, n.d.).

Health data readiness

General state of health data

In Emilia-Romagna, 100% of General Practitioners (GPs) and paediatricians, and 97% of specialist doctors within local health authorities, have utilised the EHR folder, compared to national rates of 94% and 76% respectively. The EHR/FSE includes identification and administrative details, medical reports, prescriptions, vaccination records, emergency and discharge summaries, personal health notes, and more. The region or local health authority acts as the data controller for health profiles, but may only access data under strict conditions. Access to EHR/FSE data by third parties requires explicit, informed patient consent. Data is securely stored, encrypted, pseudonymised, and access is strictly logged and role-based, ensuring privacy and accountability (Italian Ministry of Health, n.d.), (Italian Ministry of Health, 2024).

Numerous entities, including local health authorities, private/accredited facilities, and healthcare professionals, are responsible for populating the EHR/FSE. Digital authentication (using a Public Digital Identity System i.e. SPID or CIE) and role-based access control, coupled with comprehensive logging, secure the system. Despite these advancements, challenges persist, particularly data collection and storage dishomogeneity across regions, undermining initiatives like telemedicine. The EHR/FSE 2.0 aims to address this through a unified national architectural model, adoption of HL7-FHIR standards, and citizen-centric services, though it currently lacks a complete representation of patient health. Efforts are underway to align with EHDS requirements, supported by the PNRR (Italian Ministry of Health, n.d.), (Italian Ministry of Health, 2024).

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Regional healthcare in Italy results in significant variation in data collection and storage. To address this, the EHR/FSE 2.0 initiative – formalised by the Minister of Health's decree on 7 September 2023 – sets out three core objectives: establishing a unified national architecture, adopting the HL7-Fast Healthcare Interoperability Resources (FHIR) standard, and developing citizen-focused services. Despite these advances, the EHR/FSE still falls short of providing a timely and comprehensive overview of patients' health status, their broader socio-health context, and care plans. Overall, the health data landscape remains marked by highly fragmented digital systems (Italian Ministry of Health, n.d.), (Italian Ministry of Health, 2024).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

The EDS decree (31/12/2024) defines the framework within which it will operate and the different treatments provided, e.g. for study and research (Italian Ministry of Health, 2025).

Regarding the secondary use of data under the proposed regulation, it is important to note that in Italy, scientific research in medical, biomedical, and epidemiological fields is governed by Regulation 679/2016/EU and Legislative Decree 196/2003. The latter imposes additional restrictions not found in the EU Regulation or in other European countries. Italy has not embraced the simplification opportunities offered by the EU framework, creating significant challenges for Italian research institutions compared to their European counterparts. Ongoing discussions seek a more research-friendly regulatory environment, while ensuring data protection rights, and highlight the need for a clear legal basis for processing health data in developing AI systems (UNIAMO – F.I.M.R, 2024).

Interoperability of data

The EDS includes technical infrastructure, technological framework and tools enabling secure, standardised, and interoperable exchange, storage, and access to health data across the EU (UNIAMO – F.I.M.R, 2024).

The national rare disease patients' association emphasises the crucial connection between the EHDS and biobanks, stressing that this link must be guaranteed both technically and scientifically. The rare disease community fully recognises the vital role biobanks play in advancing research. They understand that data on biological samples, together with related clinical information, are stored in IT systems that must be interoperable with the platforms designated for sharing health data for secondary use, as outlined in the EHDS proposal. Ensuring this integration is essential for maximising the research potential for rare diseases (UNIAMO – F.I.M.R, 2024).

Data quality / Standardisation of data

National standards are established compliant to HL7 Italy (part of HL7 International) (Fasciolo Sanitario Elettronico, 2025).

Interoperability is foreseen, according to the HL7 standard (e.g. CDA2 (Clinical Document Architecture) for document structure, HL7 V2 for data exchange messaging), but full

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interoperability is being progressively achieved through the adaptation of all regional systems. At the same time, the INI will cover all sharing aspects (again in order to ensure full interoperability). For this specific topic (data quality), AGENAS and AGID are in charge to provide to regional HealthCare proper tools that will do the semantic and syntactic validation (EHR/FSE 2.0) (Italian Ministry of Health, 2024), (Italian Ministry of Health, 2023), (Italian Ministry of Economy and Finance, 2017).

It became apparent that, in the collection of primary data, insufficient training of professionals often results in limited attention to structuring data for both immediate clinical use and potential research purposes. Consequently, this oversight leads to a significant additional workload later on (EIT Health, 2023).

Resources

Resources and funding

LEPIDA acts as the regional infrastructure for storage and connectivity, with a dedicated branch – SOLE – facilitating healthcare data exchange among general practitioners, hospitals, paediatricians, and local health authorities. HPC capacity is provided at Tecnopolo Data Manufacturing (DA.MA.) in Bologna and through the regional MarghERita HPC platform. At the national level, GARR offers a technical infrastructure for ultra-fast data exchange, connecting regional nodes across Italy. These advancements are supported by the Italian PNRR, which has allocated €1.3 billion under M6C2 I1.3.1 to enhance technological infrastructure and tools for data collection, analysis, and simulation, driving the development of EHR 2.0 (Italian Ministry of Health, n.d.).

The Italian Budget Law for 2025, currently under negotiation, projects healthcare expenditure at around 6% of GDP (Gross Domestic Product) for the period 2025–2027 – significantly below the estimated 7.5% required to sustain current standards. While Italian Recovery and Resilience Fund (i.e. PNRR) M6C2 I1.3.1 has accelerated the digitalisation of regional healthcare, this funding alone will not be sufficient to bring all regions up to standard or to ensure their ongoing maintenance (EIT Health, 2023).

Human resources

In Emilia-Romagna, the Regional Healthcare Department is piloting a programme to improve the digital skills of healthcare and social care staff. Data controllers are required to ensure staff involved in data processing are properly trained in data protection regulations, supporting better engagement with data subjects. Regular sessions are organised to promote the correct use of the FSE, raise awareness of data security risks, and explain the measures in place to protect personal information, with particular attention to issues such as data entry errors involving similar names. Training also covers IT systems and information security, with outcomes monitored to address any gaps and foster a strong culture of security and risk management. This initiative is supported by the Italian Recovery and Resilience Fund (PNRR), which invests €18 million in developing the digital and professional skills of healthcare personnel (Italian Ministry of Health, n.d.).

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It has become evident that, during the collection of primary data, insufficient attention is given to ensuring data quality for both immediate clinical use and future research purposes. This is often due to inadequate training of professionals in this area, resulting in a significant additional workload later on. There is a clear need to strengthen digital health education for both the general public and healthcare professionals, alongside promoting communication campaigns about the secondary use of health data. Collaboration with citizens' and patients' associations is essential in this regard. According to the Federation's findings, digital literacy is key to building public trust in digital health systems, where some scepticism remains. Citizens' and patients' organisations – recognised as trusted sources of information, as highlighted by Eurordis – can play a vital role by leading targeted digital literacy campaigns at both national and European levels. These efforts should particularly focus on groups less familiar with digital technologies, such as older adults or those living in remote or underserved areas (EIT Health, 2023), (UNIAMO – F.I.M.R, 2024).

Societal readiness

In Emilia-Romagna, 89% of the population has granted consent for doctors and healthcare professionals to access their EHR, a figure significantly higher than the national average of 41% (GRUPPO24ORE, 2025). Furthermore, a Eurordis survey involving over 2,000 individuals affected by 664 different rare diseases revealed that 97% are willing to share their health data with researchers, in the hope of advancing knowledge and finding new treatments for their own conditions and for others living with rare diseases (Italian Ministry of Health, 2024), (UNIAMO – F.I.M.R, 2024).

As previously mentioned, the PNRR is investing in this area, yet the use of the FSE remains uneven across Italy (Italian Ministry of Health, n.d.). Meanwhile, a campaign has been launched allowing citizens to object to the uploading of health data and documents generated by clinical events before 18 May 2020. Since the introduction of Decree-Law 34/2020, data are now uploaded automatically to the EHR, removing the need for prior consent. The PNRR also includes training and information initiatives for healthcare professionals, ensuring action is taken for both citizens and staff. It is essential that citizens retain control over their data and associated rights, including the ability to withdraw consent, request erasure, and exercise the right to be forgotten, whether for primary or secondary use. Discussions with patient associations have shown that people are generally willing to share their data for research, provided they have made an informed choice and remain aware of who accesses their data, for what purpose, and how it is used. Crucially, individuals wish to retain the freedom to withdraw their data at any time and expect transparency and accountability throughout the process (Italian Ministry of Health, 2024).

In contrast to Emilia-Romagna, only 41% of Italians have consented to doctors accessing their EHR. Despite its potential, the EHR remains underused: just 38% of Italians are aware of it, and only 12% know they have used it. Privacy concerns are especially acute for those with ultra-rare diseases, where traditional anonymisation is insufficient due to the small number of cases. Special safeguards and clear assignment of responsibilities are essential, with

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transparent, accessible registers documenting data access requests and outcomes. This ensures both accountability and protection of individuals' identities (GRUPPO24ORE, 2025).

Data privacy and security

General Data Protection Regulation (GDPR)

Italy has a strict adherence to the GDPR. In 2018, Italy aligned its domestic data protection law with the EU's GDPR through Legislative Decree n. 101/2018, which was published on August 10, 2018 (Italian Presidency of the Council of Ministers, 2012), (Italian Presidency of the Council of Ministers, 2018), (Italian Ministry of Health, 2023).

Efforts are underway to align with EHDS requirements: the Italian Data Protection Authority (Garante per la protezione dei dati personali) has one of the most restrictive interpretations of the GDPR among the Member States (Italian Presidency of the Council of Ministers, 2018), (Italian Ministry of Health, 2023).

Data protection provision

In compliance with EHDS regulation the Italian Data Protection Authority (Garante per la protezione dei dati personali) is the supervisory authority responsible for monitoring application of the General Data Protection Regulation (Italian Presidency of the Council of Ministers, 2018), (Italian Ministry of Health, 2023).

Health Data Access Bodies (HDABs)

Italy currently lacks a dedicated HDAB. However, the March 2025 EDS decree designates AGENAS as the authority for public and private medical, biomedical, and epidemiological research entities to submit requests for anonymised data extraction, accompanied by a research project adhering to methodological, ethical, and deontological guidelines (Italian Presidency of the Council of Ministers, 2018).

Access and control

Access rights

FSE 2.0 includes a wide range of information: personal and administrative details (such as exemptions, contacts, and proxies), medical reports, emergency and discharge summaries, health profiles, prescriptions, medical records, medication dispensing (both covered and not covered by the NHS), vaccination records, specialist care, implant card data, screening invitations, and a personal health notebook (Italian Ministry of Health, n.d.). Access to the FSE is secured through digital authentication methods like SPID or CIE, with role-based authorisations ensuring users only see information relevant to their responsibilities. The decree also requires detailed access logs for monitoring and accountability. To protect privacy, sensitive data must be encrypted and pseudonymised, ensuring confidentiality throughout storage and processing (Italian Ministry of Health, 2024), (Italian Presidency of the Council of Ministers, 2018), (Italian Ministry of Health, 2023).

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Access is allowed to patients and authorised users only for primary use (treatment, prevention) but it's not yet identified a protocol for secondary use (Italian Presidency of the Council of Ministers, 2018).

Transparency

The Italian Ministry of Health has issued an information notice for patients on the processing of personal data on the EHR/FSE, together with a communication campaign towards citizens in order to sensitise them openly and transparently on how their data on the EHR is processed and how they may restrict access. Access previously given can be revoked at any time, and the consent must be renewed every 6 months (Italian Ministry of Health, 2024), (Italian Presidency of the Council of Ministers, 2018), (Italian Ministry of Health, 2023).

Unified market for EHR systems

Harmonisation of standards

Italy will adopt the FHIR standard for electronic health data exchange, ensuring interoperability and facilitating cross-border collaboration in European and international research (Italian Ministry of Health, 2023).

Promoting innovation

Technology based solutions

Emilia-Romagna Region has as a priority the digital transformation and in the last 10 years developed policies and strategies to attract investments, talents and projects on this topic. We can mention the DA.MA. Technopole, the European Digital Innovation Hub Emilia-Romagna Ecosistema Regionale di Innovazione Digitale (ER2Digit), strictly dedicated to Public Administrations, the Italy for AI (IT4LIA), one of the European AI factories, HPC Leonardo, still one of the top 10 most powerful in the world (X Engineering, 2025).

Research and development

In Emilia Romagna there are public funding initiatives that incentives industrial and translational research, such as the regional calls for proposals of Axis 1.1 of the ERDF-funded Regional Programme and calls for proposals under the STEP strategy (Emilia-Romagna Regione Governament, 2025). At national level the Ministry of Universities and Research funds the research projects under the FIS - Fondo italiano per la scienza, PRIN - Progetti di Rilevante Interesse Nazionale and FIRST 2025 - Fondo di Investimento per la Ricerca Scientifica e Tecnologica programmes (Italian Ministry for University and Research, 2025).

Public and private subjects that institutionally pursue purposes of study and scientific research in the medical, biomedical and epidemiological fields must submit their request for extraction of anonymised data, accompanied by a relative research project drawn up in compliance with methodological and ethical rules, and where applicable, the deontological rules for processing for statistical and scientific research purposes. The EDS decree only foresees a future decree that will enable access to personal data for research purposes (Italian Ministry of Health, 2025).

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At the moment, the newly published EDS decree enables only to request access to anonymised data, which can restrict the usefulness of the data to be used for research and innovation purposes (Italian Ministry of Health, 2025).

Important additional remarks

The purpose for which health data are used must be clearly defined and specific, rather than generic. It is essential to describe precisely the research activity for which data will be made available, specify the types of entities permitted access, and highlight or restrict any exceptions. The EHDS proposal allows data use for various purposes – such as public interest, support for public bodies, official statistics, scientific and clinical research, innovation, training, and personalised care. To prevent broad or ambiguous interpretation, purposes should be narrowly defined and formalised through informed consent. However, informed consent should not always be considered the primary legal basis for data sharing; greater emphasis should be placed on the public interest (Italian Presidency of the Council of Ministers, 2018), (Italian Ministry of Health, 2023)..

3.7 Lithuania

Governance

National

In Lithuania, the governance of the healthcare system is overseen by the Ministry of Health, with funding provided through a social health insurance model administered by the National Health Insurance Fund (NHIF). The system is currently undergoing restructuring, with a focus on centralisation, the development of long-term care models, and broader modernisation efforts (European Observatory on Health Systems and Policies, 2023).

Lithuania is working on strengthening its personalised medicine capabilities and health data infrastructure. However, full integration into the EHDS governance framework has not yet been achieved. While the country demonstrates a degree of engagement with international initiatives (evidenced by its participation in the BBMRI-ERIC biobanking network), it remains outside other key European research infrastructures such as Euro-Bioimaging. National-level coordination is ongoing, but further improvements are necessary to ensure complete readiness for EHDS (STRATA, 2024).

Regional

National information applies (European Observatory on Health Systems and Policies, 2023).

National information applies (STRATA, 2024).

Legal and regulatory aspects

Lithuania has implemented the GDPR to safeguard personal data, aligning with EU-wide standards for data protection (European Observatory on Health Systems and Policies, 2023).

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However, further legislative advancements are likely required for the secondary use of health data to support broader and more effective utilisation of health data in line with the objectives of the EHDS (European Observatory on Health Systems and Policies, 2023).

Technical infrastructure

Lithuania has an EHR system called State Electronic Health Services and Cooperation Infrastructure Information System (ESPBI IS) that mandates healthcare providers to use a centralised data exchange system. During the COVID-19 pandemic, telemedicine usage increased from 1% in 2019 to 30% in 2021, highlighting advancements in digital healthcare services (European Observatory on Health Systems and Policies, 2023).

This system has been under development since 2015 and still requires improvements to ensure full interoperability. There is an initiative to integrate with "MyHealth@EU," the EU's cross-border digital health network. Investment in biobank infrastructure, genomics research, and data-sharing initiatives is ongoing, but further technical enhancements are required (Registru centras, 2024).

Multiple digital systems in hospitals operate with overlapping functions, potentially leading to inefficiencies in data interoperability (Source: PRECISEU Deliverable 6.1 Cross Regional Report: Mapping Barriers & Enabling Solutions – A European Perspective on Personalised Medicine).

Health data readiness

General state of health data

In Lithuania, the use of EHR is mandatory for all healthcare providers, reflecting a national commitment to digital health transformation. However, challenges in implementation persist (European Observatory on Health Systems and Policies, 2023).

While the country is making steady progress in advancing digital health initiatives, it has not yet achieved full-scale implementation, with further developments needed to ensure comprehensive readiness for the EHDS (European Observatory on Health Systems and Policies, 2023).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

Lithuania is actively expanding the secondary use of health data, particularly through its growing biobank infrastructure. The country places a strong emphasis on personalised medicine and is participating in the European "One Million Genomes" initiative, with plans to sequence 1,570 genomes by 2026 (STRATA, 2024).

However, to fully support the secondary use of health data in line with EHDS objectives, further legislative alignment is necessary (STRATA, 2024).

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Interoperability of data

Lithuania is taking steps to enhance data standards as part of its efforts to improve health data interoperability. However, additional investment is needed to achieve full alignment with the interoperability requirements of the EHDS (STRATA, 2024).

The current landscape is characterised by multiple digital health systems that operate in parallel, underscoring the need for more effective integration and harmonisation to enable seamless data exchange and support cross-border healthcare services (STRATA, 2024).

Data quality / Standardisation of data

Ongoing efforts to standardise health data reflect Lithuania's commitment to improve data quality. However, these initiatives still require further alignment with EU-wide standards set out by the EHDS (STRATA, 2024).

Resources

Resources and funding

Efforts to strengthen Lithuania's digital health ecosystem are supported by funding from several EU initiatives, including the Recovery and Resilience Facility (RRF) and Horizon Europe. Notably, over €9 million has been allocated specifically for the development of biobank infrastructure, reflecting the country's strategic focus on enhancing capabilities in personalised medicine and data-driven healthcare (STRATA, 2024).

However, overall public spending on health remains relatively low, standing at 7.8% of GDP, significantly below the EU average of 11.0% (European Observatory on Health Systems and Policies, 2023).

Human resources

Human resources in Lithuania's health IT and data governance require further strengthening, particularly in the areas of health data management and analytics, where there is a pressing need for more skilled professionals (HEROES, n.d.)

While the country's doctor-to-population ratio stands at 4.5 per 1,000 (above the EU average of 4.1) Lithuania faces a significant shortage of nursing staff, with just 7.9 nurses per 1,000 people compared to the EU average of 8.5. Projections indicate a looming shortfall of around 3,000 nurses and 800 general practitioners by 2030, posing a serious challenge to the sustainability of healthcare delivery (European Observatory on Health Systems and Policies, 2023).

Societal readiness

Societal readiness for health data sharing is gradually improving in Lithuania. Stakeholders such as universities and research institutions are actively participating in EU-funded health data projects (EIMIN, 2023).

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🟨 Public and institutional engagement in health data sharing is growing, but data privacy concerns persist. Public awareness in digital health initiatives remain areas for growth (EIMIN, 2023).

Data privacy and security

General Data Protection Regulation (GDPR)

🟩 Lithuania has fully implemented the provisions of the GDPR, providing a solid legal foundation for personal data protection in the health sector. The National Law on the Legal Protection of Personal Data, in force since 16 July 2018, mirrors the GDPR without introducing additional national requirements or exemptions, ensuring alignment with EU-wide data protection standards (European Observatory on Health Systems and Policies, 2023).

Data protection provisions

🟩 Data protection provisions in Lithuania are fully aligned with the requirements of the GDPR, ensuring the safeguarding of personal data and the protection of individual privacy rights (CEE Legal Matters, 2024).

Health Data Access Bodies (HDABs)

🟨 Lithuania is involved in EU-level initiatives focused on the development of HDABs. However, a nationally designated HDAB has not yet been formally established. This represents a key gap in the country's alignment with the EHDS framework and may impact future capacities for facilitating secure and transparent secondary use of health data (No source, as there is no HDAB).

Access and control

Access rights

🟨 Access to health data in Lithuania is facilitated through the national electronic health system, which enables both patients and healthcare professionals to view health records. However, a fully comprehensive definition and implementation of access rights, as outlined under the EHDS framework, is still pending (STRATA, 2024).

Transparency

🟨 Lithuania supports the secondary use of health data, particularly in the area of research and innovation. Despite this commitment, the country has not yet fully implemented the transparency mechanisms required under the EHDS framework. Strengthening these mechanisms will be essential to ensure accountability, build public trust, and enable responsible data use in line with EU expectations (STRATA, 2024).

Unified market for EHR systems

Harmonisation of standards

🟨 Lithuania is actively working toward harmonisation within a unified health data market by implementing open electronic health record (EHR) systems, such as openEHR. These efforts aim to enhance interoperability across digital health systems and align national infrastructure with the broader objectives of the EHDS (STRATA, 2024)

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Promoting innovation

Technology-based solutions

Lithuania benefits from a strong digital infrastructure and is actively promoting the adoption of innovative technological solutions in healthcare, such as telemedicine and artificial intelligence. These innovations support the country's progress toward digital transformation in health and contribute to aligning with the EHDS (STRATA, 2024).

Research and development

Lithuania promote the secondary use of health data to advance scientific research and innovation, fostering initiatives such as those involving start-ups focused on cancer treatment (Lithuania Innovation Agency, 2024).

Important additional remarks

Ethical and regulatory considerations continue to pose challenges for Lithuania, especially concerning the secondary use of health data. While legal frameworks are in place, they may need further refinement to fully meet the requirements of the EHDS. Lithuania's integration into EU-wide health data infrastructure remains a work in progress, with ongoing efforts focused on enhancing genomic data collection and improving interoperability across systems. These developments will be crucial for the country to achieve full alignment with EHDS objectives (No source, as it is a conclusion).

3.8 Sweden

Governance

National

The Swedish E-Health Agency has been tasked by the government with establishing a national function for interoperability within healthcare (EIT Health , 2023). A central element of Sweden's strategy for the EHDS is the Sweden National Services for Access to Swedish Health Data (SENASH) project, which aims to streamline the sharing of health data for secondary purposes such as research, innovation, and decision-making. Running from February 2024 to January 2027 and partially funded by EU4Health with a budget exceeding 28 million SEK (Svensk krona), SENASH is led by the E-Health Agency in collaboration with the Public Health Agency, the National Board of Health and Welfare, Statistics Sweden, and the Swedish Research Council. In addition, the National E-Health Agency is actively engaged in EU projects that focus on establishing secure, cross-border health data exchange in preparation for the EHDS (SFMI, 2024). Furthermore, the government has appointed an investigator to analyse and propose measures to enable a national digital infrastructure for the entire healthcare sector as of January 2024 (Government Office, 2024).

Regional

In Sweden, the healthcare system is decentralised, with public health and care services managed by regions, local authorities, or municipalities, each responsible for allocating its own

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healthcare resources. This decentralised structure is also reflected in the management of health data: while public health data is collected nationally by bodies such as the Public Health Agency of Sweden and various national disease registries, the majority of data generated during healthcare provision is stored and governed locally within each region (EIT Health , 2023).

Legal and regulatory aspects

A 2023 report to the Swedish government found that legislative changes are needed to enable the reuse of personal data for clinical research and innovation, recommending amendments to the Patient Data Act and the Public Access to Information and Secrecy Act, along with a new regulation. While Sweden supports the EHDS and is advancing technically, its legal framework is less developed, meaning Sweden will be among the last to join myHealth@EU1. Sweden has initiated the legal work to prepare for the European Health Data Space (EHDS). Through government assignments (adapting Swedish legislation to EHDS), the process of aligning national law has formally begun. However detailed legal adjustments remain unresolved (Nyström, 2023), (EIT Health , 2023), (Government Office, 2024).

Technical infrastructure

Sweden is well positioned technically for the EHDS, with much of the necessary data infrastructure already in place or under development, including a national system for communication between hospitals and ongoing work to enable regional data exchange. Sweden also participates in several European projects, such as the Genomic Data Infrastructure (GDI) and EUropean Federation for CAncer IMages (EUCAIM), which have produced solutions and infrastructures that could support a harmonised EHDS implementation across Europe. The European Genomic Data Infrastructure, in particular, serves as both a technical foundation and a best practice example for funding and incentives (EIT Health , 2023).

Sweden has a strong foundation for health data management, with mandatory national registries and national data infrastructure already in place. The SENASH project is further strengthening this by piloting new systems for metadata cataloguing and data ordering to support readiness for the EHDS. In September 2024, the E-Health Agency was also tasked by the government with establishing a national function for interoperability in healthcare (Swedish eHealth Agency, 2025).

Health data readiness

General state of health data

Sweden has a high level of digital maturity and extensive experience with the secondary use of health data acquired through well-established (mandatory) national registries (EIT Health , 2023), (SFMI, 2024).

The National Board of Social Affairs and Health has carried out preliminary studies to assess the feasibility and requirements for implementing the EHDS in Sweden. These studies offer insights into developing a shared data environment to support research, policy-making, and

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healthcare improvements, with a focus on establishing infrastructure for secure, efficient, and privacy-conscious health data sharing across the EU (SFMI, 2024).

Sweden currently lacks unified data security governance in healthcare, resulting in a fragmented approach that could pose a significant vulnerability under the EHDS. Without common standards, organisations are not fully aligned on security requirements, which may lead to inconsistencies in patient data protection and increase the risk of misuse or breaches of sensitive information (SFMI, 2024).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

Sweden has a long-standing tradition of public health data collection, with the National Board of Health and Welfare maintaining 14 national registries that are mandatory by law (EIT Health , 2023).
Stockholm Centre for Health Data performs a service role for researchers by ensuring they do not have to refer to multiple healthcare providers to gain access to data (only valid for region Stockholm) (EIT Health , 2023).

A key limitation for the secondary use of health data in Sweden is the lack of comprehensive documentation on available regional health data, along with limited capacity to meet complex data requests from multiple sources and in various formats (EIT Health , 2023).

Interoperability of data

To support the EHDS, the National Interoperability Council was established in Sweden to prioritise and standardise national health data requirements. Comprising experts from across the health sector, the council aims to improve data sharing within Sweden and with other EU member states by harmonising data standards and streamlining data collection and sharing processes in line with EHDS requirements (EIT Health , 2023).

Sweden has a national system for sharing basic primary health data between healthcare providers. However it's based on older standards and has been in need of an upgrade for several years, in order to reduce costs and complexity to make it easier for providers (in particular smaller providers with limited resources) take part in the data sharing, while simultaneously increasing the scope of data types (eHealth Ministry Sweden, 2025), (EIT Health , 2023).

Many years and lots of funds have been spent, regionally and nationally, on efforts to further structure and align data in registries, thus making it easier to use for research (both discovery and operational use). However very little of the registry landscape has been covered by these efforts and it still does not have a unified way of managing discovery or data access (SFMI, 2024).

Data quality / Standardisation of data

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Sweden's approach to EHDS readiness is characterised by proactive initiatives, strong collaboration between national agencies, and alignment with EU projects and standards. Through projects such as SENASH, the work of the National Interoperability Council, and active participation in EU-wide initiatives, Sweden is building a solid foundation for effective EHDS implementation. These efforts will enable Sweden to participate securely and efficiently in the EU's unified health data ecosystem, benefiting both healthcare and research (SFMI, 2024).

Data quality standards in Sweden differ between primary and secondary use settings. For primary use, the National Board of Health and Welfare has issued recommendations and promoted international standards such as International Classification of Diseases, 10th Revision (ICD-10), ICD-11 – International Classification of Diseases, 11th Revision (ICD-11), and Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT); however, their adoption is not currently mandatory (EIT Health , 2023).

Sweden has been collecting health data for 70 years. Even if the latest international data quality standards were adopted today, there would still be decades of legacy data from regional systems that would need to be structured, standardised, and made accessible for secondary use (EIT Health , 2023).

Resources

Resources and funding

The total cost and potential financial benefits of the EHDS are still uncertain. The Swedish Digitalisation Agency (DIGG) lacks comprehensive cost-benefit analyses for many digitalisation projects, which may lead to budget overruns or inefficient allocation of resources (SFMI, 2024).

Further limitations for data extraction in Sweden include insufficient documentation on available regional health data and limited capacity to fulfil complex data requests from multiple sources and formats. Although funding exists, it is widely agreed that it is likely inadequate to cover the full costs of EHDS implementation, which are estimated to be in the billions of euros at both EU and potentially national level. It remains unclear how these costs will be distributed across government, regional, and institutional levels, and many hospitals, despite being aware of future requirements, have very limited resources to meet them (EIT Health , 2023).

Human resources

Educational needs should not be underestimated for both future users and operators of the EHDS. Training is required in a range of areas, including regulatory affairs, digital literacy, cybersecurity, data quality management, data analytics, and artificial intelligence (EIT Health , 2023).

For example, the Stockholm region's EHR system lacks a clear structure for data extraction, necessitating highly skilled experts to retrieve information. This requires not only programming expertise, but also in-depth knowledge of international, national, and regional medical informatics, the relevant organisational structures, and the varying ways data are recorded across different EHR modules (EIT Health , 2023).

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Societal readiness

Seven decades of experience in sharing health data have fostered high public trust and openness towards its use for research and public health in Sweden. Decision-makers must nurture and protect this trust by ensuring legal clarity, transparency, and robust security, privacy, and ethical safeguards during implementation (EIT Health , 2023).

The EHDS expands patient data access, which may conflict with Sweden's strong emphasis on individual rights over personal health information. While Article 9.4 of the GDPR allows member states to apply stricter controls on the processing of genetic, biometric, and health data, the EHDS limits Sweden's ability to enforce such restrictions. This raises ethical concerns about patient consent and data autonomy (SFMI, 2024).

Data privacy and security

General Data Protection Regulation (GDPR)

Sweden generally demonstrates a high level of compliance with the GDPR, similar to other advanced EU member states. As an early adopter of robust data protection principles, Sweden has a well-established regulatory and institutional framework (SFMI, 2024), (EIT Health , 2023).

Data protection provisions

Sweden ranks among the leading European countries in terms of data protection. The Patient Data Act regulates the handling of patient data within the healthcare system to ensure the protection and confidentiality of patient information (SFMI, 2024), (EIT Health , 2023).

Health Data Access Bodies (HDABs)

Stockholm Centre for Health Data is a collaborative organisation within region Stockholm designed as a hub for researchers who require access to health data (only available in Region Stockholm) (EIT Health , 2023).

The SENASH project supports the development of HDABs. Still, overall governance remains fragmented. A national framework is needed to align security standards (eHealth Ministry Sweden, 2025).

Access and Control

Access rights

Patients in Sweden have legal rights to access their data. However, comprehensive access frameworks under EHDS, especially for cross-border scenarios – are not fully defined (SFMI, 2024).

Transparency

Sweden's transparency practices are established but incomplete. Concerns persist over limited public oversight, especially the use of 'letter commissions' which bypass open

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consultation. Legal frameworks and ethical oversight enable patient data access, but EHDS implementation raises concerns over stakeholder oversight and transparency. Current structures lack unified processes for equitable access and cross-border consistency (SFMI, 2024), (EIT Health , 2023).

Unified market for EHR systems

Harmonisation of standards

Standardisation of EHR systems is supported by the Interoperability Council. Full harmonisation is not yet achieved, with regional fragmentation still a barrier to EHDS integration (SFMI, 2024), (eHealth Ministry Sweden, 2025).

Promoting innovation

Technology-based solutions

Sweden supports innovation through national and EU-funded projects like SENASH and X-eHealth. Technical pilots and development of metadata systems reflect a proactive stance (SFMI, 2024). Investments are made in metadata systems, pilot environments, and interoperability tools.

Research and development

R&D capacity is growing with government and EU support. Challenges include the lack of cost-benefit analyses, sustainability concerns, and workforce training (SFMI, 2024).

Important additional remarks

Despite high digital maturity, Sweden faces challenges in transparency, security governance, and regional disparities. Economic and environmental sustainability of EHDS efforts remain unclear (EIT Health , 2023).

3.9 Netherlands

Governance

National

In the Netherlands, the Ministry of Health, Welfare and Sport (VWS) is the principal authority responsible for legislating and overseeing the use of health data, including matters of data privacy, electronic health records, and data exchange within the healthcare sector. The Dutch Data Protection Authority (Autoriteit Persoonsgegevens, AP) enforces data protection laws, ensuring compliance with the GDPR and relevant national legislation. Key initiatives such as the Electronic Data Exchange in Healthcare Act (Wegiz) regulate the digital sharing of health data among providers under the ministry's guidance. Health-RI (Health Research Infrastructure) supports a national infrastructure for research and innovation, promoting interoperability and secure data sharing among stakeholders. For cross-border data exchange, the National Contact Point for eHealth (NCPeH-NL) enables secure sharing of patient data with other EU countries,

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in accordance with European directives. The Netherlands is also actively aligning its health data systems with the EHDS framework (Bouwman, et al., 2022), (E. Peelen, 2024), (HealthRI, 2025).

National governance aspects still need to be adressed, particularly the health data access barriers- this process is still ongoing (Bouwman, et al., 2022), (E. Peelen, 2024).

Regional

National information applies (Bouwman, et al., 2022), (E. Peelen, 2024), (HealthRI, 2025).

National information applies (Bouwman, et al., 2022), (E. Peelen, 2024).

Legal and regulatory aspects

In the Netherlands, the legal and regulatory landscape governing health data is carefully crafted to safeguard personal information while supporting high-quality healthcare delivery. Central to this framework is the GDPR, which, as an EU regulation, sets out robust requirements for the lawful, fair, and transparent processing of personal data, including health information, and emphasises individual rights and data minimisation. Complementing the GDPR, the Dutch GDPR Implementation Act (DGIA) addresses specific national provisions, particularly regarding the processing of sensitive health data and the responsibilities of data controllers and rights of data subjects within the Dutch context. The Medical Treatment Contracts Act (WGBO) further underpins patient rights, requiring healthcare providers to maintain accurate records and granting patients access to, and control over, their own medical information. To promote interoperability and efficient care, the Wegiz mandates the standardised electronic exchange of key health data, such as medication records, among healthcare providers. Oversight is provided by the Dutch Data Protection Authority, which enforces data protection laws, investigates breaches, and ensures compliance with both the GDPR and DGIA. Additionally, the Netherlands Standardization Institute (NEN) has established standards – such as NEN 7510, 7512, and 7513 – to guide information security management in healthcare, focusing on confidentiality, integrity, and availability of health data. The Netherlands is also actively aligning its policies with the EHDS, an initiative designed to enable secure and standardised health data exchange across EU member states, thereby fostering better care, research, and innovation. Altogether, this comprehensive framework strives to balance the protection of individual privacy with the need for effective and transparent healthcare, ensuring that health data is managed with the utmost responsibility and care (Ministerie van Volksgezondheid, Welzijn en Sport, 2022), (Radboud University, 2022).

The Netherlands requires a national implementation law for the EHDS. Additionally, the Material Transfer Agreement (MTA) remains a key aspect that needs to be resolved (Ministerie van Volksgezondheid, Welzijn en Sport, 2022), (Radboud University, 2022).

Technical infrastructure

For primary use, the Netherlands is actively participating in the MyHealth@EU pilot project. Implementation of the Dutch Hub within this European network is overseen by CIBG, an executive agency of the Ministry of Health, Welfare and Sport. At present, Dutch health

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professionals can request health data from other EU countries when treating foreign patients in the Netherlands. However, it is not yet possible for foreign health professionals to access health data for Dutch citizens requiring treatment while abroad (Bouwman, et al., 2022), (E. Peelen, 2024).

The Ministry of Health also intends to appoint the lead HDAB in the coming year as part of the ongoing project. For secondary use of health data, the HDAB-NL project was launched at the end of last year and will run for four years. Its aim is to establish the Dutch HDAB, including key technical components such as a National Catalogue, a request application, in Dutch data aanvraag applicatie (DAAMS), and Secure Processing Environments. The project is led by the Ministry of Health in partnership with Health-RI, Statistics Netherlands (CBS), the National Institute for Public Health (RIVM) and ICTU, a government foundation which provides project coordination (Bouwman, et al., 2022), (E. Peelen, 2024).

Health data readiness

General state of health data

The Netherlands has made significant strides in health data readiness, focusing on the collection, management, and utilisation of health information. However, challenges remain, particularly in data integration and reuse (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

Challenges remain, particularly in data integration and reuse. Data quality and standards are insufficient for effective secondary use. Hospitals face issues with fragmented systems, paper documentation, and manual data transfer, especially in smaller, under-resourced healthcare providers (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

The Netherlands is actively working to align with the EHDS, an EU initiative aimed at facilitating secure health data exchange across member states. Health-RI collaborates with the Ministry of Health, Welfare, and Sport to implement EHDS regulations, particularly concerning the secondary use of health data (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

The health information system is fragmented, hindering seamless data exchange between healthcare providers. An OECD report emphasized the need for an integrated health information system to enhance data interoperability. Despite robust data collection, the Netherlands faces difficulties in effectively reusing health data for research and innovation. This challenge was highlighted during the 2022 Health-RI conference (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

Interoperability of data

The information on the secondary use of health data (EHDS2) applies (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

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Data quality / Standardisation of data

The Netherlands is highly proficient in collecting comprehensive health data, utilising a range of national registries and EHR. The National Institute for Public Health and the Environment (RIVM) plays a central role in coordinating and managing these data collection efforts (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

It is important to note that while electronic health records (EHRs) are widely used in the Netherlands, they are not yet fully standardised. For instance, an EHR from one hospital is often incompatible with that of another, resulting in limited interoperability across institutions. Addressing this lack of integration and working towards greater standardisation remains a significant challenge, and is an area where ongoing efforts are being made (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

Resources

Resources and funding

In terms of digital infrastructure, the Netherlands has adopted the "once-only principle," which ensures that citizens and businesses need only provide information to the government a single time, after which it is reused across various services. The NEN has established important standards – such as NEN 7510, 7512, and 7513 – that set guidelines for information security management in healthcare, focusing on the confidentiality, integrity, and availability of health data. Additionally, Nictiz, as the national centre for standardisation and eHealth, plays a key role in developing and implementing health information standards, thereby facilitating seamless data exchange across healthcare systems (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

Human resources

The Netherlands has made considerable progress in establishing a robust health data infrastructure, underpinned by a skilled workforce in health informatics and data management. Dutch universities and research institutions offer specialised programmes in health informatics and data science, equipping professionals with the expertise required to manage and analyse health data effectively. Key organisations such as Health-RI and Nictiz play central roles: Health-RI fosters an integrated national health data infrastructure to support research and innovation, while Nictiz develops and implements health information standards to ensure seamless data exchange across healthcare systems. A notable recent development is the introduction of government funding to subsidise the creation of patient portals in hospitals. These portals, accessible to patients following hospital visits, allow individuals to view their health records and thereby promote greater transparency and patient engagement in healthcare (Van der Heide, et al., 2013), (Mancino, 2023).

Societal readiness

The Netherlands demonstrates its commitment to societal readiness for health data use through its investment in professional development. Continuous learning opportunities (including workshops, seminars, and certifications) are available to ensure that the workforce remains up to date with the latest technologies and methodologies in health data management.

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By fostering a well-informed and agile professional community, the country strengthens public trust (Van der Heide, et al., 2013), (Mancino, 2023).

Data privacy and security

General Data Protection Regulation (GDPR)

As a member state, the Netherlands fully complies with the GDPR, which provides a comprehensive legal framework for the processing of personal data, including sensitive health information. The GDPR emphasises principles such as lawful, fair, and transparent data handling, data minimisation, and the protection of individual rights. In addition to the EU-wide regulation, the Netherlands has enacted the Dutch GDPR Implementation Act, which tailors GDPR provisions to the national context. The DGIA introduces specific guidelines and exceptions for processing special categories of personal data, such as health data, and clarifies the responsibilities of data controllers and the rights of data subjects within the Dutch legal framework (Dutch Ministry of Justice and Security, and Minister for Legal Protection, Dutch Implementation Act, 2021).

Data protection provisions

The Netherlands has established clear national provisions to support data protection under the GDPR through the Dutch Implementation Act, known as the Uitvoeringswet AVG (UAVG). This legislation provides detailed clarifications tailored to the national context, such as setting the age of consent for children at 16 and outlining specific conditions for processing sensitive data categories, including health and biometric data. It also includes provisions related to the handling of employee data and data processed for archiving purposes (Dutch Ministry of Justice and Security, and Minister for Legal Protection, Dutch Implementation Act, 2021).
Oversight and enforcement are carried out by the Dutch Data Protection Authority, the Autoriteit Persoonsgegevens (AP). The AP plays a key role in supervising GDPR compliance, investigating complaints, issuing fines, and providing guidance. It has been particularly active in enforcing regulations related to health data, consent mechanisms (such as cookie use), and data security breaches (Bouwman, et al., 2022), (E. Peelen, 2024).

Health Data Access Bodies (HDABs)

In the Netherlands, the Ministry of Health, Welfare and Sport (VWS) is leading the national strategy for the implementation of the EHDS, with particular responsibility for the legal and governance frameworks surrounding the establishment of HDABs. VWS is coordinating a technical implementation project (HDAB-NL) with project partners Health-RI, CBS, RIVM and ICTU. This project is developing and implementing the infrastructure needed to support secure and efficient access to health data. Health-RI in particular focuses on building systems that support data reuse and promote FAIR (Findable, Accessible, Interoperable, Reusable) data stewardship. Ongoing pilots and frameworks are currently being explored to establish effective mechanisms for data access authorisation, opt-out management, and overall governance, in preparation for full EHDS implementation (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

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Access and control

Access rights

In the Netherlands, patients are granted robust access rights to their health data. They are entitled to view their own EHRs, which may include laboratory results, imaging, prescriptions, and vaccination histories. Furthermore, individuals can request corrections to inaccurate or outdated information and exercise their right to data portability, enabling them to download and share their health data as needed. Patients also retain control over who may access their data, with the ability to give or withdraw consent for specific healthcare providers. These rights are supported by digital platforms such as Patiëntenportalen (patient portals), typically provided by hospitals and GP networks. In addition, the MedMij initiative (MedMiJ, 2025) provides a national standard for the secure and standardised exchange of health data between healthcare providers and patients, facilitating access through certified personal health environments (PGOs). For secondary use, authorised users like researchers, public health authorities, and policymakers, may access health data under strict conditions. Consent remains a cornerstone for both primary and many secondary uses of data, reflecting the country's commitment to patient privacy and autonomy. Some of this will change with the implementation of the opt-out mechanisms of mandated by the EHDS (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

Transparency

Transparency in the use of health data is a fundamental principle of GDPR and its Dutch implementation through the UAVG. These regulations require that individuals are clearly informed by data controllers about how their personal health data is collected, used, shared, and stored. This includes making people aware of the specific purposes of data use, such as for treatment or research, the legal basis for processing, who will have access to their data (including any third parties), the duration for which data will be retained, and the safeguards in place to protect their privacy. This transparency is typically ensured through privacy notices, informed consent forms, information leaflets when admitted to hospitals and public-facing registers. In practice, several Dutch tools and initiatives support and enhance transparency, including the MedMij Framework, Patiëntenportalen (patient portals), and Health-RI (MedMiJ, 2025), (HealthRI, 2025). When it comes to secondary use of data, transparency measures are even more rigorous. Individuals must be provided with clear information, often through consent forms or information leaflets. Public registries are used to document who has requested access to health data, a key feature in the EHDS. Additionally, Data Protection Impact Assessments (DPIAs) are conducted to identify and mitigate privacy risks before data processing occurs. Ethical review boards also play a critical role by ensuring that research involving health data aligns with established privacy norms (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

Unified market for EHR systems

Harmonisation of standards

Individual healthcare providers are responsible for the purchase and implementation of EHR systems. At this time medical records and their standards are therefore fragmented across caregivers, although attempts to standardization ad alignment exist and a regional level.

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Towards the future, the Netherlands is actively aligning its health data and digital health systems with broader European regulations, particularly the EHDS and the AI Act. Central to this alignment is the MedMij programme (MedMiJ programma, 2025), which serves as the national standard for personal health environments (PGOs). This initiative enables patients to access and manage their health data across different healthcare providers by requiring the use of interoperable formats and application programming interfaces (APIs) in line with EU standards, such as HL7 FHIR. MedMij served as a precursor to the EHDS, setting a practical example for cross-institutional and, eventually, cross-border health data exchange. Nictiz, the Dutch competence centre for digital information exchange in healthcare, plays a key role in supporting harmonisation through the development and promotion of semantic and technical standards, including Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT), Logical Observation Identifiers, Names, and Codes (LOINC) and Health Level Seven (HL7). These standards ensure smooth integration of EHRs across various systems and institutions.

The Netherlands also enforces the EU Medical Device Regulation (MDR) via the Health and Youth Care Inspectorate (IGJ), ensuring that medical devices meet harmonised European requirements. This includes classification based on risk, demonstration of clinical efficacy, and the application of Unique Device Identification (UDI) protocols. In parallel, digital health applications and Software as a Medical Device (SaMD) are subject to increasing scrutiny. These technologies are evaluated through bodies such as Zorginstituut Nederland to ensure cost-effectiveness and adoption in care. In the domain of artificial intelligence, the Netherlands supports the AI Act and contributes to its implementation through the NL AI Coalition. This coalition coordinates national efforts to develop, test, and regulate AI in health, emphasising safety, fairness, and transparency in accordance with EU ethical and legal standards (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024).

Promoting innovation

Technology-based solutions

The Dutch approach to digital health and technology-based innovation is strategically coordinated at the national level, while drawing strength from close collaboration between government, academic institutions, healthcare providers, and industry. Central to the country's digital health agenda is the empowerment of citizens through digital access to their health data, the promotion of interoperability and standardisation across healthcare systems, and the acceleration of AI and data-driven tools that can enhance both clinical care and research. A strong emphasis is also placed on the integration of validated digital solutions into routine medical practice. Several concrete examples illustrate this technology-forward approach, including the aforementioned PGOs enabled by the MedMij framework. In addition, AI-based solutions are increasingly being trialled in areas such as radiology, pathology, intensive care, and mental health. Telehealth and remote monitoring are also expanding rapidly, with a growing number of clinically validated apps now embedded in the care of chronic conditions, mental health management, and rehabilitation programmes. To foster such innovation, the Netherlands can count on dedicated organisations and initiatives such as Health-RI and AI regulatory sandboxes. Funding is provided through national mechanisms such as the Topsector Life Sciences & Health (LSH), targeted ZonMw (The Netherlands Organisation for Health Research and Development) digital health calls, and the MIT-regeling, which supports SMEs.

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This financial support is complemented by collaborative innovation ecosystems that include Health Valley Netherlands, the Amsterdam Health & Technology Institute (AHTI), EIT Health nodes, and various regional testbeds (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024), (Topsector Life Sceinces & Health (LSH), 2025).

Research and development

The Netherlands demonstrate a strong commitment to advancing R&D through the strategic use of health data, supporting both academic biomedical science and industry-led innovation. The country's health data research ecosystem is underpinned by a highly collaborative environment in which Health-RI plays a central role. R&D is also strongly supported through dedicated funding programmes. ZonMw, the Netherlands Organisation for Health Research and Development, funds research initiatives in areas such as personalised medicine, AI in health, and the use of real-world data during the COVID-19 pandemic. Similarly, the Dutch Research Council (NWO) provides financial support for data-intensive research across life sciences and digital society domains, reinforcing the interdisciplinary nature of health data innovation. The Netherlands fosters strong collaboration between academia, industry, and government through Topsector Life Sciences & Health (Rijksdienst voor Ondernemend Nederland (RVO) (o.J.) Life Sciences & Health., 2025) and Health~Holland, which coordinate national health innovation agendas, as well as through innovation hubs like the Leiden Bio Science Park (HealthRI, 2025), (Bouwman, et al., 2022), (E. Peelen, 2024), (Topsector Life Sceinces & Health (LSH), 2025), (Health~Holland, 2025).

Important additional remarks

The Netherlands demonstrates a high level of societal readiness for health data integration, supported by widespread digital literacy, public health initiatives, and the growing adoption of digital health technologies. As of 2021, around 79% of Dutch citizens aged 16–74 possessed basic or higher-level digital skills, ranking the country among the EU leaders in digital proficiency. Programmes to enhance health literacy have also been implemented, aiming to improve individuals' ability to access, understand, and use health information effectively (Van der Heide, et al., 2013), (Mancino, 2023). The adoption of digital health tools (including telemedicine, electronic health records, and mobile health apps) has increased, especially during the COVID-19 pandemic, which accelerated the shift to remote healthcare solutions. Government-led campaigns have further promoted the use of digital tools for health monitoring and prevention, contributing to public engagement. Despite these strengths, challenges remain. A digital divide persists among certain population groups, such as older adults and individuals with lower incomes, who may have limited access to digital resources. In addition, privacy and data security concerns continue to affect public trust. Addressing these issues will be crucial to fully harness the societal benefits of health data use (Van der Heide, et al., 2013), (Mancino, 2023)

Comments

The successful implementation of the EHDS in the Netherlands requires addressing several key ethical, regulatory, and practical challenges.

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Ethical considerations include ensuring strong data privacy and security measures to maintain public trust, along with clear, robust frameworks for obtaining informed consent, particularly for the secondary use of health data.
Regulatory alignment is also crucial. The EHDS must harmonise with existing EU legislation, such as the GDPR, the Data Governance Act, and the upcoming Data Act, while also promoting standardization and interoperability to enable seamless data sharing across diverse health information systems.
On the practical level, the Netherlands must invest in secure infrastructure and IT systems, as well as in training healthcare professionals. Active engagement of all relevant stakeholders (patients, providers, researchers, and policymakers) is essential to shape an inclusive and responsive EHDS framework. Additionally, raising public awareness and improving digital literacy through targeted education efforts will be vital to foster societal trust and acceptance. Overall, a comprehensive, multi-stakeholder approach is required to successfully implement the EHDS and unlock its full potential for health innovation, care delivery, and research.

3.10Greece

Governance

National

The Ministry of Health is responsible for appointing such an authority and intends to do so (Ministry of Health, 2025).

Regional

National information applies (Ministry of Health, 2025).

Legal and regulatory aspects

GDPR governs the legal process for sharing data for research purposes, but the Ministry of Health currently restricts access (Ministry of Health, 2025).

Technical infrastructure

The National Contact Point for eHealth supports cross-border sharing of digital prescriptions and patient summaries, though actual data exchange depends on bilateral agreements between member states. Healthcare organisations vary in their readiness to share additional data, influenced by local infrastructure and data management. The Ministry of Health is working to improve this through the H-DAB initiative. Research infrastructures such as ELIXIR are also available (NCPE Health, 2025), (GRNET, 2025).

Health data readiness

General state of health data

There are several data registries and some data repositories in place. However, the data are predominantly unstructured, fragmented, and remain isolated in separate silos. Furthermore, data quality is often inconsistent (OHDSI Europe, 2025), (RadRounds, 2025).

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Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

There are trusted research environments for certain health disciplines, such as rheumatology, where data is accessible for research within specific healthcare organisation networks. However, overall availability is limited. While several clinical studies take place across Greece, their data remain restricted to the scope of each study and are not accessible for broader research purposes. In general, real-world data are not ready for secondary use, as most healthcare organisations lack the necessary infrastructure to anonymise data and align it with international standards (Veles, n.d.), (OHDSI Europe, 2025).

Interoperability of data

National procurement criteria include several international interoperability standards, such as HL7 and DICOM, though their implementation varies across healthcare organisations. Some efforts are underway, for example through the ODHSI programme, to prepare data sets according to the OMOP-CDM for secondary use, but this practice is not yet widespread. The Ministry of Health and IDIKA participate in various joint actions and initiatives to promote interoperability, although concrete outcomes have yet to be realised (OHDSI Europe, 2025).

Data quality / Standardisation of data

Actions to ensure data quality at the point of entry are very limited. Some data are required to adhere to ICD-10 standards. Recently, hospitals have been required to use DRGs to promote uniformity in billing for healthcare activities, including diagnostics and patient data (OHDSI Europe, 2025), (Institute of DRG (INSTDRG), 2025), (European Commission, 2025).

Resources

Resources and funding

EU joint actions have funded the Ministry of Health in developing necessary tools and infrastructure, though the long-term sustainability of these efforts remains uncertain. European Digital Innovation Hubs, such as smartHEALTH, offer expertise to public and private organisations, including test-before-invest services and training (Ministry of Health, 2025), (National Organisation for Medicines (EOF), 2025).

Human resources

The are no actions taken to raise awareness for the importance of health data collection and secondary use amongst citizens, healthcare professionals or policy makers beyond the scope of specific clinical trials, or MoH programs. There is a great need for appropriately trained staff with skills such as IT and project management. Public Healthcare organisations are largely understaffed. There is lack of incentives to support health care professionals to collect quality data that could be used for secondary purposes or to share data that already exists (Ministry of Health, 2025).

Societal readiness

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🟨 No specific actions have been taken to prepare the public for these developments. While GDPR provides some coverage of relevant issues, several matters remain unaddressed, including the absence of clear opt-in or opt-out procedures (Ministry of Health, 2025).

Data privacy and security

General Data Protection Regulation (GDPR)

🟩 Greece fully complies with the GDPR through national Law 4624/2019. Public hospitals and healthcare institutions have appointed Data Protection Officers, and the Hellenic Data Protection Authority conducts regular audits. GDPR-compliant digital health services, such as ePrescription and the ATLAS (National Health Care & Insurance Capacity Registry) platform, are widely implemented (Ministry of Health, 2025).

Data protection provisions

🟨 While Greece ensures basic GDPR compliance, advanced data protection mechanisms – such as real-time pseudonymisation, anonymisation infrastructure, and decentralised consent management – are underdeveloped. No national technical standard exists for secure secondary data use, and supervisory mechanisms remain fragmented. The legal framework supports privacy protection, but institutional implementation varies. Progress is needed to align with EHDS requirements for robust, interoperable data safeguards (Ministry of Health, 2025).

Health Data Access Bodies (HDABs)

🟥 Greece has not yet established an official HDAB as required by the EHDS regulation. Although a department within the Ministry of Health receives applications for secondary data use, the decision-making process lacks transparency. Access to secondary-use health data remains uncoordinated, with no central authority to evaluate or approve requests. This institutional gap hinders participation in EU health data initiatives and is a major barrier to EHDS compliance. Legislative and operational frameworks for the HDAB are still in development (GRNET, 2025).

Access and control

Access rights

🟩 Greece fully implements GDPR through national legislation (Law 4624/2019). Healthcare institutions adhere to strict data protection rules, with Data Protection Officers appointed in most public hospitals and regular audits by the Hellenic Data Protection Authority (HDPA). The Ministry of Health's Data protection officer (DPO) also provides updated guidance to healthcare organisations (Ministry of Health, 2025).

🟥 An office within the Ministry of Health receives applications for secondary use of data, with the Ministry's DPO responsible for access decisions. In most cases, access to secondary health data is not granted (Ministry of Health, 2025).

Transparency

🟨 Although GDPR is enforced, advanced safeguards such as real-time pseudonymisation, anonymisation infrastructures, and secure multiparty computation remain limited, with sector-specific best practices developing only gradually. Patient access to medical data is guaranteed

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by GDPR and eHealth legislation, but practical implementation differs between institutions and a unified national access portal is still in progress. While several national and EU-funded projects utilise health data for research and development, fragmented data governance, limited data quality, and the absence of HDABs hinder streamlined access and broader use (Ministry of Health, 2025), (GRNET, 2025).

The Ministry of Health's Department of Therapeutic Protocols and Health Records receives applications for secondary data use, decision-making lacks transparency. There is limited clarity on how patient data is reused, and no standard national mechanism exists for informing data subjects about processing (Ministry of Health, 2025).

Unified market for EHR systems

Harmonisation of standards

Greece utilises national EHR systems such as IDIKA (Governance Center for Social Security) and ATLAS, but adoption of EU-recommended standards like HL7 FHIR is limited, and a national interoperability framework is not yet fully in place. ICD-10 and DRGs are implemented in hospitals, with the DRG Institute developing guidelines for international standards within the Greek NHS (Institute of DRG (INSTDRG), 2025).

There is no mechanism for co-creating or evaluating AI systems, nor for health technology assessment (HTA) of digital health solutions to support reimbursement. Consequently, digital health apps and devices have not entered the Greek market via the National Health System (Ministry of Health, 2025).

Promoting innovation

Technology-based solutions

Greece supports technology-driven health solutions through R&D funding, but lengthy procurement processes often result in products remaining experimental and not integrated into the National Health System. Centralised procurement favours large tech companies, limiting SME participation and innovation. National initiatives, such as the IDIKA platform and digital prescription services, are centralised and closed to wider market entry. While Greece participates in EU-funded projects involving IoT, AI, and data analytics, there are no internal mechanisms within healthcare organisations to promote or fund innovation. Projects like SymbIASIS aim to connect companies with hospitals, but lack sustainable funding. Data on healthcare system needs is not routinely collected to inform procurement, and systems acquired through fundraising are rarely integrated with hospital information systems. Alignment with EHDS priorities is ongoing, supported by EHR deployment and stakeholder engagement (Ministry of Health, 2025).

There is no HTA mechanism for digital health systems to support reimbursement, so digital health apps and devices have not entered the Greek market via the National Health System (Ministry of Health, 2025).

Research and development

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Health data-driven R&D in Greece is supported through participation in EU projects and collaborations with academia and public hospitals. However, there is no streamlined national framework for secondary data use, and access to large-scale datasets remains fragmented due to limited infrastructure for anonymisation and data federation. Ethical review processes exist but are often slow. While national strategies to enhance data reuse are underway, a formal HDAB is still lacking. Greece has established a national infrastructure for precision medicine, but it is not integrated with the National Health System or hospital information systems (Ministry of Health, 2025).

Important additional remarks

Health data-driven R&D in Greece is supported through participation in EU projects and collaborations with academia and public hospitals. However, there is no streamlined national framework for secondary data use, and access to large-scale datasets remains fragmented due to limited infrastructure for anonymisation and data federation. Ethical review processes exist but are often slow. While national strategies to enhance data reuse are underway, a formal Health Data Access Body is still lacking. Greece has established a national infrastructure for precision medicine, but it is not integrated with the National Health System or hospital information systems (Ministry of Health, 2025).

Comments

Promote the establishment of a national Health Data Access Body and a central authority for data governance. Provide dedicated funding to support data preparation, including cleaning and harmonisation, for secondary use. Develop clear legal guidance to enable the ethical reuse of health data. Invest in strengthening digital skills across the health workforce to ensure data is used ethically, securely, and effectively.

3.11 Ukraine

Governance

National

The healthcare system in Ukraine is chiefly overseen by the Ministry of Health, with its principal source of funding provided by the National Health Service of Ukraine (NHSU). The cornerstone of this financing is the Medical Guarantee Programme, administered by the NHSU, through which medical institutions receive payment for services rendered under formal contracts. For the primary care level, it is the capitation payments, not per service (Yesakov, 2025). There are approximately forty distinct healthcare packages, ranging from primary to specialised care, collectively covering around 50% of the total cost of services – amounting to some €32 billion. Of the remainder, roughly 5% is financed through insurance, whilst patients themselves bear the cost of the remaining 45% through out-of-pocket payments (Yesakov & Korytnyi, 2025), (World Health Organisation, n.d.), (Landlord, 2024), (Finance.ua, 2024), (Ukrayinska Pravda. Life , n.d.).

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Ukraine is developing new documents to strengthen regulation in this field, including draft laws aligning national legislation with European standards – particularly the GDPR – and updated standards for data security in medical systems. Coordination is led by Maria Karchevych (Deputy Minister of Health), the National Health Service of Ukraine (Dmytro Chernysh) and the State Enterprise E-Zdorovye (Oleksandr Yemets), united under the Ministry of Health's Office for Coordination of eHealth Development. There are no separate regional regulations; policy is set nationally within the Unified Healthcare System (UHS), while regional authorities oversee implementation, fund hospital digitalisation and coordinate cooperation. The framework is grounded in national law and international standards. The Constitution guarantees protection of personal data (Article 32) and the right to health care (Article 49). Key acts include the Law on Personal Data Protection (2010), Electronic Trust Services (2017), Cybersecurity (2017), State Financial Guarantees of Medical Care (2017, establishing and funding the EHS via the NHSU) and Electronic Communications (2020). Implementation is detailed in Cabinet resolutions No. 411 (2018) on EHS functioning, No. 785 (2021) on e-prescriptions and digital records, and No. 1175 (2021) on patient access to data. Ministry orders include No. 587 (2020) on connecting institutions to the EHR and No. 311 (2021) on record storage and MIS integration. International guidance – GDPR, ISO 27799:2016 and the WHO Digital Health Strategy – shapes practice, with responsibilities shared among the MoH, NHSU, SSSCIP and the MoH Digital Transformation Office (Yesakov & Korytnyi, 2025), (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Ukraine must introduce robust legislation to regulate health data processing, storage, and sharing, with alignment to GDPR and European standards. Improvements are needed in three areas: data quality, secondary use, and protection. Data entry by healthcare professionals should be standardised to ensure accuracy and completeness, and the electronic health system (EHS) must expand beyond primary care to include inpatient, laboratory, and radiological data. Comprehensive data collection and analysis are crucial, though current server capacity limits performance.

A clear legal framework for secondary data use is essential, enabling access to anonymised EHS data for research, drug development, and medical technologies, including AI. Accelerating alignment with the EHDS will facilitate participation in European projects and funding.

Strengthening data protection and cybersecurity is vital, with improved anonymisation to protect patient identities. Pseudonimisation is already in place (Yesakov & Korytnyi, 2025). EHS needs stronger safeguards against cyberattacks, highlighted by the ongoing conflict. Transparent communication about data use and protection is key to building public trust in digital health systems (gov.ua, 2023).

Regional

Ukraine's healthcare system is highly centralised, with regional departments encountering the same challenges as those at the national level. Most hospitals have limited financial and managerial autonomy, and many managers are clinicians with little formal management experience, so major decisions are seldom made independently. There is generally a poor

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standard of cybersecurity, data management, and practical GDPR compliance at regional and local levels among practitioners, alongside a low level of digitalisation in state hospitals and ambulatory care settings (Yesakov & Korytnyi, 2025), (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Legal and regulatory aspects

Ukraine has an established legal framework for regulating health data, though further improvement is needed. Key documents include: the Law "On Personal Data Protection," which governs the processing of medical data; the Law "On Electronic Documents and Electronic Document Management," setting rules for electronic documents in healthcare; and the Law "On Electronic Medical Records," which supports the introduction of electronic records. The Ministry of Health has issued orders regulating the maintenance of electronic medical records and specifying technical and organisational requirements for the eHealth system. Additionally, the Strategy for the Development of the Digital Economy and Society (2021-2025) outlines priorities for advancing eHealth and medical data processing (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Technical infrastructure

Ukraine's health data space centres on the Electronic Health System (EHS) with a Central Component (CC) operated by the NHSU. The CC manages national clinical and administrative data, registers patients and providers, supports e-prescriptions, sick leave, referrals, and patient accounts, and aggregates data for financing (including capitation). MIS used by providers maintain records, generate referrals/prescriptions, report to the NHSU, and integrate via the CC's APIs; examples include Helsi, MedAir, Medstar, Askep, and Electronic Hospital. The Master Patient Index (MPI) uniquely identifies individuals using attributes (e.g., phone, passport, TIN, ID) and stores administrative data only; clinical histories are held in the Centralised Clinical Data Repository (CCDR). Patient access is delivered by decentralised Patient Information Systems (PIS); there is no national portal yet, and appointments are provided by specific PIS–MIS integrations. Cybersecurity uses OAuth 2.0 authentication, ABAC authorisation, practitioner digital signatures, disk-level encryption, pseudonymisation of clinical payloads, audits/penetration testing, and certification by Derzhspeczvyazok. The EHS links to state registries (legal entities, electronic sick leave with the Pension Fund, Civil Status, State Registry of Individuals, MIA, and Finance). Diia accesses EHS data one-way. Overall, the architecture enables secure, pseudonymised data exchange and practical access for patients and clinicians (Yesakov & Korytnyi, 2025), (World Health Organisation, n.d.), (Landlord, 2024), (Finance.ua, 2024), (Ukrayinska Pravda. Life , n.d.).

Ukraine's technical infrastructure for medical data is anchored by the national Electronic Health System (EHS), creating a unified space where health data are securely collected, stored, and processed. Uniform data standards (e.g., ICD-10) are already in place, and interoperability is mediated via the Central Component (CC): Medical Information Systems (MIS) exchange data

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seamlessly with the CC rather than directly with each other. Security uses encryption in transit and at infrastructure/storage level (already implemented; further cryptography needs clear justification), OAuth 2.0 for authentication (no multi-factor at present), Attribute-Based Access Control (ABAC) for authorisation, and practitioners' digital signatures on clinical entries. Patient-facing "accounts" exist only in some MIS and may be fee-based. Functionality is expanding through telemedicine and AI for analytics, and integrations with state services, including one-way Diia access to EHS data, are active and growing. Multi-factor authentication can be considered as a future enhancement (Yesakov & Korytnyi, 2025), (gov.ua, 2023).

Health data readiness

General state of health data

Ukraine's health data ecosystem is anchored by the Electronic Health System (EHS), which securely collects, processes, and exchanges information across certified Medical Information Systems via the Central Component (CC). Interoperability uses standardised models (e.g., ICD-10), identity is managed by the Master Patient Index (MPI), and clinical histories reside in the Centralised Clinical Data Repository (CCDR). Security and compliance rely on OAuth 2.0 (no multi-factor yet), ABAC, practitioner digital signatures, infrastructure encryption, and GDPR-aligned pseudonymisation. EHS supports e-prescriptions, referrals, sick leave, and financing/reporting (including capitation). Patient access is via decentralised PIS; no national portal yet, and appointments depend on PIS-MIS integrations. State-system links (including one-way Diia access) enable eligibility checks and public health functions. Standardised, pseudonymised datasets and governed APIs support secondary use for research, AI analytics, and telemedicine (Yesakov & Korytnyi, 2025), (World Health Organisation, n.d.), (Landlord, 2024), (Finance.ua, 2024), (Ukrayinska Pravda. Life , n.d.).

Secondary use of health data (EHDS2)

Research and innovation & policy making and regulation

The secondary use of health data, particularly within the framework of the EHDS2 initiative, is becoming increasingly important for enhancing Ukraine's healthcare system. This topic is gaining relevance, as secondary use enables greater efficiency in medical care, research, and data analysis. While Ukraine already has some practices for collecting and processing health data, formalising and improving their use for secondary purposes remains necessary.

Ukraine is actively working towards the adoption of international standards and recommendations for health data usage. Plans include developing a national strategy for secondary use, with robust mechanisms for data collection, storage, and analysis. Infrastructure improvements are also on the agenda, with the introduction of modern technologies such as big data and advanced analytics. Furthermore, Ukraine intends to collaborate with international partners to implement best practices, and to invest in education and professional development for healthcare professionals and data analysts. Such training may be supported by the EDIH network, which is set to launch in 2025 (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

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Interoperability of data

Ukraine's health data interoperability is improving but remains uneven. The national eHealth system underpins exchange across hospitals and pharmacies, enabling services such as e-prescriptions, referrals and COVID certificates. Technically, HL7 FHIR is recommended and supported via APIs and cloud services, but adoption, conformance testing and profile use vary. Semantically, standards like SNOMED CT, LOINC, ICD and ICPC-2 are applied inconsistently, limiting comparability and secondary use. Organisationally, governance has strengthened, yet consistent policy execution, clear roles and enforceable quality standards are still required. To align with the EHDS, priorities include mandated national FHIR profiles with guidance and testing, coordinated terminology management, standardised identity and data-quality procedures, and robust consent, audit and security controls enabling lawful, reproducible and cross-border data use (Yesakov & Korytnyi, 2025), (World Health Organisation, n.d.), (Landlord, 2024), (Finance.ua, 2024), (Ukrayinska Pravda. Life , n.d.).

However, several challenges remain. Healthcare systems across Ukraine are fragmented, with hospitals and medical facilities often using incompatible software solutions. Standardisation is also insufficient; although the Ministry of Health recommends international standards such as FHIR, HL7, and DICOM, their full implementation is still underway. Data protection and security pose further difficulties, as compliance with personal data legislation requires robust encryption and secure access mechanisms (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Further improvements are needed to expand the use of FHIR standards, enhance interoperability between private and public health information systems, and implement a comprehensive national healthcare data strategy. HL7 is not used. While Ukraine has made significant progress in establishing an interoperable health data space, considerable work remains to achieve truly seamless data exchange both within the country and with international partners (Yesakov & Korytnyi, 2025), (gov.ua, 2023).

Data quality / Standardisation of data

High-quality, standardised healthcare data underpins effective electronic health record (EHR) operations, supports clinical decision-making, and enables reliable information exchange across institutions. In Ukraine, data quality is defined by accuracy, completeness, consistency, relevance, and accessibility, and these attributes guide improvement efforts within the national eHealth ecosystem.

Ukraine's approach to standardisation draws on international norms, with important clarifications. HL7 v2 is not used in the Ukrainian EHS. FHIR is the principal modern standard for exchanging medical data within EHRs. ICD-10 codes diagnoses across care settings, while ICPC-2 supports coding at the primary care level. SNOMED CT is being implemented to unify clinical terminology. LOINC facilitates the exchange of laboratory results, and DICOM governs medical imaging (CT, MRI, X-ray).

Implementation is coordinated by the Ministry of Health (MoH) and the National Health Service

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of Ukraine (NHSU), which regulate standards for electronic records. The unified EHS is progressively integrating international standards to strengthen interoperability between institutions, with FHIR enabling streamlined interactions across connected Medical Information Systems. LOINC-based integration of laboratory data enhances interoperability and supports automated transfer of test results (Yesakov & Korytnyi, 2025), (World Health Organisation, n.d.), (Landlord, 2024), (Finance.ua, 2024), (Ukrayinska Pravda. Life , n.d.).

Improving data quality in healthcare rests on a few essentials: using an EHR as a single digital source, automating data entry to minimise human error, employing a national patient identifier to prevent duplicates, and enforcing real-time data validation to ensure correctness and completeness.
To further enhance quality and standardisation: broaden the use of SNOMED CT; require compliance with international standards across public and private providers; and continue automated data-quality checks for duplicates, inaccuracies, and missing data – recognising that the EHS Central Component (CC) already performs this. Training should remain with MIS vendors under Ukraine's public–private model, where the state provides the Central Component and multiple MIS connect to it. Standardising and digitising clinical guidelines, potentially using CQL, would improve consistency. Establishing a separate national data centre is not clearly justified for data quality/standardisation, given EHS is already hosted in a Ukrainian data centre.
Ukraine is progressing, but gaps persist. Continued adoption of FHIR, SNOMED CT, and LOINC, coupled with targeted automation, will improve accuracy, interoperability, and efficiency, supported by ongoing financial and human resources (Yesakov & Korytnyi, 2025), (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Ukraine faces several recurring challenges in health data quality, with important nuances. Apparent fragmentation across different clinical systems is a common issue internationally; however, when a robust data-exchange standard such as FHIR is in place, the internal storage format of individual systems matters far less, as interoperability is achieved through the standard interface. Duplicate and incomplete records persist where a single, unified longitudinal record is not consistently maintained across facilities. Inconsistent data entry – especially free text without shared templates or controlled vocabularies – introduces inaccuracies and limits reuse. Patient identification errors, stemming from incorrect names, dates of birth, or identifiers, further degrade data quality and complicate record linkage (Yesakov & Korytnyi, 2025), (gov.ua, 2023).

Resources

Resources and funding

Ukraine is actively participating in the EU4Health programme, an initiative of the European Union designed to strengthen health systems. As of January 2025, Ukraine is implementing 14 joint projects under this programme, with a total confirmed budget of €8.84 million – 80%

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funded by the European Commission and 20% contributed by Ukrainian institutions. The development of Ukraine's health data space is supported by both financial and human resources, with EU4Health playing a significant role.
Nationally, funding is provided according to the Law of Ukraine "On State Financial Guarantees of Medical Care for the Population", which ensures a guaranteed package of medical services through the Medical Guarantee Programme (MGP). The National Health Service of Ukraine (NHSU) serves as the sole national purchaser of healthcare services, contracting with providers of all forms of ownership and paying for the services delivered. Although state funding is increasing each year, it remains insufficient and continues to place a considerable financial burden on patients (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Human resources

Human resource development is central to Ukraine's healthcare modernisation. Management courses (e.g., "Human Resources in Healthcare") strengthen leadership, while innovative training centres are needed to advance clinical skills and continuous professional development. Digital transformation via eHealth demands IT, data, and interoperability expertise, creating new roles; an official eHealth knowledge base consolidates resources. International support, national funding, and targeted skills development enable an interoperable health data space; alignment with European standards requires a robust regulatory framework, technical infrastructure, and consistent governance of interoperability standards. Ukraine maintains an eHealth knowledge base – the Electronic Healthcare Education System (EHES). Recent conferences set digital priorities for 2024; EU4DIGITAL reports inform cross-border interoperability pilots. The e-Health Association convenes MIS vendors, MoH, and the state eHealth enterprise; Ukraine joined the European Digital Identity Wallet consortium in 2022, strengthening identity and trust. Security should be risk-based across all critical services (including e-Prescriptions). Success depends on adoption by clinicians and citizens, supported by training, clear guidance, and ongoing engagement (Yesakov & Korytnyi, 2025), (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Societal readiness

Digital literacy in Ukraine is gradually improving, helping the rollout of eHealth services. However, challenges remain, especially in rural areas where access to devices and the internet is limited. Some citizens still struggle with online appointments or remote consultations due to a lack of technical skills or resources. Most Ukrainians view digital health services positively, seeing them as convenient and modern, but greater awareness and training are needed to fully realise their benefits.
Healthcare professionals require training to use new digital tools effectively; insufficient preparation can hinder the adoption of eHealth solutions. Attitudes among staff are mixed – some welcome digitalisation for its potential to improve services, while others are resistant due

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to traditional habits or concerns about increased workload. Education and support are vital during this transition.
Institutionally, the Ukrainian government is working to create a unified medical space and integrate healthcare facilities into a common system. The Cabinet of Ministers has approved the Healthcare System Development Strategy for 2025–2030, which focuses on digitalisation, telemedicine, and AI, aiming to make the system more resilient and transparent.The strategy includes the introduction of an electronic healthcare system for reliable data and decision-making, the integration of research institutions, and new laws regulating public health. Overall, successful implementation of the health data space in Ukraine depends on improving digital literacy, staff training, and public awareness, alongside strategic planning and legislative support. This will enhance the quality and efficiency of healthcare nationwide (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Data privacy and security

General Data Protection Regulation (GDPR)

Ukraine is not an EU member, so the GDPR does not directly apply to Ukrainian organisations. However, Ukraine is actively harmonising its laws with European standards, and the Law "On the Protection of Personal Data" incorporates many similar principles. Ukraine's approach to data protection is essentially "de facto implementation" – if a Ukrainian company processes the personal data of EU citizens (such as offering services to Europeans, operating in the EU, or monitoring EU users online), it must comply with the GDPR or risk significant fines. Ukrainian legislation, specifically Law No. 2297-VI, is similar to the GDPR but less strict, with lower penalties. For instance, it guarantees data access rights but does not go as far as GDPR provisions like the right to be forgotten or data portability. Under the Association Agreement with the EU, Ukraine has committed to further aligning its data protection laws with European standards, including amending its legislation to closely match the GDPR (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Data protection provisions

In Ukraine, there is no separate law specifically addressing the protection of personal data in healthcare. Instead, these matters are regulated by the general Law on the Protection of Personal Data (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Health Data Access Bodies (HDABs)

Ukraine has not yet established an official HDAB as required by the EHDS regulation. However, the Ministry of Health has appointed a deputy for digitalisation and created a state enterprise, Electronic Health, which coordinates activities among stakeholders and manages the main state health database (gov.ua, 2023).

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Access and control

Access rights

Secondary use of medical data in Ukraine is permitted under strict personal-data protection rules. The core principle is de-identification; in practice, clinical data within the national Electronic Health System (EHS) are already pseudonymised, so they cannot be linked to personal identifiers outside the Central Component (CC). Use-case examples (research, AI development, system planning) are valuable but should be placed in dedicated sections rather than here.

Legal basis: the Law of Ukraine "On the Protection of Personal Data" governs collection, processing, storage, and secondary use, requiring anonymisation or pseudonymisation for statistical or scientific purposes. The Law "On Electronic Trust Services" and related regulations ensure integrity, qualified electronic signatures, and secure circulation of electronic records. In short, re-use is lawful only when data are de-identified and legal requirements are rigorously followed (Yesakov & Korytnyi, 2025), (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Transparency

Transparency in the use of medical data in Ukraine is governed by several key laws that balance public access with patient privacy. The Law of Ukraine 'On the Protection of Personal Data' guarantees individuals the right to access their own medical data and restricts its use or disclosure without consent, ensuring patients know who is processing their data and for what purpose.

The Law 'On Access to Public Information' allows public access to generalised, anonymised, and statistical information from state bodies and healthcare institutions, such as hospital financial reports, disease statistics, and procurement data, but does not grant access to personal patient data.

Ukrainian healthcare legislation further protects medical confidentiality, limiting access to health information, medical history, and diagnoses to authorised persons in legally defined cases.

In practice, transparency is supported by the Electronic Health System (eHealth), which gives patients secure access to their own medical records, referrals, and prescriptions, while anonymised data is published for public analysis, research, and oversight. Thus, Ukraine achieves transparency by keeping personal data confidential and making aggregated, anonymised information publicly available (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Unified market for EHR standards

Harmonisation of standards

In Ukraine, the support and regulation of the single market for electronic medical records, medical devices, and high-risk artificial intelligence systems is managed through comprehensive

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legislation and government initiatives aimed at harmonising with European standards. The central Electronic Health System (eHealth) forms the foundation for a unified electronic space for medical data, ensuring secure access for patients and healthcare professionals. Regulation of medical devices follows principles aligned with EU directives, guaranteeing quality and safety. High-risk AI systems, viewed as specialised medical devices due to their direct impact on patient health, are subject to strict evaluation for safety and effectiveness. AI regulation is still being developed, with the Ministry of Digital Transformation publishing a 'White Paper' that reflects the European approach. Ukraine's interoperable eHealth system currently integrates over 30 medical IT solutions via open APIs, supporting a connected and secure healthcare environment (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Full interoperability with EU systems and EHDS certification remain pending. In the interim, cross-border clinical data exchange could be advanced by implementing the International Patient Summary (IPS), providing a standardised, concise snapshot of a patient's key clinical information to support safe care across borders. This would be a pragmatic step towards EU alignment while broader EHDS compliance is pursued (Yesakov & Korytnyi, 2025), (gov.ua, 2023).

Promoting innovation

Technology-based solutions

Ukraine's digital healthcare is delivered through a public–private partnership centred on the national eHealth system, which combines a state-owned Central Component with privately developed Medical Information Systems (MIS). The Central Component provides the core platform and national services, while MIS vendors supply clinician- and patient-facing applications that connect to it. Funding is mixed: the Central Component is financed from the state budget and operated by the National Health Service of Ukraine and the state-owned enterprise Electronic Health, though audits indicate these resources are insufficient; substantial international assistance – from the World Bank and partner governments such as the United States and Switzerland – adds financing and expertise critical to development and implementation; and private investment drives MIS development, with healthcare providers procuring solutions in a competitive market. In practice, the state supplies foundational infrastructure, and the private sector delivers end-user interfaces and services, promoting speed, competition, and flexibility. However, Ukraine does not provide grant funding or state reimbursement for digital solutions, so digital tools and innovations are typically paid for by patients or funded by private medical institutions where services are fee-based (Yesakov & Korytnyi, 2025), (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

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Ukraine currently does not offer telemedicine services in the public healthcare sector; they are only available in private hospitals. Although there are plans to develop telemedicine, the state budget does not allocate funds for digitalisation in healthcare. As a result, all innovations in this area rely on funding from international donors or partners (gov.ua, 2023).

Research and development

Ukraine promote data-driven research and development under legislation requiring de-identification for scientific use. The national eHealth system centralises depersonalised clinical data (records, prescriptions, referrals), creating large analytical datasets. The Law of Ukraine "On the Protection of Personal Data" permits research use only when data are de-identified; in practice, clinical data within the EHS are pseudonymised and cannot be linked to personal identifiers outside the Central Component. The Ministry of Health and the NHSU encourage analysis of aggregated data for programme planning (e.g., Affordable Medicines, vaccination), though there are no dedicated state funding programmes or established collaboration hubs for clinicians and IT specialists. Public resources include eHealth.gov.ua summary statistics, MoH open data portals, and the NHSU public BI dashboards (nszu.gov.ua), which, while focused on services and expenditure, can be extended using CC data, for example to support public health surveillance. The COVID-19 response illustrated how these datasets enable monitoring, forecasting, and vaccination management (Yesakov & Korytnyi, 2025), (Verkhovna Rada of Ukraine, 2010), (Verkhovna Rada of Ukraine, 2003), (Cabinet of Ministers of Ukraine, 2018), (Ministry of Health of Ukraine, 2021), (Ministry of Health of Ukraine, 2020), (Cabinet of Ministers of Ukraine, 2013), (Verkhovna Rada of Ukraine, 2015).

Ukraine does not conduct research projects using state budget funds, nor is there funding available for such projects at the state or regional level. Instead, research is carried out in partnership with international organisations, relying entirely on their financial support (gov.ua, 2023).

Important additional remarks

Implementing digital healthcare in Ukraine requires far more than technical build-out; ethical, regulatory, and operational factors are decisive. Privacy and consent must be protected with clear, revocable permissions, supported by Ukraine's existing "Approvals" mechanism for patient consent and authorisation, while fairness demands measures to prevent a digital divide affecting older, rural, or low-literacy users. Legal alignment with EU frameworks, including the GDPR and standards for medical devices and AI, is essential to build trust and enable cooperation, and liability for digital or AI-related errors must be explicitly defined across clinicians, vendors, and institutions. Operationally, interoperability risks are mitigated by the well-documented EHS API and an open sandbox enabling MIS integration through uniform protocols; however, success still hinges on comprehensive staff training and sustained support. Finally, stable, long-term funding insulated from political cycles is critical to maintain infrastructure, ensure continuity, and scale services.

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4 EHDS REQUIREMENTS ANALYSIS (STATUS QUO OF EU-COUNTRIES OF PRECISEU)

The readiness for the EHDS varies significantly across the European Union (EU), reflecting diverse technical, legal, and organisational landscapes among member states (TEHDAS, 2023). While the EHDS regulation entered into force on 26 March 2025, its application is phased, with key implementing acts due by March 2027 and major obligations applying progressively from March 2029 and March 2031; third countries may seek to join HealthData@EU for secondary use from March 2034. This staged approach means that full implementation will take several years, by design, to enable a smooth transition and operational clarity. Surveys indicate high awareness and motivation regarding the EHDS, but persistent challenges remain – most notably in interoperability, legacy IT constraints, and data protection. Member states also differ in their level of preparedness, with some requiring additional resources and legal adjustments to comply with EHDS requirements (ICT&health, 2024), (The Financial Analyst, 2025).

The following section analyses the status of EHDS requirements from a European perspective. To illustrate progress, a color code is used:
Green: Set Actions for EHDS readiness.
Yellow: Actions in process for EHDS readiness.
Red: Not set actions for EHDS readiness.

This approach provides a clear, topic-based overview of maturity and existing gaps across key EHDS requirements. The assessment draws the information on the country requirements from each of the ten EU-member states of PRECISEU (Germany, Spain, Belgium, Bulgaria, Romania, Italy, Lithuania, Sweden, Netherlands and Greece) as presented before (see 3. Country Requirements). Ukraine is not mentioned in this Requirement Analysis, as they have the EHDS not in force.

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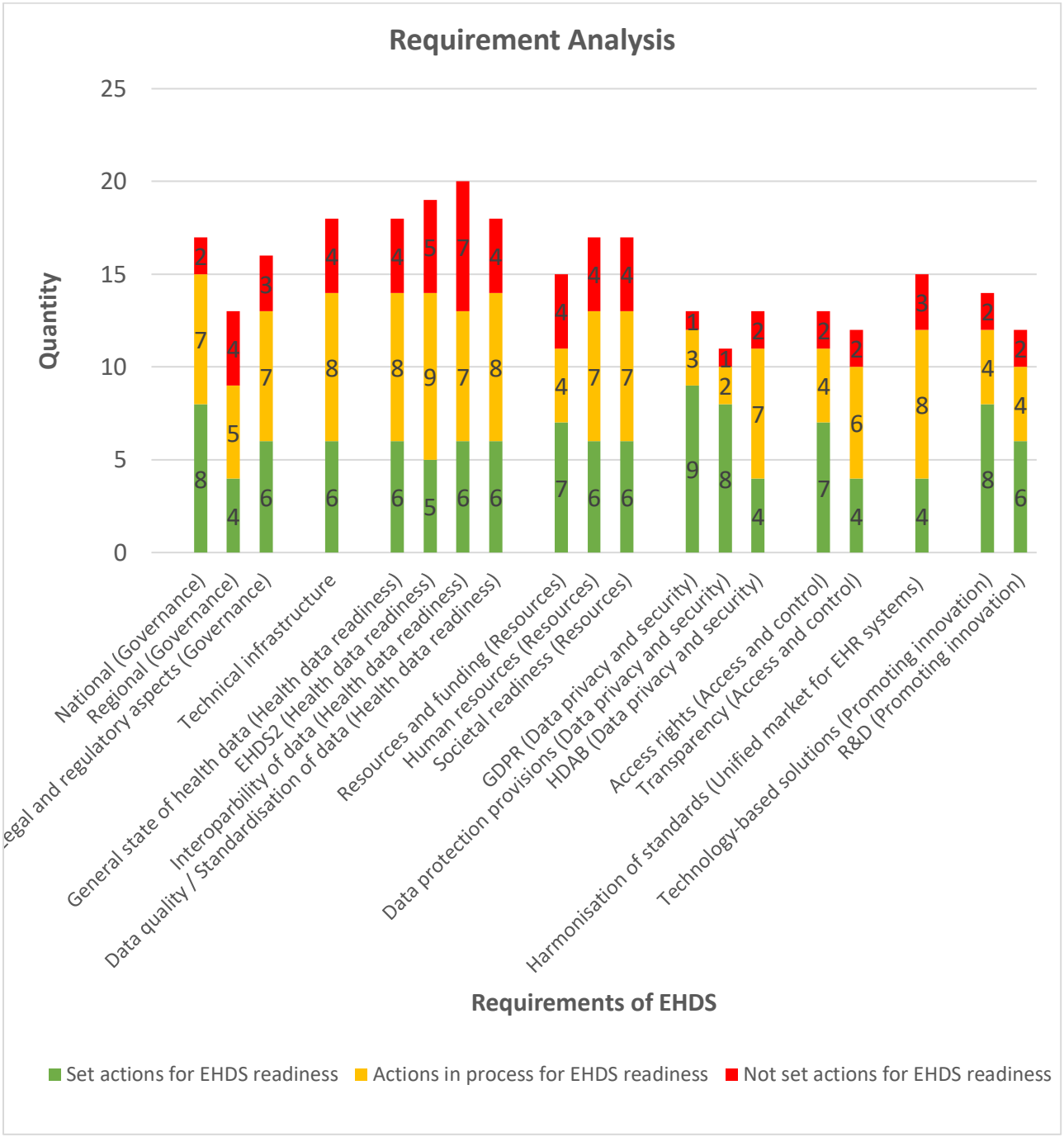

Figure 2 Bar chart for the readiness of EHDS based on the requirements in PRECISEU countries (Green: set actions for EHDS readiness; Yellow: actions in process for EHDS readiness, Red: not set actions for EHDS readiness). Numbers in the bars shows the amount of color-marked information (readiness level) of the 10 EU-member states of PRECISEU (Germany, Spain, Belgium, Bulgaria, Romania, Italy, Lithuania, Sweden, Netherlands and Greece).

4.1 Governance

The "Governance" requirement of the EHDS is organised on three levels: National, regional, and legal and regulatory aspects. All member states must designate authorities to coordinate EHDS implementation, protect citizens' rights, and participate in developing cross-border digital infrastructure, ensuring patients can benefit from the EHDS.

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At the **national level**, most countries are still in the process of establishing or adequately empowering such authorities. The bar chart clearly shows that many member states remain in a transitional phase (7 of 10 countries, yellow) or fully prepared (8 of 10 countries, green). Only a minority face significant implementation gaps (2 of 10 countries, red) (see Figure 2). This means that in some countries, national coordination, oversight and operationalisation of governance structures are not yet robust or consistent. There is clearly a need for further action to accelerate the establishment and effective functioning of these authorities, clarify responsibilities and ensure comprehensive national oversight. Overall, however, the PRECISEU countries that belong to the EU are in a good position at the national level.

At the **regional level**, governance often reflects the decentralised nature of healthcare systems. The integration of regional structures into national EHDS governance remains incomplete, with many regions also rated yellow (5 of 10 countries) or red (4 of 10 countries) (see Figure 2). This underscore persistent challenges in harmonising governance approaches, achieving interoperability, and ensuring effective coordination between regional and national bodies. To address these issues, member states need to strengthen mechanisms for regional-national collaboration, develop clear governance models for data sharing, and invest in capacity-building at the regional level.

For **legal and regulatory aspects**, member states are required to adapt their legislation to EHDS standards, particularly regarding digitalisation and data protection. The bar chart reveals that more than the half have fully aligned their frameworks (6 of 10 countries, green), while most are still in the adjustment phase (7 of 10 countries, yellow). The minority have notable legal gaps (3 of 10 countries, red) (see Figure 2). This highlights the need for legal harmonisation, updating national laws to comply with EHDS requirements, and ensuring effective enforcement of data protection and interoperability standards.

4.2 Technical infrastructure

The requirement "**Technical infrastructure**" within the EHDS is foundational for all member states. Secure technological frameworks and tools are essential to enable the safe management, sharing, and use of health data across borders. Member States are expected to establish networks, data repositories, and digital platforms that support interoperability and compliance with EHDS standards.

While some countries have already set up secure national networks, digital health platforms, and electronic health record (EHR) systems, others are still in the early stages of implementation. There is a strong emphasis on creating technological solutions that not only allow for secure storage and transmission of data but also ensure real-time access and integration with European infrastructures such as MyHealth@EU.

The bar chart on technical infrastructure reveals a mixed picture: a few countries are rated green (6 of 10 countries), indicating that their technological frameworks and tools are largely in place and operational. Many countries, however, are marked yellow (8 of 10 countries), meaning that while initial frameworks, pilot projects, and digital health initiatives exist, full-scale deployment and integration are still lacking. Red-coded countries (4 of 10 countries) face substantial challenges, such as outdated or fragmented systems, insufficient secure data transfer mechanisms, or a lack of standardized interfaces (see Figure 2).

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These challenges signal a clear need for action. Many member states must accelerate efforts to upgrade their technological infrastructure by investing in secure networks, harmonising data standards, and ensuring interoperability between national and European systems. Only by closing these gaps and moving beyond pilot solutions can member states ensure the secure, efficient, and cross-border exchange of health data that is central to the vision of the EHDS. The bar chart makes it clear: robust, harmonised technical infrastructure is not yet a reality throughout Europe, and targeted action is still required to achieve a truly integrated EHDS.

4.3 Health data readiness

The "Health data readiness" is a critical requirement for the EHDS on the ability to securely manage, share, and **(secondary) use health data**, as well as the **general state of health data, data quality, standardisation, and interoperability**. Member states are expected to ensure not only the availability of health data but also its quality, security, and readiness for both national and cross-border use.

In some countries, there are already established processes and systems for collecting, storing, data minimisation and sharing health data, including electronic health records, cancer registries, and billing data. However, there is significant variation in how far these efforts have progressed. Some member states have implemented high-quality data management and standardisation protocols, ensuring that health data is reliable, accessible, and fit for secondary uses such as research and policymaking. Others are still developing or piloting such frameworks, and in some cases, data is fragmented or lacks interoperability, making cross-border exchange difficult.

The bar chart on health data readiness clearly illustrates these disparities: Only a minority of countries are rated green (5 or 6 of 10 countries), indicating strong systems for secure management, high data quality, and standardised processes. A large number of countries fall into the yellow category (7-9 of 10 countries), where foundational structures exist but are not yet fully operational or harmonised. Red-coded countries (4-6 of 10 countries) face major challenges, such as inconsistent data formats, insufficient data quality controls, or a lack of robust mechanisms for data sharing and secondary use (see Figure 2).

These ongoing challenges highlight the urgent need for further action. Member States must focus on improving data quality, enforcing standardisation, and developing interoperable systems that enable seamless and secure data exchange. Without addressing these gaps, the EHDS cannot fulfil its promise of supporting research, innovation, and better patient care across Europe. The bar chart makes it evident (see Figure 2): Health data readiness is one of the most significant hurdles for EHDS implementation, and sustained, coordinated efforts are essential to achieve a functional and integrated EHDS.

4.4 Resources

Across the EU, **Resources and funding (Financial resources)** for the implementation of the EHDS remain unevenly distributed and are often insufficient to ensure long-term sustainability. While most countries have secured or mobilised initial funding – through the EU recovery and resilience facility or national digital health strategies – enabling progress in infrastructure development (for example, in Spain, the Netherlands, Germany, and Italy), in other countries,

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investments are largely project-based and lack sustainable follow-up financing. This often leads to partial implementation or delays in integration, as seen in Greece, Bulgaria, and Lithuania. High-cost requirements, such as cross-border interoperability and advanced analytics, remain unmet in several contexts, including Sweden and parts of Spain and Lithuania. The european framework reveals differentiated challenges and gaps between countries. Well-resourced countries, such as the Netherlands, Germany, and Belgium, demonstrate maturity in funding and basic infrastructure, yet still face challenges in ensuring regional equity (as in Germany) or in scaling beyond pilot projects. In countries in transition or with uneven preparedness (such as Spain, Italy, and Greece), national frameworks and funding exist, but regional disparities result in patchy implementation – for instance, between Catalonia and other Spanish regions, or between northern and southern Italy. In under-resourced or structurally constrained countries (including Romania, Bulgaria and Lithuania), centralised governance structures and limited decentralised capacity, combined with reliance on EU or world bank funding, hinder sustained national investment. The bar chart on Resources and funding clearly illustrates these disparities: A majority of the countries are rated green (7 of 10 countries). Less than the half of the countries fall into the yellow category (4 of 10 countries) and a few countries fall into the red category (4 of 10 countries) (see Figure 2).

Human resource readiness remains a systemic bottleneck across Europe. While some countries (such as the Netherlands and certain regions of Spain and Italy) have well-developed educational systems and national workforce training strategies, most occupy an intermediate position. These countries are actively implementing upskilling programmes but still lack sufficient personnel with advanced expertise in health informatics, data governance, and cybersecurity. Furthermore, several member states – including Lithuania and Romania – report critical shortages of digital health professionals, outdated university curricula, and limited digital competencies within the healthcare workforce.
It is important to note that even in countries with advanced educational systems, shortages of multidisciplinary experts – those with technical, clinical, and regulatory skills – persist, especially at regional and local levels. Although workforce development initiatives are underway in most countries, these efforts are often fragmented or inconsistent, highlighting the need for integrated strategies and effective incentives. The bar chart on Human resources clearly illustrates these disparities: More than the half of the countries are rated green (6 of 10 countries). A majority of the countries fall into the yellow category (7 of 10 countries) and a few countries fall into the red category (4 of 10 countries) (see Figure 2).

Societal readiness for the EHDS varies widely across the EU, resulting in a fragmented landscape. Key factors shaping this readiness include public trust, levels of digital and health literacy, transparency in data use, and citizen engagement in health data governance. While some countries exhibit high readiness, the majority remain at either a developmental or critical stage. More than the half of the countries are rated green (6 of 10 countries). A majority of the countries fall into the yellow category (7 of 10 countries) and a few countries fall into the red category (4 of 10 countries) (see Figure 2).
An emerging East-West and North-South divide reflects differences in the maturity of health systems, public communication strategies, and established digital habits. Public trust in data sharing is closely tied to the digital maturity of regions and the digital literacy of their citizens.

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High levels of trust are found in countries/regions such as Sweden, the Netherlands, Belgium, and Emilia-Romagna (Italy), where longstanding registry use, public dialogue, and transparent policies have fostered societal confidence in data sharing. In countries like Spain and Germany, longstanding concerns over data misuse result in reluctancy to allow data sharing for research or policymaking, even when strong security guarantees exist. In addition, less digitally mature regions also show a hesitation to share data, particularly for secondary uses.
Access to digital health services depends on both digital and health literacy. Integrating health system education into schools, as well as leveraging media campaigns and community outreach, is essential. The Netherlands, Sweden, and Catalonia benefit from high digital penetration, widespread smartphone usage, and educational programs that enable citizens to engage with digital health platforms. Other countries, such as Spain (regionally), Belgium, and Lithuania, have introduced campaigns or institutional initiatives to improve transparency and involve citizens. In Germany, Catalonia, Italy (excluding the most digitally advanced regions in the north), and Greece, communication efforts exist but are often fragmented or technocratic, and frequently fail to meaningfully engage or involve patients.

4.5 Data privacy and security

The General Data Protection Regulation (GDPR) serves as the foundation for data privacy across the EU. While all Member States comply in principle, national interpretations, particularly regarding health data, differ significantly, leading to uncertainty and affecting the rollout of the EHDS. Although the GDPR establishes a common legal framework, divergent national approaches, especially for secondary uses such as research and AI, highlight the urgent need for harmonised guidance.
The bar chart (see Figure 2) illustrates that most countries are progressing well in implementing GDPR and Data protection provisions, with many coded in green (8-9 of 10 countries). Nearly as many countries have begun taking the right steps, though these are not yet fully operational (2-3 of 10 countries, yellow). Only a few have yet to initiate effective action (1 of 10 countries, red).
Germany for example, demonstrates strong GDPR compliance, with clear rules and robust data protection authority involvement. Italy, although compliant, applies a restrictive approach to secondary use for research, leading to delays. In Spain, compliance is undermined by the lack of a national opt-out and conservative legal interpretations, limiting data reuse and public trust. Technically and organisationally, EU countries have introduced various health data protections, but maturity and consistency differ. Some have advanced systems for pseudonymisation and secure environments, while others face fragmented implementation and uneven safeguards.
The EHDS requires each member state to establish a Health Data Access Body (HDAB), but only a few countries are EHDS-ready (7 of 10 countries, yellow & 2 of 10 countries, red) (see Figure 2). Many still need to define governance and infrastructure. Belgium already has a functioning federal health data authority, while in Italy the designated HDAB, AGENAS, is still developing its mandate and infrastructure. In Greece, no formal HDAB exists, and national coordination is lacking.

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4.6 Access and control

Across the EU, countries have made significant progress in establishing legal frameworks that give citizens **access rights** over their health data, in line with EHDS objectives and GDPR principles. This is represented in the bar chart with many countries being coded in green (7 of 10 countries) and nearly as many coded in yellow (4 of 10 countries) (see Figure 2). Meaning, that actions have been started and are either already implemented or within the implementation process. Nearly all member states analysed, including Germany, Spain, Belgium, Bulgaria, Romania, Italy, Lithuania, Sweden, and the Netherlands, recognise rights that allow individuals to view, correct, and sometimes restrict or delete their data. Countries such as Italy, Spain, and the Netherlands have implemented secure digital authentication systems (e.g., SPID, CIE, DNIe, Cl@ve, national eID) and centralised online portals like Germany's ePA, Catalonia's La Meva Salut, Belgium's mijngezondheid.be, and Dutch patient portals, which have improved **transparency** and patient empowerment.

Despite strong legal foundations, practical challenges remain. In Romania and Bulgaria, patients face technical barriers and outdated systems that hinder access. Even in more advanced countries, public awareness of access rights is low. In Italy, digital identities and portals exist, but usage is limited, and regional disparities persist. In Germany and Spain, legal opt-out mechanisms for secondary data use are poorly understood, leading to confusion and underuse. These issues show that legal frameworks alone are not enough, active engagement and education are essential.

Fragmentation within federal or decentralised health systems, as seen in Germany, Spain, and Italy, leads to regional inequalities in access and patient experience. Digital literacy is another barrier, especially for elderly and rural populations, who often lack the skills to use digital health platforms. Even where technical solutions exist, insufficient support and education leave many unable or unwilling to engage.

Another challenge to making healthcare data more accessible is that, in some countries, healthcare professionals remain protective of patient data, often viewing it as their own property and resisting broader access.

Additionally, cultural attitudes toward data privacy and trust in digital systems further influence patient behaviour, as discussed in section 4.5 on societal readiness.

4.7 Unified market for EHR systems

Across the EU, countries are steadily advancing towards creating a unified and interoperable market for **electronic health record (EHR)** systems, a cornerstone objective of the EHDS. Many member states have developed or are actively modernising national or federated EHR systems to integrate data from hospitals, clinics, and primary care providers. Countries like Germany, Spain, and Italy operate federated systems that aim for national interoperability through technical coordination and common standards. Meanwhile, Bulgaria and Lithuania have opted for centralised national systems, which simplify integration but still face challenges around legacy infrastructures and data standardisation. The widespread adoption of international standards such as HL7 FHIR, SNOMED CT, and openEHR is a promising sign of alignment with EHDS interoperability goals and supports future cross-border health data exchanges.

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Despite these strong foundational efforts, full harmonisation remains a significant challenge, which is also represented in the bar chart. The bar chart shows that most member states remain in a transitional phase (8 of 10 countries, yellow), with actions for progress on the way but not fully implemented yet (see Figure 2). Legacy systems, some of which are decades old, continue to impede seamless data exchange in countries such as Romania, Belgium, and Lithuania. Even in technically advanced settings like the Netherlands, data remains fragmented across different hospital networks, creating operational bottlenecks and limiting real-time data sharing. Regional disparities further complicate the picture. In Spain and Italy, for example, certain regions have achieved impressive levels of EHR adoption and standardisation, while others lag considerably, creating a patchwork effect that undermines national and EU-level coherence. Germany faces similar obstacles, where varying adoption rates and different regional strategies impede the development of a fully unified market.

In Sweden, despite its mature digital health infrastructure and long-standing tradition of national registries, regional fragmentation and different data collection standards still hinder seamless interoperability. Belgium, too, is advancing toward national FHIR adoption but struggles with inconsistent EHR systems across different regions and providers. These disparities reflect broader systemic issues around governance and funding, as regions with fewer resources often lack the capacity to modernize and align with national and EU standards. Efforts to ensure not only syntactic (format-based) but also semantic (meaning-based) interoperability remain incomplete in most member states. Data might technically be exchanged but cannot always be effectively integrated or interpreted across systems, limiting its usability for cross-border care, research, and policymaking. In addition, the lack of centralised oversight in some countries means that even when standards exist, they are not uniformly enforced, leaving individual hospitals and regions to implement their own variations.

4.8 Promoting innovation

Across the EU, countries are increasingly recognising the transformative potential of health data in driving innovation, **research and development**, and **technology-based solutions**. The bar chart reveals that more than the half have fully aligned their frameworks (6-8 of 10 countries, green), while most are still in the adjustment phase (4 of 10 countries, yellow). The minority have notable legal gaps (2 of 10 countries, red) (see Figure 2).

Germany stands out with flagship initiatives like genomDE and GHGA, along with powerful AI research centres at Helmholtz Munich and the Max Delbrück Center, which contribute to breakthroughs in personalised medicine and diagnostics. Spain is similarly ambitious, investing heavily through programs such as Vanguard Health PERTE, regional biobank networks, and Catalonia's Biocat, which fosters rapid adoption of new technologies in healthcare. Italy, with its advanced Emilia-Romagna region, has created strong digital health policies, regional AI hubs, and powerful computational capabilities exemplified by HPC Leonardo, positioning itself as a leader in integrating technology and healthcare.

Bulgaria has focused its strategy on AI diagnostics, genomics, and telemedicine, supported by initiatives like the VELES Excellence Hub and the national AI strategy. Sweden, known for its robust national health registries and high digital maturity, actively participates in EU-level projects such as the European Genomic Data Infrastructure and EUCAIM for cancer imaging, further reinforcing its commitment to data-driven innovation. The Netherlands coordinates its

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efforts through Health-RI and the HDAB-NL project, which support the development of secure environments for secondary data use, personalised medicine, and advanced analytics. Lithuania is building momentum through participation in the One Million Genomes initiative and expanding telemedicine services, signaling its commitment to integrating health innovation into its national strategy.

The various challenges described throughout this chapter, including irregular governmental frameworks, technical obstacles, insufficient digital literacy, regional inequalities, low levels of public awareness, and prevailing cultural concerns about data privacy and trust in digital systems, have been examined in detail in the preceding sections. Each of these factors presents a significant barrier to the advancement of accessible healthcare data and collectively they slow down progress and restrict the potential for innovation within the European health data landscape. The combination of outdated systems, inconsistent implementation across regions, and a lack of patient engagement or education complicates efforts to achieve the goals set out by the EHDS. All of these issues must be addressed in order to realise a more equitable, efficient, and innovative use of health data. Concrete recommendations and suggestions for overcoming these barriers are presented in the conclusion of this report.

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5 CONCLUSION

The PRECISEU readiness framework developed in Task 4.1 provides a robust, multidimensional tool for assessing how prepared national and regional health information systems are for integration into the EHDS. By employing the MGM, the project systematically evaluated key requirements such as governance, technical infrastructure, data quality, resource allocation, data privacy, societal readiness, and innovation capacity across all participating countries and regions.

The analysis reveals significant progress in several areas, including the designation of responsible authorities, initial steps toward legal harmonisation, and the development of pilot infrastructures for data sharing and interoperability. However, notable challenges remain:

- Technical infrastructures and data standards are still fragmented, impeding seamless cross-border data exchange.
- Data quality and semantic harmonisation are insufficient for enabling secondary use and large-scale research.
- Smaller and less-resourced providers face greater difficulties in meeting EHDS requirements, risking increased disparities.
- Societal acceptance and trust in data sharing, especially for secondary use, remain limited due to privacy concerns and lack of transparent communication.

Despite the existing hurdles, PRECISEU's collaborative approach has strengthened knowledge exchange and mutual learning, thereby highlighting best practices and priority areas for action. The findings from Task 4.1 provide the foundation for subsequent project activities, notably the development of technical standards, interoperability tools, and concrete policy guidance. They also advance the broader EHDS vision of secure, innovative, and patient-centred healthcare across Europe, with particular benefits for the progression of personalised medicine. In this context, policymakers should address the following recommendations based on the county requirememts of the EHDS and the identified gaps (red-marked information) (see 3. Country Requirements and 4. Requirement Analysis):

Recommendations for policymakers for EU-countries from PRECISEU improving the EHDS

Strengthen strategic vision and governance

- Move beyond generic benefits of a unified (or at least federated) European health data environment to show concrete improvements for all key stakeholders: citizens (tangible improvements in individual and collective health outcomes), Member States (economic efficiency and enhanced quality of care), and industry (access to larger volumes of standardised data for research and reduced operational costs).

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- Establish a network or academy of experts and stakeholders to serve as a hub for discussing standardisation and normalisation issues and that that can provide targeted technical assistance and governance guidance based on demonstrated success.
- Create unified, transparent governance structures and legislation for health data management and sharing across the EU, aligned with EHDS standards and the GDPR, to enhance collaboration among regional, national, and European stakeholders.

Promote standardisation and interoperability

- Enforce the EU-wide adoption of standardised data formats, interfaces, and protocols to ensure the reliability and usability of health data.
- Provide clear upgrade pathways for regions currently below minimum viable ineroperability standards, ensuring that technical requirements reflect realistic implementation timelines based on existing infrastructure and capability assessments."mplementation timelines based on existing infrastructure and capability assessments.
- Encourage the provision of standard tools to enable smooth adoption of standards by European data stakeholders.
- Define, tested and validated shared semantics and a unified data model at the EU level to ensure coherence and interoperability.

Modernise and harmonise IT infrastructure

- Invest in high-performance, interoperable systems that enable secure, seamless, and standardised data sharing within and between countries. Targeted investment programs should bring regions below minimum thresholds up to viable implementation levels, recognising that high-performance, interoperable systems require substantial foundational capabilities that vary significantly across the EU.

Approach data privacy and security with nuance

- Recognise that anonymisation is highly context-specific and that setting uniform standards for data minimisation and pseudonymisation may not be feasible.
- Introduce an EU evaluation framework for data privacy and security, aligned with unified standards, to foster trust among both data users and citizens.
- Safeguard the legitimate protection of intellectual property and commercially sensitive information; while data access restrictions should not undermine the public benefits that justify EHDS investment, the private sector must retain the right to refuse access to data if economic harm is likely.

Allocate financial resources strategically

- Provide targeted financial support, especially for structurally weaker regions, and invest strategically in infrastructure and innovation. Long-term EHDS success requires sustained

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investment beyond deployment phases and operational costs may vary significantly across different regional contexts.

Strengthen education, training, and interdisciplinary expertise

- Modernise educational curricula to introduce and enhance digital and AI skills, support ongoing professional development, and establish multidisciplinary centres that bridge health, digitalisation, and data management.
- Prioritise attracting, training, and retaining skilled professionals in digital health and health data governance.

Empower citizens through user-centred systems

- Develop accessible, standardised solutions that ensure all individuals can easily access, control, and understand their health data irrespective of their level of digital literacy, health knowledge, and technical access.

Foster public trust and societal readiness

- Promote transparency about data use and rights, actively involve citizens in governance, and strengthen digital and health literacy through education and outreach.
- Encourage open dialogue and a culture that views health data as a shared societal asset to support research, innovation, and collaboration.

Enable dynamic evolution and reuse of best practice

- Ensure the EHDS framework remains dynamic and adaptable to new developments in health research and policy, so it can incorporate new evidence and adjust requirements based on empirical outcomes rather than theoretical expectation.
- Capture implementation experiences from both successful and problematic deployments and encourage the reuse and adaptation of validated models to avoid fragmentation and ensure semantic consistency and interoperability across research efforts.

Recommendations for policymakers on advancing Ukraine's health data infrastructure to fulfill EHDS requirements

Ukraine has a solid foundation (national systems, introduction of electronic health records, basic legislation), but still needs to close significant gaps in governance, interoperability, data protection, security, patient control and infrastructure to enable secure, interoperable and AI-enabled use of health data. The following recommendations are aimed at policymakers and healthcare executives.

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Cross-border integration and medical data flow (EU ↔ Ukraine)

Reason

There are significant legal and technological barriers between the EU and Ukraine that hinder controlled medical data exchange. With Ukraine's ongoing EU integration, growing EU citizen engagement in reconstruction, and Ukraine's unique war-time medical expertise, overcoming these barriers is essential for safe, effective cross-border care.

Recommendations

- Adopt FHIR IPS (International Patient Summary) as the baseline standard to enable secure, interoperable exchange of core clinical data across EU–Ukraine systems.
- Establish a unified, central Patient Information System (PIS) for citizens and foreign nationals to:
- Access their personal medical data,
- Manage GDPR-aligned consents,
- Receive personalised recommendations and health predictions.
- Drive bottom-up integration of fragmented medical data (including private providers) to create a complete longitudinal patient view.
- Develop the PIS under state authority in partnership with the EU and qualified external developers to ensure technical and regulatory alignment.
- Harmonise AI medical-device and AI-ready data rules with EU principles, supporting local specifics (e.g., human-in-the-loop in low-resource settings, explainability for varied digital literacy).
- Mandate common interoperability: officially adopt FHIR, publish mappings for EHDS priority categories (patient summaries, medications, labs, imaging), and require EHR vendors to pass an API conformance test harness within 24 months.
- Publish reference terminologies and mappings (ICD, LOINC, SNOMED CT or licensed equivalents) with translation guidance to support multilingual, cross-border use.

Secondary use of medical data

Reason

Ukraine can contribute meaningfully to R&D, clinical trials, and policy through its post-war medical and social experience. To unlock this value, robust frameworks for secondary use are needed.

Recommendations

- Prioritise critical topics such as mental health and PTSD among veterans, families and civilians, leveraging ongoing initiatives (e.g., Healthy Mind, Kyiv School of Economics).
- Coordinate prosthetics production and war trauma rehabilitation across public and private systems, engaging companies, funds and NGOs.

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- Expand access to generalised/anonymised datasets to:
- Build BI dashboards,
- Support AI-based prognostics,
- Identify development opportunities.
  Improve and extend open dashboards (e.g., NSZU statistics) beyond administrative data.
- Adopt FHIR-compatible BI/AI solutions to enable deeper analytics, scenario modelling and predictive insights.
- Establish a Health Data Access Body (HDAB) with clear mandate, review criteria, standardised applications and maximum response times (e.g., 30 days); pilot decisions on three priority datasets in secure environments and publish transparent decision summaries with an appeals process.
- Standardise data quality and metadata: require provenance, collection methods, transformations and update frequency; introduce a visible Data Quality & Utility Label (completeness, bias assessment, freshness) in catalogues; track provenance end-to-end for auditability.

Strengthen GDPR and cybersecurity infrastructure and knowledge

Reason

GDPR compliance and strong cybersecurity are essential to protect personal medical data. Every environment where such data is stored or processed must be resilient, monitored and well-governed.

Recommendations

- Strengthen the legal framework to EU standards: adopt a GDPR-aligned personal data law with breach notification, data-protection-by-design, rights around automated decision-making and clear sanctions.
- Issue healthcare-specific implementation guidance (breach timelines, DPO requirements, record-keeping templates) and harmonise AI regulations with EU principle-based approaches.
- Conduct comprehensive technical audits for GDPR and cybersecurity across all medical systems handling personal data; develop GDPR/cybersecurity heat maps for institutions to visualise and manage risks.
- Implement mandatory training and certification for all operators of personal medical data (e.g., via platforms such as CyberUnit).
- Introduce routine assessment of stress levels among data operators to reduce human-factor breaches (e.g., via Healthy Mind).
- Enforce “Governance by Design” across health systems:
- Role-Based Access Control (RBAC) and Multi-Factor Authentication (MFA),
- Integrated consent management (time-stamped provenance, revocation),
- Comprehensive audit trails (access, processing, export, anonymisation),
- Standard breach-response protocols (detection, alerting, logging, notification).
- Enhance privacy and security controls:

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- State-of-the-art encryption (AES-256 at rest, TLS 1.3 in transit) and secure key management,
- Differential privacy or high-quality synthetic data for shared/public releases,
- Continuous re-identification risk monitoring,
- Regular security audits and penetration testing,
- Standardised certifications (e.g., Cyber Essentials).
- Harden healthcare cybersecurity as critical infrastructure:
- Define minimum security baselines (patching cadence, MFA for admins, segmentation, encrypted backups, secure logging),
- Targeted grants to uplift high-risk hospitals (prioritise large or critical institutions),
- Require 24-hour incident reporting to the national CERT for health and annual tabletop exercises.

Patient access, consent management and portability

Reason

Citizens need clear, convenient control over their health data to build trust, enable safe sharing and improve continuity of care domestically and across borders.

Recommendations

- Provide a national patient portal (or extend an existing one) with strong authentication (e.g., national ID) offering:
- Patient summary views,
- Consent and sharing controls,
- Export of FHIR bundles for portability.
- Implement end-to-end audit trails visible to patients, showing where and how their data has been used.
- Integrate the portal with the central PIS to streamline GDPR consent management for cross-border data exchange.

Modular anonymisation and pseudonymisation

Reason

Different contexts and outputs require tailored privacy protection. Modular approaches allow flexibility while maintaining robust safeguards.

Recommendations

- Issue national guidelines for anonymisation/pseudonymisation (e.g., statistical disclosure control, differential privacy) with risk-tiering.
- Require that data leaving secure environments or original clinical contexts be processed through the anonymisation layer unless explicit consent for identifiable data is present.
- Certify tools and open-source libraries implementing these layers; provide centrally managed services or broad access to all labs and research centres.

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- Operationalise context-aware anonymisation by region, use-case and output type to strengthen privacy without stifling utility.

Social readiness: Transparency, trust and consent

Reason

Technical compliance alone is insufficient. Public understanding and trust determine adoption, responsible use and the societal value of health data.

Recommendations

- Launch public awareness campaigns explaining health data uses, benefits, protections and rights.
- Provide mechanisms in patient portals for citizens to see data-use audit trails.
- Establish ethics panels or advisory boards for health data projects to address fairness, mitigate bias and guide responsible innovation.
- Share transparent summaries of HDAB decisions and outcomes to reinforce accountability and legitimacy.

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6 GLOSSARY

Advanced Therapy Medicinal Products (ATMPs)
Innovative medicines based on genes, tissues, or cells, used to treat or prevent diseases.

Artificial Intelligence (AI)
Computer systems capable of tasks that typically require human intelligence, such as pattern recognition, decision-making, and language understanding.

Barcelona Supercomputing Center (BSC)
Public research infrastructure providing high-performance computing for health data analytics and AI workloads.

BIGAN [Aragón]
Regional health data lake consolidating multi-source health data under a single citizen identifier to support research and public health management.

Data Access Body (DAB) / Health Data Access Body (HDAB)
Public authority designated to manage and authorise access to health data for secondary use under strict safeguards.

Data Lake
Large, centralised repository storing raw data in native formats until needed for analysis.

Data Minimisation
GDPR principle requiring organisations to collect and process only the personal data necessary for a specific purpose.

Data Pseudonymisation
Processing personal data so it can no longer be attributed to a specific person without additional information kept separately.

Data Quality
The degree to which data are complete, accurate, timely, consistent, and fit for their intended purpose; critical for reliable secondary use.

Data Sovereignty
The concept that individuals retain control over their personal data, including access rights, corrections, and restrictions on use.

Decentralised Health Data Management
Organisation of health data systems at regional or institutional levels rather than via a single national repository.

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Digital Health Act (DigiG) [Germany]
Law aimed at accelerating the digitalisation of healthcare services and infrastructures.

Digital Spain 2026
National strategy leveraging Next Generation EU funding to advance digital transformation, including health data initiatives.

EHDS Primary Use
Use of health data for direct patient care (e.g., diagnosis, treatment, prescriptions, care coordination).

EHDS Secondary Use (EHDS2)
Responsible reuse of anonymised or pseudonymised health data for research, innovation, public health, and policymaking.

Electronic Health Record (EHR)
A digital, longitudinal record of a patient's medical history, treatments, test results, and other clinical information, accessible to authorised healthcare professionals.

Electronic Medical Record (EMR)
Digital record within a single provider organisation; often a source system for EHR aggregation.

Electronic Patient Record (ePA) [Germany]
The German implementation of an EHR that enables patients to store and manage their health information digitally.

European EHR Exchange Format
Standardised format enabling cross-border exchange and interoperability of electronic health data within the EU.

European Health Data Space (EHDS)
EU initiative establishing a secure framework for access, sharing, and reuse of health data for primary care and secondary purposes (research, innovation, policy).

Fast Healthcare Interoperability Resources (FHIR)
HL7 standard using modern web technologies to enable interoperable health data exchange.

GDPR (General Data Protection Regulation)
EU regulation governing personal data protection, emphasising principles like purpose limitation, data minimisation, and security.

genomDE [Germany]
National initiative integrating genomic medicine into routine care and enabling secure access to genomic data for clinical and research use.

Genomics Data Infrastructure (GDI)

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European initiative enabling secure access to genomic data for healthcare and research.

German Human Genome-Phenome Archive (GHGA)
Secure platform for sharing omics datasets to support personalised medicine and research in Germany.

Health Data Infrastructure
Combined technical, organisational, and legal components enabling collection, storage, exchange, and analysis of health data.

Health Data Lab [Germany]
Centre planned under Germany's Health Data Use Act to provide access to pseudonymised datasets (e.g., insurance billing data, EHR extracts) for research.

Interoperability (Health Data)
The ability of different information systems and devices to exchange, interpret, and use data reliably and meaningfully (syntactic and semantic).

La Meva Salut [Catalonia]
Patient portal enabling access to personal health data and services.

Material Transfer Agreement (MTA)
Contract governing the transfer of tangible research materials (e.g., samples, reagents) between organisations.

Maturity Grid Model (MGM)
Structured assessment tool that evaluates readiness across domains (e.g., governance, technical infrastructure, data quality) using a colour code: green (actions set), yellow (actions in progress), red (actions not set).

Medical Informatics Initiative (MII) [Germany]
Programme linking clinical and research data across institutions to improve interoperability and enable data-driven healthcare.

MyHealth@EU
EU-wide infrastructure enabling citizens and healthcare providers to access and share electronic health data securely across borders.

Observational Medical Outcomes Partnership Common Data Model (OMOP CDM)
Standard data model to harmonise healthcare data for large-scale, multi-centre observational research.

Opt-out Mechanism

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Policy allowing individuals to refuse or withdraw consent for certain data uses unless they explicitly opt out.

PADRIS [Catalonia]
Programme coordinated by AQuAS to facilitate reuse of healthcare data from multiple sources (EMRs, prescriptions, labs, registries, images) for research and planning.

Picture Archiving and Communication System (PACS)
Technology for storing, retrieving, and sharing medical images such as X-rays and MRIs; commonly uses DICOM.

PNRR (Piano Nazionale di Ripresa e Resilienza) [Italy]
National Recovery and Resilience Plan leveraging EU Next Generation funds for reforms and investments, including health digitalisation.

Pseudonymised Data
Personal data processed so individuals cannot be identified without separate, securely held information; still personal data under GDPR.

SNOMED CT
Comprehensive, standardised clinical terminology used to capture healthcare concepts consistently in EHRs.

TEHDAS (Towards European Health Data Space)
Joint action providing recommendations for cross-border collaboration and governance for the EHDS.

Trusted Third Party (TTP)
Independent entity that manages sensitive operations (e.g., data linkage) to preserve privacy and security.

Unified Market for EHR Systems
Harmonised EU environment where EHRs follow common rules and technical specifications to ensure seamless interoperability.

Use Case (Health Data)
Specific scenario describing how health data are collected, processed, and used to achieve an objective (e.g., AI model training, public health surveillance).

Variant of Unknown Significance (VUS)
Genetic variant whose association with disease risk is not yet established.

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