



PeRsonalised medicine Empowerment Connecting Innovation ecoSystems across EUrope

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Deliverable deso	Comprehensive analysis of Hungary's ecosystem in the context of personalized me	
	in particular regarding advanced therapies and with a particular focus on digital	
	innovation. The primary objective is to evaluate the current state and prosp	
	country's PM landscape, including the existing legal framework, innovation agenda	
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Partners

Participants of the PRECISEU Consortium are referred to herein according to the following codes:

- 1. BIOCAT. Biocat La Fundació Bioregio de Catalunya (Spain)
- 2. SALUT. Departament de salut Generalitat de Catalunya (Spain)
- BSC CNS. Barcelona Supercomputing Center Centro Nacional de Supercomputación (Spain)
- 4. BIORN. Biorn Cluster Management GMBH (Deutschland)
- 5. BIOPRO. Biopro Baden-Wuerttemberg GMBH (Deutschland)
- 6. NE RDA. Agentia Pentru Dezvoltare Regionalanord-Est (Romania)
- 7. DIZNE. Asociatia Digital Innovation Zone Zona De Inovare Digitala (Romania)
- 8. **IMAGO-MOL**. Clusterul Regional Inovativ De Imagistica Moleculara si Structurala Nord-Est (IMAGOMOL) (Romania)
- 9. HLSCB. Biotehnologichen i Zdraven Klaster (Bulgaria)
- 10. SIA. Stolichna Obshtinska Agentsia za Privatizatsia i Investitsii (Bulgaria)
- 11. CLUST ER. Clust er Industrie della Salute e del Benessere (Italy)
- 12. RER. Regione Emilia Romagna (Italy)
- 13. ART-ER. Art-Er-Societa Consortile per Azioni (Italy)
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- 24. RIMC. Rivne Interregional Medical Cluster (Ukraine)
- 25. ASTRAZENECA. Astrazeneca Farmaceutica Spain, S.A (Spain)

Glossary of terms

- **Grant Agreement**. (Including its annexes and any amendments) The agreement signed between the beneficiaries of the action and the EC for the undertaking of the PRECISEU project (Grant Agreement No. 101161301).
- Project. The sum of all activities carried out in the framework of the Grant Agreement.
- Work plan. Schedule of tasks, deliverables, efforts, dates, and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.



- Consortium. The PRECISEU Consortium, comprising the above-mentioned participants.
- **Consortium Agreement**. The agreement concluded amongst PRECISEU participants for the implementation of the Grant Agreement. The agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.
- **Deliverable review**: An evaluation procedure by one or more reviewers, which precedes the distribution of a deliverable (as defined in the Work plan) to the EC.
- **Quality assurance**: All the planned and systematic activities implemented to provide adequate confidence that an entity will fulfil requirements for quality.
- **Quality policy**: A set of principles on which quality assurance procedures are based.
- Risk: Uncertainty that may have a significant impact on the execution or outcome of the project, and which effect may be negative – a threat risk, or positive – an opportunity risk.



Acronyms

AI - Artificial Intelligence ATMPs - Advanced Therapies Medicinal Products BEMOSZ-HAPO - Hungarian Alliance of Patient Organizations CGT – Cell and Gene Therapies DHTs - Digital Health Technologies EDHS – European Health Data Space EDIH – European Digital Innovation Hubs EESZT – National Electronic Health Service Space eHDSI – eHealth Digital Service Infrastructure EHR – Electronic Health Records ETOSZ – Association of Healthcare Technology and Medical Technology Suppliers EU – European Union **GDPR** – General Data Protection Regulation **GP** – General Practitioners HMC – Hungarian Medical Cluster HNHRA – Hungarian National Health Research Agency HPC – High-Performance Computing HTA – Health Technology Assessment HUPHAR – Hungarian Society for Experimental and Clinical Pharmacology ICT – Information and Communications Technology INTERREG HSRU – INTERREG Hungary-Slovakia-Romania-Ukraine MDR – Medical Device Regulation MEMT – Hungarian Healthcare Management Association MOTESZ - Association of Hungarian Medical Societies and Associations NAVÜ – National Data Asset Management Agency NEAK – National Health Insurance Fund RRF - Recovery and Resilience Facility SME - Small and Medium-sized enterprises STEM – Science, Technology, Engineering and Mathematics SWOT – Strengths, Weaknesses, Opportunities and Threats



1. Executive summary

Europe ambitions to have the best talent working with the best companies, with deep-tech innovation creating breakthrough solutions across the continent and inspiring the world. The Regional Innovation Valleys (RIVs) aim to strengthen and better connect regional innovation players throughout Europe, including regions with lower innovation performance.

RIV initiatives will support Member States (MS) and regions in bridging the gaps and activating innovations in deep-tech for key priorities of the European Union (EU); directing funding to concrete interregional innovation projects —complementing large networks and consortia at the MS Level and placing Europe at the forefront of wellbeing and sustainable transition.

Europe's competitiveness relies largely on technology-based innovations in the health sector. Healthcare innovations represent a pillar of all EU policies and a cross-cutting priority, with fundamental importance to public authorities and local communities in terms of investment opportunities and the quality of life of the 448 million citizens of the European continent. And the most transformative commitment that the European Commission (EC), along with National and Regional Authorities, is acquiring toward healthcare is to channel huge efforts and funding towards Personalised Medicine (PM), which is on the backbone of several initiatives for building the European Health Union, and the ground test for the technology-driven transformation of the health care domain.

According to the European Council's conclusion on Personalised Medicine for patients, Personalised Medicine refers to "a medical model using the characterization of individuals' phenotypes and genotypes for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention."¹

PRECISEU envisions accelerating the integration of the PM paradigm across Europe, sustainably connecting regional innovation ecosystems, reducing the gap between regions, and facilitating patients' access to deep-tech innovations. In five years, we will have successfully improved the framework for the secondary use of health data and the development of ATMPs, supporting the access of PM technologies to the market and becoming a trusted player in the EC's strategy to empower PM at the regional level.

2. Introduction to this report

The partners of PRECISEU identified the relevance of highlighting the challenges of an effective implementation of Personalised Medicine model across EU by aligning their actions to the events taking place during the Presidencies of the EU. At the moment of publication of this case study, Hungary holds the presidency of the Council of the EU (for the second time) between 1 July 2024 and 31 December 2024. During this period the priorities of the Hungarian presidency are the following²:

¹ Council of the European Union, Official Journal of the European Union, Council conclusions on personalised medicine for patients (2015/C 421/03); from <u>https://op.europa.eu/en/publication_detail/-/publication/f416ce37-a48c-11e5-b528-01aa75ed71a1/language-en</u>

² parleu2024hu - ParlEu2024 - Országgyűlés (parlament.hu)



- New European Competitiveness Deal.
- The reinforcement of European defence policy.
- A consistent and merit-based enlargement policy.
- Stemming illegal migration.
- Shaping the future of cohesion policy.
- A farmer-oriented agricultural policy.
- Addressing demographic challenges.

The PRECISEU consortium understands that their project contributes largely to the New European Competitiveness Deal and to Shaping the Future of Cohesion Policy.

The partners also highlight the underrepresentation of Health, Health innovation, Personalised Medicine, health Data and Advanced Therapies in the Hungarian presidency Program. For this reason, and complying with the commitments of PRECISEU's Grant Agreement, the partners deliver this first case study reviewing the capacities, assets, gaps and opportunities of Hungary in this field, and have already engaged with Hungarian partners in the celebration of activities during this presidency.

3. Hungarian ecosystem overview

3.2. National Health System

Hungary's healthcare system, funded by taxes and managed by the National Health Insurance Fund (NEAK), provides nearly universal coverage to its population of approximately 9.6 million people, with about 5% of the population having unclear insurance status. As of 2023, public health insurance costs slightly over 24 euros.³

- Secondary and tertiary care are primarily public sector responsibilities shared by municipalities and the central government, with limited private involvement.
- Primary care is managed by municipalities, with general practitioners (GPs) mainly in private practices. A 2022 reform centralizes primary care under the National Directorate-General for Hospitals and incentivizes GPs to form group practices. Municipalities also oversee polyclinics for secondary ambulatory care.
- Public financing covers 72.5% of healthcare costs, below the EU average of 81.1%, leading to high out-of-pocket expenses (25%) for households, compared to the EU average of 15%.
- In 2021, inpatient care accounted for 31% of healthcare spending, outpatient care 29%, and outpatient pharmaceuticals and medical devices 25%, all higher

³ Business Process Innovation, 2022. Increase in the amount of the health service contribution from January 1, 2023. <u>https://bpion.com/increase-in-the-amount-of-the-health-service-contribution-from-january-1-2023/</u>



than EU averages. Long-term care received only 4%, much lower than the EU average of 16%.⁴

- Despite recent wage increases, salaries for healthcare professionals in Hungary remain lower than in many other EU countries, while long hours, underresourced hospitals, and insufficient medical equipment contribute to widespread job dissatisfaction and burnout.
- Hungary has one of the lowest doctor-to-population ratios in the European Union. As of 2022, the country had only 3.5 doctors per 1,000 inhabitants, compared to the EU average of 3.9. The shortage has resulted in longer waiting times for treatments, overworked staff, and reduced quality of patient care.
- In the past decade, over 8,000 healthcare professionals left Hungary for better conditions in other EU countries, leading to one of the EU's lowest doctor-topopulation ratios and severe staff shortages. In 2022 alone, more than 800 doctors sought certification to work abroad.⁵
- The SME sector is facing a continuing erosion of innovation capacity, largely due to inadequate funding, regulatory challenges, and a declining workforce, which hinder the development of new medical technologies and solutions. Despite having a strong base in medical technology and biotechnology, many SMEs struggle to seize opportunities for growth and innovation, as they often lack access to the necessary resources and support⁶.
- Hungary is a leading destination for medical tourism, particularly for dental care.

Demographic factors	Hungary	EU	
Population size		446 735 291	
Share of population over age 65 (%)	20.5	21.1	
Fertility rate ¹ (2021)		1.5	
Socioeconomic factors			
GDP per capita (EUR PPP²)	27 259	35 219	
Relative poverty rate ³ (%)	12.1	16.5	
Unemployment rate (%)	3.6	6.2	

Fig. 1: Demographic and socioeconomic factors in Hungary, 2022 (source: State of Health in the EU Hungary Country Health Profile 2023)⁷ 1. Number of children born per woman aged 15-49. 2. Purchasing power parity (PPP) is defined as the rate of currency conversion that equalises the purchasing power of different currencies by eliminating the differences in price levels between countries. 3. Percentage of persons living with less than 60 % of median equivalised disposable income. Source: Eurostat Database.

⁴ OECD/European Observatory on Health Systems and Policies, 2023. *Hungary: Country Health Profile 2023, State of Health in the EU,* OECD Publishing, Paris/European Observatory on Health Systems and Policies, Brussels.

⁵ Euro News, 2023. Hungary's healthcare system struggles as doctors leave for Western Europe.

https://www.euronews.com/my-europe/2023/06/04/hungarys-healthcare-system-struggles-as-doctors-leave-for-western-euro ⁶ Interreg Europe, 2021. Economic diversification in the Hungarian health sector. https://www.interregeurope.eu/find-policy-solutions/expert-support-reports/economic-diversificationin-the-hungarian-health-sector

⁷ https://www.oecd.org/en/publications/hungary-country-health-profile-2023_8d398062-en.html



3.3 Health data Landscape

Hungary has implemented national Electronic Health Records (EHR) with two main systems, including the National Electronic Health Service Space (EESZT). EESZT links public and private healthcare providers, pharmacies, and the public, enhancing diagnosis and therapy by sharing patient data. Key features of EESZT include: eRecipe, Health Documents, Event Catalog, eReferral, eProfile, Digital Self-Determination.

Patient data is also accessible through the National Health Insurance Fund (NEAK) portal, focusing on the financial aspects of healthcare services provided. Hungary plans to join the eHealth Digital Service Infrastructure (eHDSI) by 2025 to share prescriptions and patient summaries, contributing to the EU eHealth Network.



Fig 2.: Screenshot of the portal for the National Electronic Health Service Space (EESZT) (https://www.eeszt.gov.hu/oldalvalaszto.jsp).

3.4 Advanced Therapies Landscape

As of 1 August 2023, the National Institute of Pharmacy and Nutrition (OGYÉI) merged into the National Public Health Center. The resulting new authority is the National Public Health and Pharmaceutical Center (NNGYK). The new authority headed by the Chief Medical Officer is under the supervision of the Minister of the Interior, acting in the capacity of Minister responsible for Health.⁸

Regarding Advanced Therapy Medicinal Products (ATMPs), the NNGYK created the "ATMP roundtable" in which many Hungarian experts participate and try to find ways to improve Hungary's activities in the ATMP field. The European Society of Cell and Gene Therapy map of capacities9 on ATMP across EU points at 1 main center working on ATMPs in Hungary, the Department of Biophysics and Cell Biology, Faculty of Medicine, University of Debrecen, working on immune therapies and CAR-Ts, among other areas of interest.

⁸ APH – DDRS 2021 Conference – Plenary Presentations. Mátyás SzentIványi. Future of the Hungarian Drug Market – Role of the Hungarian Regulatory Authority. <u>https://www.aph-hsps.hu/acta/index.php/aph/article/view/71/57</u>

⁹ ESGCT European Gene and Cell Therapy Database. <u>https://www.esgct.eu/heatmap</u>



3.5 Industry

Hungary's medical technology industry is export-driven contributing 5.3% of exports yet has challenges with domestic market size. Key companies such as Elektronika, Mediso, Sanatmetal, Innomed Medical Zrt., and Lasram Engineering Ltd. are actively involved in research and development collaborations with universities, focusing on medical imaging, electric and biosensor devices, and laboratory diagnostics. These companies have global ambitions, aiming to play a major role in clinical trials, biopharmaceutical development, in-vitro diagnostics, animal biotechnology, molecular medicine, and bioreactor technology.

Pharmaceutical Industry focuses on gene therapy, stem cell research, and genetic engineering. The National Research, Development, and Innovation Office supports biotechnology as a strategic area for growth. Hosting approximately 300 clinical trials annually, with €76 million investment involving around 17,000 patients. Key international companies: Richter, Amgen, Omixon, Biogen, Servier, UD-Genomed, and Solvo Biotech.

One of the major programs, The Healthy Hungary Program (2019-2030) focuses on cancer, cardiovascular, locomotor, mental health, and pediatric care. From 2021 to 2024, €28 million has been allocated to upgrade medical technology in Budapest's public healthcare institutions.

Telemedicine and Digital Health have become crucial, especially during the pandemic. Act 58 of 2020 formalizes telemedicine to ensure continuity of patient care. There is no comprehensive Health Technology Assessment (HTA) framework for Digital Health Technologies (DHTs).

3.6 Patients' associations

Hungarian Alliance of Patient Organizations (BEMOSZ-HAPO) is an Umbrella organization advocating for patient interests. Its' main goals: promote health literacy, ensure equal access to quality healthcare, engage and educate patients, and combat discrimination.

3.7 Clusters and networks

- **Hungarian Medical Cluster (HMC)** focuses on strengthening medical electronics manufacturing through innovation and collaboration with universities.
- Thermal-Health Industrial Cluster promotes thermal-health tourism and regional development.

3.8 Profesional Associations

- Association of Innovative Pharmaceutical Manufacturers includes 26 R&D-focused pharmaceutical firms. It focuses on innovating and improving healthcare quality, ensuring access to cutting-edge medical solutions.10
- Association of Healthcare Technology and Medical Technology Suppliers (ETOSZ) focuses on providing innovative healthcare technologies, advocate for ethical business practices, and ensure healthcare financing.
- Hungarian Society for Experimental and Clinical Pharmacology (HUPHAR) focuses on advanced pharmacology research and education. It also represents the country in international pharmacological organizations.

¹⁰ Association of Innovative Pharmaceutical Manufacturers, 2024. Our Activity. <u>https://wp.aipm.hu/en/our-activity/</u>



- Hungarian Healthcare Management Association (MEMT) focuses on enhancing healthcare management practices through coordination, education, and gatherings.
- Association of Hungarian Medical Societies and Associations (MOTESZ) comprise 124 member organizations, representing around 30,000 professionals.11

3.9 Academia

- Semmelweis University, Budapest is the top medical institution in Hungary, renowned for education and research. It also offers training programs for clinical investigations and medical research, with a strong emphasis on hands-on experience and compliance with Medical Device Regulation (MDR) standards.12
- University of Debrecen offers diverse English-language programs, especially in Medicine and Engineering.
- **University of Pécs** offers extensive academic support with 10 faculties and multiple research centers.
- **University of Szeged** is a comprehensive public research university with a health center and multiple faculties.
- **Óbuda University** has specialized courses to address the qualifications required by the MDR, focusing on areas like regulatory affairs, clinical investigations, and medical device design.

3.10 Research Centers

- **Biological Research Centre** (Hungarian Academy of Sciences) focuses on molecular and cell biology research with applications in health and environmental protection.
- HUN-REN Research Centre for Natural Sciences focuses on interdisciplinary research in natural sciences, including chemistry, cancer research, and neuroscience.
- Hungarian National Health Research Agency (HNHRA) focuses on coordinating scientific endeavors, translate research into practice, and enhance access to innovative therapies.

4. Existing legal framework

The existing regulatory framework aims to balance data protection, efficient healthcare delivery, and patient rights, while addressing challenges related to cross-border data exchange and the secondary use of health data.

Recently, the Hungarian government has repealed Government Decision 1517/2020 (VIII. 14.) concerning the Comprehensive Health Strategy of Hungary and its implementation, along with Government Decision 1518/2020 (VIII. 14.) related to the enhancement of the clinical trials

¹¹ Association of Hungarian Medical Societies and Associations (MOTESZ), 2024. Organizational Structure. <u>https://motesz.hu/info.aspx?sp=2&web_id=</u>

¹² Semmelweis University, 2023. Central Europe Clinical Scholars Research Training program hosted by Semmelweis University kicks off in Budapest. <u>https://semmelweis.hu/english/2023/08/central-europeclinical-scholars-research-training-program-hosted-by-semmelweis-university-kicks-off-in-budapest/</u>



and medical research institutional framework. Additionally, the newly adopted Hungarian Public Health Strategy has been introduced.¹³

4.1 Primary use of Health Data

Healthcare and social care providers use patient data primarily for direct care. This is governed by the Medical Data Act^{14} and GDPR Article 6 (1)(c)¹⁵ and Article 9(2)(h)¹⁶, which permit data processing for healthcare purposes without additional consent.

4.2 Secondary use of Health Data

The secondary use of health data in Hungary faces regulatory challenges, complicating data governance and privacy protection. While Electronic Health Services Space (EESZT) and the National Data Asset Management Agency (NAVÜ) allow data use for healthcare planning and public health, the legal framework remains unclear. Patient-level data collected through EESZT helps authorities optimize resource allocation, track healthcare outcomes, and support evidence-based reforms. Additionally, the National Health Insurance Fund provides insights into healthcare expenditures, aiding in efficient service management and promoting digital healthcare transformation.

In Hungary, both public and private organizations can access health data for research, but this requires ethical committee approval and data anonymization under the Privacy Act (2018) and Health Act (CLIV). The Medical Data Act governs research access, ensuring consent from healthcare institutions and protection of personal identifiers. Although datasets from institutions like the National Healthcare Service Centre are available, their unstructured format, often in PDFs, limits usability. Efforts to standardize data formats, aligned with the upcoming European Health Data Space (EHDS) regulations, aim to improve research efficiency and data quality by 2025.

Categories of electronic data available for secondary use in Hungary

- EHRs PARTIALLY (EHRs are available for secondary use, but access may be restricted and regulated depending on the purpose and data sharing agreements)
- data impacting on health, including social, environmental behavioral determinants of health NO
- relevant pathogen genomic data, impacting on human health NO
- health-related administrative data, including claims and reimbursement data -YES
- human genetic, genomic and proteomic data NO
- person generated electronic health data, including medical devices, wellness applications or other digital health applications PARTIALLY (some person-

¹³ Daily News Hungary, 2024. National public health strategy announced in Hungary <u>https://dailynewshungary.com/national-public-health-strategy-announced-in-hungary/</u>

¹⁴ EESZT Information portal, 2024. The legal framework of the EESZT. Act XLVII of 1997 on the Processing and Protection of Health Care Data and Related Personal Data ¹⁵ Art. 6 GDPR. <u>https://gdpr-info.eu/art-6-gdpr/</u>

¹⁶ Art. 9 GDPR. <u>https://gdpr-info.eu/art-9-gdpr/</u>



generated data can be shared, but this often depends on agreements and willingness of healthcare providers)

- identification data related to health professionals involved in the treatment of a natural person PARTIALLY (this data can be accessed for certain administrative purposes but is subject to strict regulations)
- population wide health data registries (public health registries) YES
- electronic health data from medical registries for specific diseases YES
- electronic health data from clinical trials PARTIALLY (available but access is tightly controlled based on regulations and consent)
- electronic health data from medical devices and from registries for medicinal products and medical devices PARTIALLY (data may be available but often requires specific conditions for access)
- research cohorts, questionnaires and surveys related to health PARTIALLY (access can be granted but is often dependent on ethical approvals and regulations)
- electronic health data from biobanks and dedicated databases PARTIALLY (available with specific conditions, often requiring ethical oversight)
- electronic data related to insurance status, professional status, education, lifestyle, wellness and behavior data relevant to health NO
- electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data permit - PARTIALLY (such data can be used but is subject to strict processing and sharing regulations)

4.3 Legal mechanisms for research use

The use of health data for research is regulated by the Privacy Act and Health Act, requiring ethics approval and compliance with anonymization procedures. Disease registries and public health initiatives are governed by sector-specific laws like the Medical Data Act and Decree No 49/2018.¹⁷

4.4 Patient's rights

Patients have the right to access and modify their medical records through the eHealth Space (EESZT). Hungary employs a presumed consent model for healthcare data, with an opt-out option for the National eHealth System and written consent for waiving confidentiality in specific situations.

4.5 Electronic Health records and standards

The National eHealth System (EESZT) serves as a centralized platform for electronic health records, facilitating both national and cross-border data exchanges. Patients can opt out, and

¹⁷ 49/2018. (XII. 28.) EMMI decree. https://net.jogtar.hu/jogszabaly?docid=A1800049.EMM



technical standards ensure secure data handling and exchange, supported by the National Data Asset Management Agency (NAVÜ).

The list below indicates the status of digital maturity of the healthcare system in Hungary¹⁸

- patient summaries YES
- electronic prescriptions YES
- electronic dispensations PARTIALLY (while there is a system for electronic prescriptions, the full integration of dispensations into electronic formats may vary across healthcare providers)
- medical images and image reports PARTIALLY (some systems are in place, but the extent of digitalization and access can differ by facility)
- laboratory results YES
- discharge reports PARTIALLY (discharge reports are often created in electronic format, but access and standardization may not be uniform across all healthcare institutions)

4.6 ATMPs regulation

The regulation of ATMPs in the EU, governed by Regulation (EC) No 1394/2007, establishes a framework for the classification, marketing authorization, and monitoring of gene therapies, somatic cell therapies, and tissue-engineered products. Key elements include the requirement for marketing authorization based on quality, safety, and efficacy assessments by the Committee for Advanced Therapies (CAT), strict traceability and labeling standards, and provisions for risk management and Good Manufacturing Practice (GMP). Additionally, the regulation allows for a "hospital exemption" for certain unapproved ATMPs under specific conditions, promoting flexibility while ensuring patient safety.¹⁹

5. Innovation Agenda on the field

Future plans about innovation in healthcare, with specific focus on health data, are described across three main official national documents: Health Sector Strategy, the AI Strategy and the Recovery and Resilience Facility.

¹⁸ EDAH's case study on Hungary https://edahproject.info/wp-content/uploads/2024/05/Web-HUNGARY-CASE-STUDYvf73.pdf

¹⁹ European Medicines Agency, 2024. Advanced therapy medicinal products: Overview. https://www.ema.europa.eu/en/human-regulatory-overview/advanced-therapy-medicinal-productsoverview



5.1 Healthy Hungary 2021-2027 – Health Sector Strategy (2021)

The document outlines a national innovation agenda focused on enhancing digital health and health data management. It highlights the critical role of e-health in transforming healthcare by optimizing resource allocation, improving patient care, and promoting preventive health measures. The strategy promotes healthier lives through infrastructure investments, digital health advancements, and public health strengthening. It supports targeted treatments, healthier lifestyles, and the Hungarian e-Health Space (EESZT) for integrated e-health solutions.

5.2 Artificial Intelligence Strategy

Focuses on utilizing healthcare data, enhancing AI-driven diagnostics, and supporting AI in medical decision-making. It aims to facilitate healthcare data access under GDPR, promote AI research, pilot AI applications in healthcare, and improve health administration through AI tools. Planned actions include developing infrastructure for health data management, promoting AI research and innovation, and supporting AI pilot programs in healthcare settings.

Key bottlenecks identified are infrastructure gaps and the need for more effective health data utilization. The strategy envisions AI tools supporting healthcare administration, capacity planning, and patient care, with a long-term objective of providing AI-based services to at least 3 million citizens through an integrated digital health system by 2030. However, current implementation remains in its early stages, with efforts to build the necessary framework still underway.

5.3 Recovery and Resilience Plan

The Hungary Recovery and Resilience Plan prioritizes healthcare modernization, with a significant focus on digital health. Of the EUR 5.8 billion allocated to Hungary under the Recovery and Resilience Facility (RRF), 22% (EUR 1.3 billion)²⁰ is designated for healthcare investments, targeting digitization as a core goal. Key initiatives include IT infrastructure upgrades in healthcare facilities, expanding telemedicine, and creating mobile health applications. Another planned action is establishing a remote health monitoring system for the elderly.

The plan aims to improve prevention, diagnosis, treatment, and service access through ICT, while enhancing care quality and efficiency. It also includes the development of telemedicine centers, IT management systems, and a National Biobank Framework. Despite this, the

²⁰ European Commission, 2024. Hungary's recovery and resilience plan. https://commission.europa.eu/business-economy-euro/economic-recovery/recovery-and-resiliencefacility/country-pages/hungarys-recovery-and-resilience-plan_en



release of funds is tied to achieving 27 "super milestones", focusing on transparency and governance. While efforts to digitize healthcare are underway, barriers remain in infrastructure development, the adoption of smart health solutions, and addressing the skill gaps needed to sustain digital reforms.



6. SWOT analysis

Strengths	Weaknesses
 Most health information managed by general practitioners (GPs) and hospitals has been digitized. All data centrally collected in the EESZT and mandatory for all healthcare providers, both public and private. High level of trust of the citizens in the system managing their data. Scientific research is listed among the purposes of data processing. The National Health insurance fund provides universal coverage through a single payer. Increased acceptance and utilization of remote healthcare services. 	 The information (data) systems of the hospitals are not unified. The healthcare system is hospital centric. No health technology assessment framework for digital health. Lack of ICT talent as the great brake on the digital transformation of the health sector. Only one Hungarian Competent Authority for medical devices and <i>in vitro</i> medical devices, and 2 notified bodies. Inadequacy of public funding. Hospital debts are accumulating.
Opportunities	Threats
 The percentage of structured data is on the rise. Health and personal data from different sources can be connected. The newly established National Data Asset Agency has been assigned to create a public data inventory. Mapping and understanding the healthcare decision makers information needs about DHTs and the barriers to utilizing them. 	 Discrepancy in the willingness to try and the ability to harness HealthTech. There are underserved segments of society regarding the use digital health technologies: older adults, people with long-term activity-limiting conditions, and homeless people. Some resistance to change from healthcare players. Not being able to transform the health system, making of it a lost opportunity. Political and economic factors in the country that confront policies. Cash flow disruptions and increased debt for SMEs due to late payments by the Treasury.



 High certifier pricing is expected to raise product costs in
Hungary's healthcare market,
compelling manufacturers to pass
these expenses onto consumers,
increasing the resource demands
of domestic holistic health and
enabling large corporate suppliers
to dictate the market, which could
transfer added costs to the public
budget.

7. Transferable good practices7.2 Health data EDIH

HDIH is part of the European Digital Innovation Hubs (EDIH) network, focusing on the digital transformation of SMEs and public sector organizations, particularly in healthcare and health data management. It is led by Neumann Nonprofit Ltd. in collaboration with universities, healthcare institutions, and public organizations across Hungary.

Objectives & Expected results:

- Increase the digital maturity of SMEs and public organizations by 5% over 3-5 years, with a focus on healthcare data digitization by reaching 15,000 entities, pre-screening 6,000, and serving 490 organizations.
- Foster digital integration and improve data management and operational efficiency in healthcare by providing training and technical support.
- Trigger 2 million EUR in investments and establish collaborative networks with other European EDIHs.²¹

Key activities:

- Provide training and digital literacy programs for organizations to improve their technical skills.
- Offer technical support to integrate digital solutions into healthcare operations.
- Support access to funding and financial services to accelerate investments in digital technologies.
- Conduct pre-screenings and diagnostics for potential clients to tailor solutions.

HDIH's scalable model of support, training, and funding is highly transferable to any region aiming to boost digital maturity in healthcare, benefiting public bodies, innovation hubs, and industry associations focused on SMEs and digital innovation.

²¹ European Commission, 2024. Hungarian DATA EDIH (Data-EDIH). <u>https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/org-</u> details/999999999/project/101083971/program/43152860/details



7.2 Data Warehouse at the University of Debrecen

This project is based at the University of Debrecen in Hungary, focusing on optimizing medical data storage and processing for research and innovation. It involves key players such as Microsoft Azure for scalable computing solutions and research groups in areas like Clinical Big Data, Genomic Processing, Artificial Intelligence (AI), and High-Performance Computing (HPC).

Objectives & Expected Results:

- Establish a comprehensive data warehouse, optimized for the management of medical data related to specific diseases by 2024.
- Enhance data handling for research by developing secure research environments that facilitate safe access to medical data for innovation and study.
- Ensure compliance with GDPR standards by implementing stringent data privacy regulations that protect sensitive health information while making it available for research.
- Expand Data Management Services by introducing of data as a new service for market participants, thereby enhancing the university's offerings in data management and research support.²²

Key activities:

- Implement a scalable cloud computing platform (Microsoft Azure) to manage large volumes of medical data.
- Engage research groups in Big Data, genomics, AI, and HPC to process and data.
- Prioritize data security, application development, and the creation of GDPR-compliant environments for research.
- Develop data asset management regulations and operational guidelines for secure usage.

This practice is highly transferable due to its scalable cloud infrastructure and focus on data security and GDPR compliance, making it applicable in any research institution or healthcare organization handling sensitive medical data.

7.3 Hungarian National eHealth Infrastructure (EEZST)

EESZT centralizes health data to improve communication among healthcare professionals, supporting tools like ePrescriptions and storing medical records. Established in 2017, it

²² University of Debrecen, 2024. TKP2021-NKTA-34. <u>https://palyazatok.unideb.hu/node/390</u>



serves over 26,000 professionals and enhances healthcare by reducing redundant exams, improving diagnosis accuracy, and providing citizens with centralized access to their medical data. Key features include eHealth History, eProfile, and integration of smart device data.

Objectives & Expected Results:

- Process 800,000 electronic prescriptions daily, enhancing prescription management and reducing errors.²³
- Record 75 million medical documents and 180 million appointments annually, streamlining data access and reducing redundant exams.²⁴
- Enhance patient care by integrating smart device health data, leading to more personalized and accurate diagnoses.
- Facilitate online appointment bookings, improving healthcare access and reducing administrative burdens for both patients and providers.

Key activities:

- Centralize patient data into a single platform accessible to healthcare professionals and patients.
- Launch tools like eHealth History, eProfile, and integrate smart device data to track health metrics.
- Support ePrescriptions.
- Allow citizens to book appointments online and manage their own health data.

EESZT is highly transferable due to its comprehensive digital infrastructure and focus on data integration, which any country or region could adopt to improve healthcare delivery. Governments, health ministries, and public health organizations aiming to digitize health services and enhance data accessibility for both healthcare providers and citizens should implement similar systems.

²³ Interreg, 2022. Practical Manual for Good Practices. <u>https://d-care.mgfu.hu/medias/64/d-caremanualgpsfinal.pdf</u>

²⁴ EESZT Information portal. The role of the EESZT in Hungarian Healthcare. <u>https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/the-role-of-the-eeszt-in-hungarian-healthcare</u>





8. Good Practices Related to Gender Diversity and Inclusiveness

Hungary has made significant strides in promoting gender diversity and inclusiveness within its health sciences and innovation sector. Several key practices have been observed:

- **Gender-Inclusive Policies** implementation of anti-discrimination laws, provisions for maternity and paternity leave, measures to address gender pay gaps.
- Support for Women in Leadership Roles initiatives for women entrepreneurs, researchers, and decision-makers, funding schemes, networking opportunities, and leadership development programs.
- Research and Data Collection prioritization of data collection to understand gender disparities, Use of data for evidence-based policy-making and targeted interventions.

8.1 Good Practices in Hungary's Health Sciences and Innovation Sector

Various organizations, including universities, non-profits, and tech companies, are dedicated to promoting gender diversity in technology. Key players include women's advocacy groups, educational institutions, and industry leaders committed to creating an inclusive environment for women in STEM fields.

 Women in Technology Initiatives - aim to increase the representation of women in technology and innovation sectors by establishing mentorship programs, networking events and providing training opportunities.



- Entrepreneurship and Leadership Programs focus on empowering women entrepreneurs and leaders in the health sciences and innovation sector. These programs providing funding, mentorship, and networking opportunities for women-led startups and businesses.
- Healthcare Access and Awareness Campaigns improve healthcare access and awareness among marginalized communities, including women. These initiatives could address specific health issues, promote preventive care, and empower women to take control of their health.
- Institutional Mechanisms establish institutional mechanisms at both national and local levels address gender equality issues. These mechanisms could include governmental bodies, commissions, or councils responsible for developing and implementing gender equality policies.

9. Potential Synergies with Other EU Regions

Hungary and its neighboring countries have a wide range of cross-border cooperation in healthcare programs and projects.

Program, Project	Countries	Focus Areas	Focus Activities and Outcomes
INTERREG HSRU	Hungary, Slovakia, Romania, Ukraine	Healthcare infrastructure, training, prevention	Upgraded health capabilities, partnerships between hospitals and NGOs, enhanced medical technology and services, infectious disease control projects like IDHB and TBCHB, modernization of healthcare infrastructure. ²⁵
Babies Across Borders	Romania, Hungary	Obstetrics- gynecology, neonatology	Construction of new clinics, modernization of departments, procurement of new equipment, knowledge exchange among professionals, public awareness campaigns. ²⁶
HEAL NOW	Austria, Hungary	Cross-border healthcare partnership	Established cross-border network, implemented pathology pilot program with rapid tele-diagnostic system, procurement of high-resolution medical equipment. ²⁷
EOSC-ENTRUST	15 European countries including Hungary	Trusted research environments	Implementing a unified European framework for trusted research environments, developing interoperability blueprint, assessing capabilities

²⁵ Interreg, 2023. Interreg Vi-A Next Hungary-Slovakia-Romania-Ukraine 2021-2027 Programme. <u>https://next.huskroua-cbc.eu/</u>

²⁶ Interreg, 2024. Romania-Hungary. <u>https://interreg-rohu.eu/wp-content/uploads/2024/02/ROHU-</u> 443-EN-final.pdf

²⁷ Interreg, 2024. Austria-Hungary. HEAL NOW. <u>https://www.interreg-athu.eu/en/healnow/</u>



			through driver projects in Genomics, Clinical Trials, Social Science, and Public-Private Partnerships. ²⁸
Towards GEMINI	Europe including Hungary	Stroke patient digital twins	Creating computational models for acute strokes, validating personalized digital twin models for stroke treatments, establishing data management processes, benefiting clinical practice and research. ²⁹
SECURED	Europe including Hungary	Health data processing and anonymization	Enhancing secure multiparty computation, data anonymization, and synthetic data generation, focusing on health data security and cross-border collaborations. ³⁰
XpanDH	Europe including Hungary	Digital health solutions	Empowering development of interoperable digital health solutions, adopting EEHRxF format, enhancing healthcare value, supporting Health Data Spaces. ³¹
IMI BIGPICTURE	Europe including Hungary	Digital pathology repository	Creating a digital repository of disease slides, developing AI tools for slide analysis, addressing legal and ethical issues, enhancing diagnostic capabilities. ³²
BY-COVID	Europe including Hungary	COVID-19 data and infectious diseases	Providing open data on SARS-CoV-2, facilitating data integration and analysis, ensuring compliance with data protection regulations, harmonizing metadata and sample identifiers. ³³
TEHDAS	25 European countries including Hungary	European Health Data Space (EHDS)	Developing principles for secondary use of health data, forming governance structures for cross-border cooperation, enhancing health data accessibility, clarifying individuals' positions in health data usage. ³⁴
PHIRI	Europe including Hungary	Population health information	Facilitating data-driven research on COVID-19 impacts, providing a Health Information portal, promoting interoperability and tackling health information inequalities. ³⁵
B1MG	Europe including Hungary	Genomics infrastructure	Supporting the European 1+ Million Genomes initiative, creating genome-based health data infrastructure, collaborating with international initiatives, implementing personalized medicine. ³⁶
Digital Health Transition Project	Hungary	Digital healthcare transition	Supporting digital healthcare transition, improving health data assets, enhancing IT security, developing telemedicine services and national health mobile application.

²⁸ European Network of Trusted Research Environments, 2024. <u>https://eosc-entrust.eu/</u>

 ²⁹ Gemini, 2024. <u>https://dth-gemini.eu/</u>
 ³⁰ Secured EU Project, 2024. <u>https://secured-project.eu/</u>

³¹ XpanDH, 2024. <u>https://xpandh-project.iscte-iul.pt/</u>

³² Bigpicture, 2024. A central repository of digital pathology slides to boost the development of artificial intelligence. https://bigpicture.eu/ ³³ By-Covid, 2024. https://by-covid.org/ ³⁴ TEHDAS2, 2024. https://tehdas.eu/

³⁵ Population Health Information Research Infrastructure, 2024. <u>https://www.phiri.eu/</u>

³⁶ Beyond 1 Million Genomes, 2024. <u>https://b1mg-project.eu/</u>



10. Conclusions

Positive Developments

- The National eHealth Infrastructure (EESZT) enhances healthcare communication and reduces redundant examinations.
- Cross-border cooperation, like Interregional programs, improves disease prevention and healthcare outcomes in border regions.
- Hungary's involvement in European health data projects (e.g., EOSC-ENTRUST, GEMINI, SECURED) advances interoperable research and secure data processing.

Gaps and Challenges

- Hungary's healthcare system faces hospital debt, low spending, and high out-ofpocket costs, straining access to care.
- Shortages of physicians due to emigration worsen the quality and availability of medical services.
- Discrepancies in "techquity" limit digital technology benefits for underserved groups.
- Limited cooperation with non-neighboring EU countries, which could hinder broader integration and innovation in healthcare.

Improvement Opportunities

- Implementing key recommendations from Digital Health working groups can enhance digital technology use in healthcare.
- Preparing for EU-wide e-health data regulations and transitioning health data to searchable formats is essential.
- Strengthening clusters and networks, like the Hungarian Medical Cluster, can drive medical technology and pharmaceutical innovation.

