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European Health Data Space: Serbia's Path Forward



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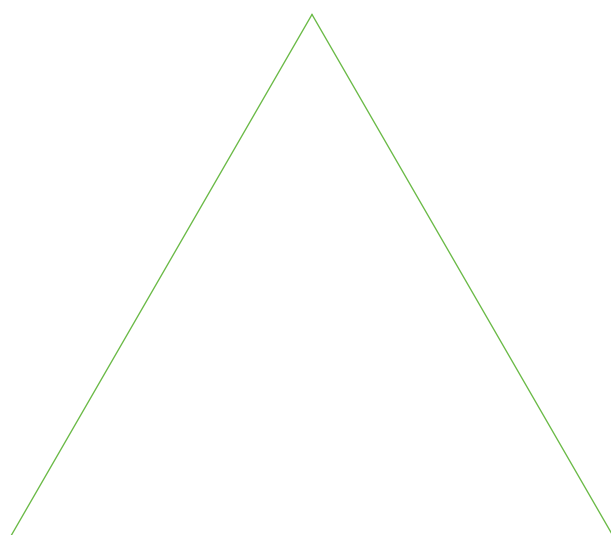
Serbia

Centre for the
Fourth Industrial
Revolution

GENIAL

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Context

This white paper is the result of a collaborative effort led by EIT Health InnoStars, C4IR Serbia, Takeda Serbia, and Genial, incorporating insights from policymakers, healthcare professionals, researchers, patient advocates, and experts in the life sciences industry. Their observations on Serbia's digital health landscape and its alignment with the EHDS framework have been essential in shaping this report.

The Steering Committee provided continuous dialogue and feedback throughout the drafting process, ensuring the report's structure, content, and style were aligned with its objectives.

Members of the steering committee are Inês Matias (EIT Health InnoStars), Jelena Bojovic (Centre for the Fourth Industrial Revolution in Serbia), Nevena Veljkovic PhD (Genial Ltd), and Dejana Rankovic (Senior Advisor, Health Systems Digitalisation).

About EIT Health

EIT Health is a network of best-in-class health innovators with approximately 100 partners, supported by the <https://eit.europa.eu/> European Institute of Innovation and Technology (EIT), a body of the European Union. It collaborates across borders to deliver new solutions that can enable European citizens to live longer, healthier lives.

As Europeans tackle the challenge of increasing chronic diseases and multi-morbidity and seek to realise the opportunities that technology offers to move beyond conventional approaches to treatment, prevention and healthy lifestyles, we need thought leaders, innovators and efficient ways to bring innovative healthcare solutions to market.

EIT Health's commitment to driving healthcare advancement is evident in a proactive role in mentorship, funding, and research facilitation. Recognised as a pivotal player in healthcare innovation, EIT Health's record of accomplishment includes: catalysing over 2,998 start-ups and scale-ups, helping EIT Health-supported startups attract €2.2 billion in investment,

propelling 123 healthcare solutions to the market, and training 65,000 students and professionals.

EIT Health addresses these needs by connecting all relevant healthcare players across European borders – making sure to include all sides of the “knowledge triangle”, so that innovation can happen at the intersection of research, education and business for the benefit of citizens.

About EIT Health InnoStars

The InnoStars cluster is one of the eight geographical areas of EIT Health. It covers half of Europe, including Poland, Hungary, Italy, and Portugal, as well as additional regions included in the EIT Regional Innovation Scheme – the Baltic States, Croatia, Slovakia, the Czech Republic, Slovenia, Greece and Romania. This is a group of countries qualified by the European Innovation Scoreboard (EIS) as moderate innovators. InnoStars is focused on promoting entrepreneurship, innovation and education in the domain of healthcare, healthy living and active ageing in the region and closing the gap between regions that are leaders in innovation and those regions which are progressing.

EIT Health: Together for healthy lives in Europe.

About Centre for the Fourth Industrial Revolution in Serbia

The Centre for the Fourth Industrial Revolution in Serbia (C4IR Serbia) was jointly established by the Government of the Republic of Serbia and the World Economic Forum in February 2022 as a platform for interaction and cooperation among various social actors to enhance the environment for the application of Fourth Industrial Revolution technologies.

The Centre began operating in March under the auspices of the Office for IT and eGovernment of the Government of the Republic of Serbia, with a specific focus on two priorities: biotechnology and the application of artificial intelligence in healthcare. Its primary goal is to facilitate the rapid utilisation of scientific knowledge within the

economy and position Serbia as a global exporter of intelligent services and innovations.

C4IR Serbia aims to unite scientists, representatives of the state, industry, and civil society to create conditions for the development, testing, and advancement of new technologies for the benefit of society. Alongside fostering dialogue between these stakeholders, the Centre also proposes regulations to facilitate the adoption of new technologies^[2].

About GENIAL

GENIAL is a research and scientific consultancy specialising in life and data sciences. The company excels in mapping complex data landscapes, including biomedical, multi-omics, and health data, and provides advanced analytical solutions tailored to the life sciences sector. By integrating expertise in bioinformatics and data analysis, GENIAL supports projects that unlock the full potential of healthcare and biomedical data for innovation and decision-making^[3].

About EIT Health Morning Health Talks – Events for Healthcare Transformation

The EIT Health Morning Health Talks (MHT) is a series of events launched in 2020 to stimulate thought-provoking discussions on the most pressing innovative healthcare topics and create a network environment for healthcare thinkers and doers in Central, Eastern and Southern Europe. Based on several years of tradition, the EIT Health Morning Health Talks format provides a special space for honest and effective discussions among high-level stakeholders, encouraging future collaborations toward more advanced healthcare ecosystems.

On October 25, 2024, an EIT Health Morning Health Talks event titled "Implementing the European Health Data Space in Serbia" was organised within the AI_4_LIFE: Biotech Future Forum, in Belgrade.

Its participants explored diverse perspectives on EHDS implementation, spotlighting varying approaches and timelines from different nations. Participants shared and discussed different government strategies, pilots, the transformative impact on healthcare systems, and the essential collaborations needed to make this vision a reality.

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Methodology ▼

The preparation of this white paper involved the following steps:

Review of Publicly Available Sources, including Policy and Regulatory Frameworks, EU and EIT Health Initiatives and Reports, National Strategies and Local Systems, Academic and Industry Contributions, and Organisational and Project Resources in order to provide a better understanding of EHDS and Serbia's current state in the healthcare digitalisation process.

Insights from the EIT Health Morning Health Talks roundtable discussion, held on 25 October 2024 during the Biotech Future Forum. The event in Belgrade featured representatives from diverse organisations, including the Prime Minister's Office of Serbia, Ministry of Health Serbia, Office for IT and eGovernment, Centre for the Fourth Industrial Revolution Serbia, Takeda Serbia, the Medicines and Medical Devices Agency of Serbia, EIT Health InnoStars, EIT Health France, Prologica Portugal, Spicy Analytics Hungary, the Polish Hospital Federation, Italian Association of Healthcare Information Systems, along with notable representatives from Serbia's academia, civil society and industry.

Stakeholder Interviews and Analyses for Landscape Mapping. The research for this study involved conducting interviews with stakeholders' representatives to comprehensively map the Serbian landscape regarding its preparedness and integration within the EHDS. Stakeholder interviews were conducted to gather in-depth insights from key groups across healthcare, policy, data management, academia, and patient associations. This combination of expert interviews and rigorous analysis provides a structured and context-specific understanding of the Serbian healthcare data landscape, with implications for both national policy alignment and strategic development.

Identification of Challenges and Recommendations.

Current and future challenges were identified, along with recommendations to address and mitigate them, outlining their potential impact.

Summary ▼

The European Health Data Space (EHDS) is a European Union (EU) initiative aimed at establishing a unified and secure framework for health data exchange across member states. Its objectives are to foster healthcare innovation, safeguard data privacy, and enhance patient outcomes^[4]. EHDS is part of the EU's broader strategy to enhance digital services, foster innovation, while ensuring robust data protection^[5]. Proposed in 2022 and politically agreed upon in 2024, the EHDS regulation was published on March 5, 2025 and officially came into force on March 26, 2025^[4].

Serbia, a candidate country for EU membership since 2014, maintains strong trade and political ties through Stabilisation and Association Agreements and actively participates in several EU programmes, including Horizon Europe and Erasmus+^[6].

In recent years, Serbia has made significant progress in digitalising its public administration. According to the World Bank's GovTech Maturity Index, Serbia ranks fourth in Europe and eleventh globally for integrating technology into public services. Through its ongoing digitalisation efforts, Serbia aims to enhance service quality, improve system efficiency, and build public trust in data sharing. As the country continues its EU accession process, aligning with the EHDS represents a significant opportunity to integrate promptly into Europe's digital health ecosystem.

This white paper serves as a resource for stakeholders in Serbia's health data ecosystem, offering insights into the EHDS, healthcare digitalisation initiatives across the EU, and the current state of digitalisation in Serbia. It outlines actionable steps, based on sector research and stakeholder input, to align with EHDS goals and facilitate integration into the framework.

Setting the Scene ▼

A | European Health Data Space

Health data in Europe has long been siloed within national borders, with each member state operating distinct EHR systems and data governance frameworks. The level of digitalisation of health data across the EU varies significantly between member states, making cross-border data sharing more challenging.

This fragmentation has limited healthcare providers' ability to access patient information across countries, posing challenges to delivering continuous care for EU citizens ^[7]. EHDS is designed to enable secure and unified health data exchange across member states. The concept of the EHDS builds on insights gained during the COVID-19 pandemic, which revealed fragmentation in health data management across Europe. The crisis revealed that cross-border data sharing was often inefficient and inconsistent due to varying regulations, the lack of a harmonised digital health infrastructure, and challenges in interoperability ^[8,9].

Although the General Data Protection Regulation (GDPR) ^[10] established a baseline for personal data protection, it has not fully addressed the specific complexities of cross-border health data sharing. Initiatives such as the MyHealth@EU and HealthData@EU platforms have laid foundations for cross-border health data exchange. MyHealth@EU is a service under the eHealth Digital Service Infrastructure (eHDSI) that ensures continuity of care for European citizens while travelling abroad within the EU, offering several cross-border services, including ePrescriptions and eDispensation, enabling citizens to access medication in another EU country, and Patient Summaries, which provide essential health information – such as allergies, current medications, and medical history – in a doctor's native language to overcome linguistic barriers.

The exchange of ePrescriptions and Patient Summaries is open to all EU countries. In the long term, additional data types such as medical images, lab results, and hospital discharge reports will also be made available across the EU, followed eventually by the complete health record ^[11].

HealthData@EU facilitates the secondary use of health data across Europe through its Central Platform, which hosts the EU Dataset Catalogue, compiling metadata from various sources, including member states and research infrastructures ^[12]. The 2022 HealthData@EU Pilot project focused on implementing priority services such as metadata discovery and a unified health data access request system ^[13]. Complementing this, the TEHDAS2 project develops guidelines and technical specifications to support data holders, users, and access bodies, which member states will establish once the EHDS is operational ^[14]. The EHDS regulation introduces a requirement for all EHR systems to comply with the European electronic health record exchange format (EEHRxF), enhancing interoperability at the EU level ^[15].

The EHDS will support both the primary and secondary use of health data, enabling cross-border access to medical records and essential health information for healthcare delivery, while ensuring secure, consent-based access to data for research, clinical trials, policymaking, and AI development.

As a result, the EHDS is expected to:

- **Empower Citizens:** by providing individuals with electronic access to their health data, allowing control over portability and the ease of sharing information with healthcare providers across the EU.
- **Strengthen Healthcare:** by standardising electronic health record (EHR) exchange, improving efficiency and interoperability across EU health systems, and enabling healthcare providers to securely access patient data with consent.
- **Support Research and Innovation:** by facilitating the use of health data beyond direct patient care to develop treatments, advance AI, and shape health policies, with strict privacy measures such as pseudonymisation and anonymisation.
- **Drive Economic Growth:** by creating a unified digital health market that supports innovation in AI, medical devices, and digital health products^[1,13].

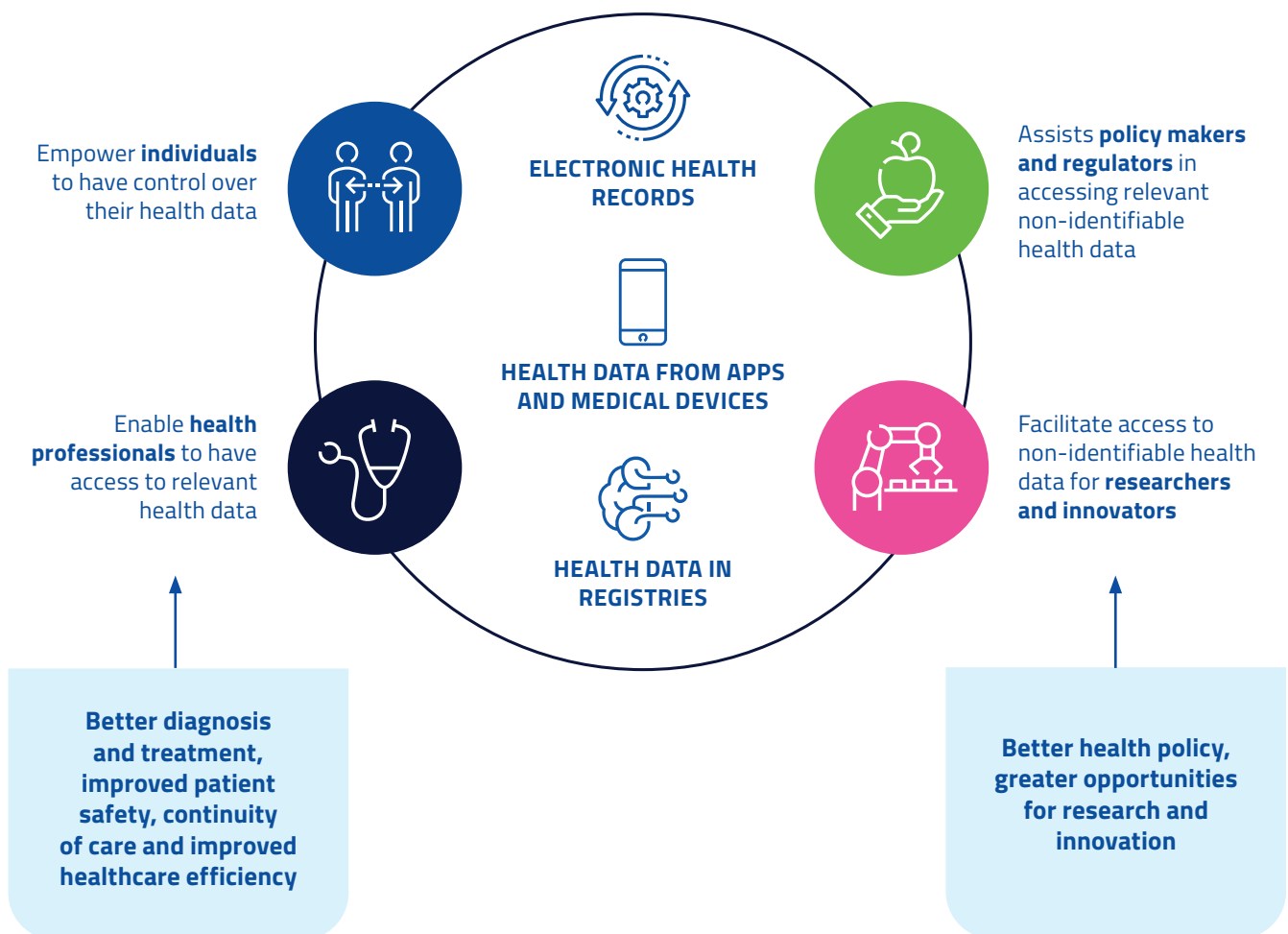


Figure 1 – EHDS Objectives^[16]

B | Health Data Space in Serbia

In Serbia, health data has been strategically recognised as a key resource in the digital era, offering opportunities to improve healthcare outcomes and drive innovation. Following the establishment of healthcare system digitalisation, the country is now advancing towards detailed regulation and integration of its health data space.

Since 2000, Serbia has undertaken the digitalisation of its healthcare system with support from the World Bank, the European Union, the European Bank for Reconstruction and Development, and other donors. At this moment, local health information systems are introduced in nearly all primary, secondary, and tertiary healthcare institutions, alongside advanced digital solutions for specific needs. This established a robust network of local data sources.

In 2017, a significant milestone was achieved with the establishment of the Office for Information Technologies and eGovernment, which serves as the central hub for the government's digital infrastructure. This entity manages the national data centre, provides essential digital services to both public institutions and private entities and hosts a portal, eHealth (eZdravlje), that allows electronic appointment scheduling, referral systems, access to health documents, electronic prescriptions, information on wellness exams for school

enrolment, and services for Childbirth Registration and Death Certificates^[17]. Its robust infrastructural support proved vital during the COVID-19 pandemic, enabling the rapid deployment of digital health solutions. During the pandemic, Serbia adopted an agile approach, leveraging its digitalised healthcare system to introduce solutions such as real-time monitoring of infection, hospitalisation, and vaccination rates. Citizens gained digital access to COVID test results and vaccination certificates, while telemedicine and eConsultations enabled contactless medical appointments, showcasing the country's adaptability during a time of crisis.

Recently, steps have been taken to establish the strategic and regulatory foundation for continued modernisation, enabling more efficient healthcare and swift integration with the EHDS. The most significant milestone is the new Law on Medical Documentation and Records in Healthcare, which introduces key innovations, including the integration of archives from all healthcare institutions into a unified data system and the creation of the so-called e-karton (centralised EHR)^[18].

This paper explores the groundwork for further eHealth progress through three critical areas:



1. eHealth and Data Governance

Effective eHealth and data governance is vital for managing healthcare data throughout its lifecycle, from collection and storage to standardisation, analysis, and reuse. This ensures secure sharing and integration with other datasets.

Healthcare digitalisation in Serbia began with the introduction of local information systems in healthcare institutions, supported by standards for structured data entry at the point of care. These systems are now widely used across public healthcare and major private chains, although the quality and completeness of data still vary considerably between institutions.

Serbia's healthcare system is divided into three main sectors: publicly funded healthcare (available to all citizens), private healthcare institutions, and the military sector. At present, these operate in silos with minimal data exchange between them. The lack

of integration between public and private health data systems particularly affects healthcare professionals and patients, causing delays in decision-making and requiring repetitive data entry for the same patient across multiple applications. As a result, patients may undergo repeated examinations, which can delay diagnosis and lead to suboptimal outcomes. Access to comprehensive patient data will enable contextual patient monitoring and is particularly crucial during emergency admissions, where timely and informed decisions are vital for ensuring safe and effective care.

Over the past few years, the public healthcare sector has implemented several central services and databases (Figure 2). Despite this, integration within the sector remains incomplete, highlighting the need for systematic solutions to connect separate parts of the healthcare system.

CURRENT STATE / USE OF DATA FROM LOCAL HEALTH INFORMATION SYSTEMS FOR ANCILLARY SERVICES AND ONGOING PROJECTS

SERVICES		ONGOING PROJECTS	
ePrescription	eRecept is a national prescription system which allows public provider prescriptions and dispensary in the network of public and private pharmacies	E-Referral	Fully implemented, pending to enable validation of referrals for surgery
eRadiology	Implemented for patients to schedule with a GP. In order for patients to schedule, primary healthcare centres must open slots in the portal since they don't have the shift schedule.	Data centralisation and safety	Building an independent health data network, commencing with transferring data from local information systems to the National Data Center
Patient portal	Available for every citizen with a registered eID, offers all health documents from the public sector	EHR	Connecting all data from mandatory health documents from the public, private and military sectors
eInvoice	Processing invoices from public health institutions and interconnectedness with the National Health Insurance Fund	e-SickLeave	To speed up and facilitate the process of opening a sick leave, to eliminate the need for patients to carry remittances when they are sick, and to enable the RFZO to extend the sick leave beyond 30 days
Public health reports and analytics	Sistem javnog zdravlja - a National institute for public health system to track and report on issues and registries for diseases of public health interest, as per the law	Digital records of health resources	Data on: 1) health institutions, private practices and other legal entities; 2) employees; 3) equipment; 4) construction facilities; 5) medicines and medical devices; 6) resources of information and communication technologies
Medicines and med. devices regulatory body system	Approval of medicines and medical devices registration, variations, clinical trials, reporting adverse effects	National registry of Genetic data	The registry will represent a place where genetic data, generated in Serbia by processing and sequencing biological samples, as well as necessary biomedical data obtained in the health system, will be stored

Figure 2 – Data Use from Local Health Systems in Public Central Services
(presented at the Morning Health Talks in Belgrade (2024), Courtesy of Mrs. Pavicic)

1. To improve eHealth management, Serbia established its first Coordination Body for Digitalisation in the Health Care System in 2021, chaired by the Prime Minister. This body brought together representatives from the Ministry of Health, the Ministry of Finance, and other key stakeholders, consolidating all healthcare digitalisation initiatives. As a result, in February 2022, the eHealth Strategy 2022–2026, titled “Programme for Digitalisation of the Health System in the Republic of Serbia”^[19] and its accompanying Action Plan 2022–2023^[20] were approved.
2. In the following phase, Serbia identified e-karton (centralised EHR) as a strategic priority. In 2023, a second Coordination Body for Digitalisation in the Healthcare System was established, focusing on legislative changes – most notably the new Law on Medical Documentation – and on the standards and architecture for the national e-karton (centralised EHR).

“*Digitalising the healthcare system requires navigating a complex network of stakeholders. A successful model implemented in the previous period showcased its effectiveness through the establishment of a Coordination Body for Digitalisation in the Health Care System led by the Prime Minister. This body played a crucial role in facilitating major decision-making by offering suggestions, recommendations, and fostering agreements. The goals of digitalisation are the consolidation of health data and the services we provide to citizens, as well as simplifying and streamlining processes without placing additional burdens on healthcare professionals, but rather easing their workload and supporting them in their roles.*

— Katarina Pavicic
Advisor to the Prime Minister of the
Republic of Serbia

“*It is not feasible to design healthcare software without the active involvement of doctors to identify the data required for effective and comprehensive care provision and subsequent uses, such as registries. Digitalisation is not a one-time effort but an ongoing process that evolves through continuous assessment, refinement, and long-term monitoring. The Ministry of Health will oversee and coordinate the digitalisation efforts.*

— Ivana Stasevic Karlicic, MD, PhD
State Secretary at the Ministry of Health of the
Republic of Serbia

The next paragraph outlines two key governance frameworks for health data and eHealth in Serbia, developed by the Ministry of Health with the support of the Coordination Body:

1) Digital Health Strategy^[19]

A primary objective of the eHealth strategy is to enhance infrastructure and technology, allowing seamless information exchange and data interoperability throughout the healthcare ecosystem. Another important element is strengthening governance mechanisms to ensure coordinated efforts and collaboration among all digital health stakeholders. This includes forming partnerships between government entities, private sector organisations, and professional associations to jointly drive the digital transformation agenda.

The strategy also highlights the need to upgrade infrastructure for efficient collection, storage, and retrieval of health-related data. This entails implementing a robust e-karton (centralised EHR) system and other digital resources to facilitate smooth information flow and better decision-making.

The action plan^[20] outlines specific goals for improving eHealth governance, developing healthcare infrastructure and IT services, fostering secondary use of health and biomedical data, and furthering education and communication.

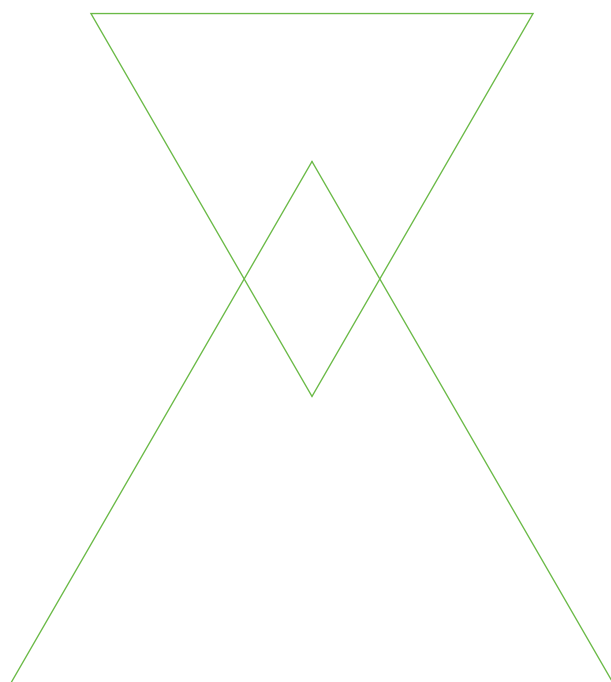
2) Law on Medical Documentation and Health Records ^[18]

A new Law on Health Documentation and Health Records was adopted by the National Assembly on 26 October 2023. This legislation brings key innovations: integration of the data of all health institutions into a single data system – Integrated Health Information System of the Republic of Serbia, establishment of the e-karton (centralised EHR) , and the Genetic and Biomedical Data Registry. It also stipulates that the Ministry should establish integrated eHealth, with technical support of the Office for Information Technologies and eGovernment, which is also responsible for the tasks related to the storage, implementation of protection measures and ensuring the safety and security of data from the registers, in accordance with the regulations governing electronic administration and information security.

Further progress with e-karton (centralised EHR) and healthcare digitalisation will require strong governance to ensure sector-wide integration and secure, structured data access tailored to the needs of all relevant stakeholders. Thorough centralisation should allow the consolidation of data and smooth exchange with the EHDS.

“ *The establishment of a modern and advanced electronic healthcare system in Serbia involves two processes: the transfer of local information systems of healthcare centres, clinical and hospital centres to the Government Data Centres in Kragujevac and Belgrade, and the establishment of various central registers and health records such as eHealthRecord. It is very important that the Republic of Serbia adopted appropriate legislation that precisely defines the possibility of implementing these two processes, as well as the role of the Ministry of Health and the Office for IT and eGovernment in them. In the next 2 years, I expect a lot from these two processes, which will lead to the health data of citizens being stored safely, according to the highest technical and security standards, and the existence of central registers will enable strictly controlled access to data and numerous electronic services for both Serbian citizens and employees of healthcare institutions.*

— Dr. Mihailo Jovanovic
Director of the Office for Information Technologies
and Electronic Administration



2. Secondary Use of Health Data

Secondary use of health data refers to the utilisation of existing medical data, genomic data, insurance claims, disease registry data, and clinical trial data for purposes beyond direct patient care. This includes improving and planning healthcare, analysing population characteristics, developing therapies, and informing policies. To protect privacy, the data is often anonymised and aggregated.

Serbia's vision, as outlined in its *Digitalisation Programme for Healthcare (2022–2026)* ^[19], aligns with the EU perspective by recognizing the significant potential of secondary use of health data.

	USE TYPE		
	Primary use Health and genomic data collected directly from the patient, in person or remotely	Secondary use Repeated use of health data originally collected in the context of the provision of health services	MIX Data processing by organisations other than the original data controllers
Data collection in clinical setting	Prevention, diagnosis and treatment of individual patients	Use of existing patient data for the benefit of other patients	Use of existing patient data for clinical trials
Data collection in health-related research and innovation	Collection, creation (processing) and use of data in research protocols	Use of data generated during the research protocol for treatment purposes (integrating research into clinical practice)	Use of targeted datasets collected for the purpose of a scientific study
Health systems governance and management	Registries of diseases, resources, etc.	Further utilization of the same data: management, administration, reimbursements, financial reports, registers, etc.	Repeated processing of tissue and cell samples, and data collected within previous research
Commercial purposes	Development of new technologies for diagnostic and treatment needs	Further utilization of the same data for commercial purposes	For example repeated use of data from clinical tests for purposes different from the original (secondary health research)

Figure 3 – Scope of health and genome data collection and its use in different scenarios
(presented at Morning Health Talks at Belgrade in 2024, Courtesy of Mrs. Pavicic)

Currently, healthcare institutions and private practices submit data to the Ministry of Health, the Republic Fund for Health Insurance, the Medicines and Medical Devices Agency, and the Institute of Public Health of Serbia “Dr. Milan Jovanovic Batut” (IPH Batut). Some of these consolidated datasets can be utilised for secondary purposes, such as public health monitoring and supporting decision-making processes. While certain data submissions are mandated by law, other data flows are driven by specific operational needs and institutional requirements. IPH Batut and the Republic Fund for Health Insurance collect data in the following ways:

1. District Institutes of Public Health gather healthcare data from providers at the primary, secondary, and tertiary levels, then compile reports on the health status of their respective populations. They also regularly submit information to the national disease registry, vaccination records, healthcare quality databases, healthcare financing systems, and other health indicators governed by the national IPH Batut.
2. Local health information systems at the facility level generate electronic invoices for the Republic Fund for Health Insurance, capturing detailed information about the medical procedures and treatments administered to each patient.

The newly adopted Law on Medical Documentation and Records defines data management rules and authorisations for secondary use. Under this framework, the Ministry of Health is responsible for overseeing central registers and the data they contain, while IPH Batut and the Republic Fund for Health Insurance each serve as data controllers for their own registries.

This new legislation lays the groundwork for practical secondary use of health data, but Serbia is still in the early stages of implementing both the strategy and the law, facing multiple challenges in meeting its objectives. The use of de-identified or aggregated health data for analytics and reporting remains limited. In many healthcare software solutions, most information is not captured in a structured format, and data entry often relies on free-text fields. Consequently, the limited availability of machine-readable data significantly restricts secondary data use, impeding research and healthcare improvements while also limiting the commercial potential of de-identified data.

According to several key stakeholders, the lack of well-maintained clinical and disease registries is a major obstacle to more efficient data use. These registries, which exist at national and clinical levels, are a vital source of data for secondary purposes. However, they often do not support longitudinal patient tracking or real-time monitoring – capabilities essential for evaluating treatment outcomes and shaping healthcare and commercial strategies.

One major issue is that maintaining registries demands significant time from physicians, as they are often overly detailed and lack pre-population capabilities using data from routine clinical practice. Another critical challenge involves data ownership and the ability to repurpose registry data for objectives beyond their original collection intent.

While the establishment of a centralised EHR should greatly enhance the potential for secondary data use, large amounts of vital information – including that stored in clinical registries – still need to be centralised.

Furthermore, the private healthcare sector has a smaller role in national registries, despite the potential benefits

of integrating its data with the public sector. Such integration could improve data comprehensiveness, enhance healthcare coordination, and support better patient outcomes. When it comes to real-world data, Serbia's standards and data structures are fully aligned with global standards for observational studies. Through European projects, databases from primary, secondary, and tertiary healthcare institutions have been successfully mapped to the OMOP data standard for observational studies ^[21]. However, the use of this data in global consortia remains limited, as does its utilisation at the national level.

To maximise the value of data generated within the healthcare system and increase its accessibility for research, innovation, public health policies, and commercial strategies, it is essential to leverage the central EHR *e-karton* system, adopt best practices from other countries, and build trust among stakeholders. Recognising the importance of data for developing AI solutions and tailoring models to local populations is crucial to enhancing the local health data ecosystem. These efforts align with key analytic readiness indicators outlined by the OECD, such as the ability to access and link data for primary and secondary uses, as well as ensuring AI and algorithmic integrity ^[22].

A successful example of an innovative solution based on data from Serbia's healthcare system is the mammogram analysis software developed by the Institute for Artificial Intelligence of Serbia in collaboration with the Institute for Oncology and Radiology of Serbia. This tool utilises anonymised patient data to prioritise high-risk patients, enabling doctors to reduce false-negative results and improve diagnostic efficiency ^[23].

Another critical aspect is enabling patients to control access to their data and manage consent for its reuse. While the current *eZdravlje* (eHealth) ^[17] portal allows patients to track who has accessed their data, it lacks a digital solution for granting permissions or withdrawing consent when needed. Promoting existing features and enhancing consent management will significantly strengthen trust and transparency.

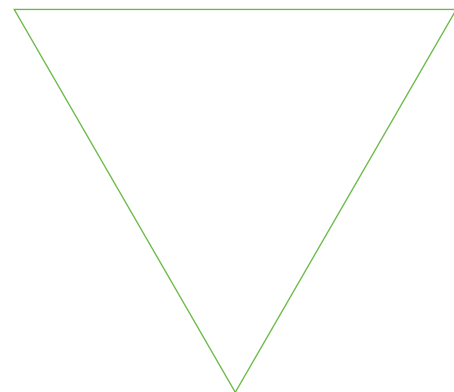
3. Education, Awareness and Readiness to use eHealth

Fully realising the potential of digital health solutions requires addressing key challenges related to the education and awareness of healthcare professionals, patients, and other stakeholders.

Healthcare professionals often lack training in the effective use of digital tools, including understanding the capabilities and risks of AI-based solutions. While there is openness toward adopting AI in healthcare, these solutions are still not sufficiently integrated into clinical practice. Additionally, there is a need for continuous education and upskilling of IT staff within healthcare institutions to ensure they are equipped to support the implementation, maintenance, and advancement of digital systems. Investing in targeted training programmes for both healthcare and technology professionals is essential to bridging these gaps and building a more effective use of digital health solutions.

Patients face additional barriers, including low awareness of existing digital health services. For example, while portals like eZdravlje (eHealth) ^[17], Moj Doktor (MyDoctor) ^[24], Moj RFZO (My NHIF - My National Health Insurance Fund) provide access to health records, prescriptions, appointment scheduling and NHIF records, many citizens remain unaware of these services. Low adoption rates can be addressed with annual campaigns that raise awareness and improve digital literacy. These can include digital caravans and instructional videos to help users become familiar with new tools. Feedback mechanisms are then crucial for continuous improvement, ensuring that digital solutions align with users' needs.

Additionally, involving users in the development of digital tools is essential to creating solutions that are practical, efficient, and meet their real-world needs. Healthcare professionals often express a willingness to participate in the design of digital solutions if they receive meaningful feedback from the systems they use. For example, tools that pre-fill data fields, generate visual insights like graphs, or suggest referral options based on patient symptoms could significantly improve their daily workflows. A best practice example is the implementation of Electronic Clinical Pathways in all primary healthcare institutions within the public sector through a project by the Ministry of Health. These pathways standardise workflows by outlining a precise sequence of clinical processes, expected outcomes, and timeframes for patients with specific conditions, based on national guidelines and local practices. Following training organised by the Ministry, healthcare professionals now widely use this digital solution. Similarly, patients should be actively involved in the design of digital tools, expert systems, and AI models. Incorporating their perspectives ensures solutions are intuitive and aligned with user needs, while addressing concerns about data ownership and consent management.



Addressing the challenges in Serbia and Charting the Path Forward ▼

This section examines the needs and challenges of Serbia's Health Data Space and its integration with the EHDS, while also presenting actionable steps to advance digitalisation and enhance the functionality of the healthcare system. The challenges are followed by recommendations, which were developed by summarising roundtable discussions, the objectives outlined in the digitalisation programme, and conclusions drawn from interviews.

1. eHealth and Data Governance

CHALLENGES:

- **Accessibility and interoperability of health data**
- The entire body of patient data generated across the health sector must be accessible to healthcare professionals and patients to improve outcomes. Secure and comprehensive access reduces redundant tests, enhances patient safety, and accelerates diagnoses, while empowering patients to engage in their treatment. Centralising health data and interconnecting systems across public, private, and military sectors are crucial for higher-quality, coordinated healthcare. Achieving this requires addressing the current fragmentation, where most healthcare data remain siloed within local systems and are not seamlessly integrated or shared across sectors.
- **Robust governance and coordination at the national level** - The complexity of the healthcare system demands collaboration among ministries and other stakeholders, including healthcare, industry, insurance funds, and citizens. Without robust governance structures, ensuring timely, synchronised, and secure activities is challenging.

A central coordinating structure, the Coordination Body for Digitalisation in the Healthcare System has proven to be a successful model. By bringing together key stakeholders, this mechanism has effectively overseen and aligned healthcare digitalisation efforts.

- **Strengthening IT capacity in the healthcare sector**
- A shortage of skilled IT personnel and limitations in network capacity and hardware infrastructure present significant challenges for healthcare institutions, hindering the implementation and effectiveness of digital solutions and data security measures. Active support from the Office for IT and eGovernment is essential to address these issues by ensuring seamless integration, robust infrastructure, and a strong emphasis on data security. At the same time, enhancing IT human capacity within healthcare institutions by hiring and training motivated technology professionals is crucial. These experts are key to driving digitalisation processes and supporting healthcare workers in effectively utilising digital tools and managing data.

RECOMMENDATIONS:

- **Establish a central EHR (e-karton) system.** Implementation of the new law on healthcare documentation, which treats all healthcare subsystems equally in terms of universal EHR information, establishes the basis for exchanging data and ensuring consistent data handling across Serbia's healthcare subsystems (public, private, and military).
- **Harmonise of the legal framework for managing processes in the digitalisation of healthcare** through adoption of by-laws established by the Law on Health Documentation and Records and adoption of the Law on Healthcare and Health Insurance for Military Insured Persons.
- **Establish a coordination body for digitalisation in healthcare system creation.** The existence of such a body has proven to be an effective model,

as all major decisions made by the healthcare digitalisation team were first presented to the Coordination Body, which would provide suggestions, recommendations, viewpoints, and agreements.

- **Improve the information and communication infrastructure in the healthcare system.** Study on health institutions' network capacities, hardware infrastructure, and improvement plan. Migration of Local Information Systems to the National Data Centre.
- **Explore interoperability in data standards with EHDS** through mapping the similarities and differences between EHDS and e-karton, and then the potential alignment and consolidation of the two systems in the future.
- **Strengthen IT departments in healthcare institutions** by hiring staff and ensuring competitive conditions for engaging IT professionals. Ensuring additional support through the establishment of an organisational unit at the Office for IT and eGovernment.
- **Provide expert support in the IT domain for healthcare workers**, along with defined procedures and instructions for data entry.
- **Implement the solution promptly** because digital products can be continuously adapted based on needs, which is an important advantage.

The expected impact includes: streamlined implementation of digital health initiatives, optimised resource utilisation, improved transparency and trust and better decision-making and system efficiency.

2. Secondary use of data

CHALLENGES:

- **Availability of comprehensive and high-quality health data** - Currently, patient data in Serbia are fragmented and duplicated due to unconnected systems and minimal input from private institutions into state registries. This leads to unsynchronised records, delays in diagnosis and treatment – especially for rare diseases – and complicates

healthcare planning. Consolidating patient data into a centralised system with unified patient identification across all healthcare institutions, is essential to improve data quality, prevent duplication, provide a comprehensive view of patient health, enable data-driven policies, support scientific research, and foster AI innovations.

- **Development and improvement of disease registries** - Serbia currently lacks comprehensive disease registries, with existing ones being fragmented, underpopulated, and poorly integrated with national systems. This limits the ability to track patient outcomes, conduct real-time epidemiological analysis, and assess disease trends, ultimately hindering high-level research. To address this, simplifying and automating data entry processes is crucial to ensure ease of use and accuracy. Additionally, integrating clinic-level registries with national systems and connecting them to other national databases would enhance data consistency and completeness. These improvements would create a more robust and interconnected health data ecosystem, supporting better research, planning, and decision-making.

“*The data must be structured so that registries are automatically populated from reports. An automatically populated registry would provide demographic data, track all risk factors, and more. EHR should be structured in a way to direct public health policy toward prevention, acute care, and resource allocation. There should also be clear instructions on how to complete all required fields. At the same time, the process should be straightforward yet comprehensive and functional to ensure the collection of essential data. To start with, all registries must be concise and not overly complex.*

— Marijana Vukicevic, MD, PhD
Acting Director of the Special Hospital for Cerebrovascular Diseases 'Sveti Sava'

- **Clear and unambiguous guidelines on data sharing and anonymisation** - Clear guidelines on data usage and sharing rights are essential to enable collaboration between healthcare institutions, academia, and commercial entities. A governing body should oversee the use of healthcare data to centralise authority and support research efforts.

Ambiguity about data usage rights and de-identification standards creates concerns about misuse and discourages participation, limiting the potential of healthcare data for research and innovation. Developing and implementing certified de-identification services will protect patient identity and foster trust in data use.

RECOMMENDATIONS:

- **Connect registries and enable access to de-personalised data** within the healthcare system. Enable the use of registry data for all interested parties in accordance with laws and procedures.
- **Create dynamic registries.** Develop dynamic registries to track patient groups over time, enabling the analysis of treatment outcomes and supporting evidence-based decision-making.
- **Automation of data entry processes.** Minimise manual data entry by automating registry data collection. This will enhance accuracy, reduce errors, and alleviate administrative burdens.
- **Form a regulatory body.** Establish a regulatory body to oversee access to biomedical and genetic data, ensuring ethical and legal compliance while providing agile and timely responses to evolving community needs along with ensuring mechanisms for the reuse of data from the Integrated Health Information System of the Republic of Serbia (anonymisation, approval, use of data).
- **Guidelines on data usage and sharing.** Create and disseminate comprehensive guidelines on data usage and sharing rights, offering clear instructions and transparency for all stakeholders.
- **Facilitate data access.** Enable authorised access to registry data for researchers, healthcare providers, and other relevant parties, ensuring transparency and adherence to established protocols.

- **Engage patient associations.** Foster trust and encourage participation by involving patient associations in healthcare data initiatives. These groups play a critical role in educating patients about the benefits of contributing their data and ensuring alignment with patients' needs and concerns.
- **Regularly share the outcomes of scientific studies with patients and stakeholders** to demonstrate the value of their contributions. Clear and consistent communication fosters trust and strengthens engagement in research initiatives.
- **Implement certified services to de-identify sensitive data,** ensuring patient privacy and facilitating secure and responsible access for research and innovation purposes.

The expected impact includes: facilitated data access for research and innovation, improved data quality and utility, strengthened data privacy and security, increased trust and motivation and improved public health decision-making.

3. Education, awareness and communication

CHALLENGES:

- **Advancing digital literacy and knowledge translation capacity** - Continuous education is crucial for improving healthcare professionals' digital literacy in IT, AI, and UX principles, fostering effective adoption of digital tools. Equally important is ongoing training for IT staff to support the maintenance and advancement of complex systems.

A lack of structured training and assumed digital proficiency often create challenges. Healthcare workers may feel overwhelmed by new tools, skip data fields, or rely on workarounds that compromise data quality. Similarly, insufficient training leaves IT staff unprepared to manage and update advanced systems effectively.

Closing these gaps is essential for the seamless adoption and optimal use of digital solutions.

There is a need for dedicated resources and structured activities focused on knowledge translation within Serbia's health sector. While training sessions on knowledge translation concepts, tools, and skills were previously supported by international projects, no manpower is currently assigned to this area. Additionally, there is no clear strategy for training relevant actors to interpret and effectively use data. This leaves users to independently seek clarifications or navigate the data without adequate support.

- **Increasing awareness and utilisation of digital health solutions among patients** - Raising awareness of digital health services, such as portals, telemedicine, and rare disease registries, is essential to improve patient access and engagement. Educational initiatives and feedback mechanisms should be established to enhance digital skills, enabling patients to access health information, manage appointments, and benefit from these tools. Patient associations play a key role in promoting the advantages of digital tools and AI applications while addressing concerns about privacy and data security.
- **Involving healthcare professionals and patients in the design of digital solutions** - Active participation from healthcare professionals and patients is crucial to create digital health solutions, expert systems, and AI models that are intuitive, user-friendly, and aligned with real-world needs. This involvement ensures tools address clinical challenges, integrate seamlessly into workflows, and simplify data entry while enhancing usability and efficiency.

Currently, limited engagement from these stakeholders results in poor usability, misalignment with workflows, and low adoption rates for digital solutions.

RECOMMENDATIONS:

- **Develop simple guides, tutorials, and educational videos** accessible to a wide audience is essential for promoting use of digital health services and improving of user experience.
- **Deliver communication strategies** that ensure diverse target groups not only understand but actively benefit from existing and planned digital healthcare solutions.
- **Conduct interviews with healthcare workers**, and facilitate effective communication between software developers and healthcare workers, as this will ensure the technical solutions developed are serving their purpose.
- **Provide continuous education for healthcare professionals and IT staff**, focusing on the benefits of digital health solutions and building the skills needed to implement, maintain, and use these tools effectively.
- **Organise conferences** on this topic for exchanging experiences, insights, and ideas for future steps.
- **Provide valuable, simple services** for healthcare workers and citizens in order to ensure adoption.

The expected impact includes: successful implementation and wide adoption; engagement and innovation; building trust and enhancing collaboration; empowering healthcare workers to understand what can be shared, how, and when; and shifting to a human-centric approach.

“

Raising awareness of the value that digital services bring to doctors, hospitals, payors, patient associations and the whole healthcare eco-system must be a priority. Regardless of how advanced a technical solution may be, its impact is diminished if its value is not recognised and if it is not used to generate data that will help us improve the health of our citizens. Only through digitalisation and data centralisation, will it become possible to create dynamic registries that track disease epidemiology, patient journeys throughout the healthcare system, and to assess treatment outcomes. These registries are vital for monitoring public health improvements, developing strategies for specific diseases, and prioritizing healthcare needs. This aligns with the global trend of integrating patient-reported outcomes through real-time connectivity between doctors and patients, enabling the recording of quality-of-life scores and patient satisfaction to create a more balanced approach to treatment and disease management.

— Milena Agrirovic
Country Head Serbia, Albania, Macedonia,
Kosovo and Montenegro at Takeda

“

Involving patients in designing digital solutions is crucial, particularly regarding data usage, control, permissions, and access for research or other purposes. Including patient perspectives ensures a more comprehensive approach, as their views often differ from those of other stakeholders. By integrating these diverse viewpoints, it becomes possible to create solutions that effectively evaluate the benefits, drawbacks, and risks associated with digital healthcare initiatives.

— Stefan Zivkovic
Project Coordinator at the National Organisation
for Rare Diseases of Serbia

EU Perspectives: Insights on Healthcare Digitalisation and Data Space ▼

At the EIT Health Morning Health Talks Roundtable, distinguished speakers shared their experiences, discussed challenges, and provided insights into the current state of digitalisation in their respective countries.

- **Jérôme Fabiano from EIT Health France** shared France's approach to health data governance. The country established the Health Data Hub to improve access to health data, maximise their value, and support public collaborations in innovation and evaluation. While this model inspired the health access body under the EHDS, it must be adapted to suit each country's specific needs.

Significant investments have been made in health data warehouses in France, but funding for data scientists is lacking. Although specific projects can finance these roles, a sustainable strategy is needed to combine infrastructure with expertise. Without such a plan, organisations risk having warehouses without a clear path to monetise them. Debates continue on whether these warehouses should focus solely on care or also support research and innovation. Partnerships with private companies are being explored, but a viable model to capitalise on the government's investment is urgently required.

Striking a balance between primary and secondary data use is crucial. For example, France is digitising decades-old data, but focusing on creating interoperable, modern datasets that meet current standards would be more efficient.

Awareness and communication about health data must align with national cultures. Scandinavian countries have successfully implemented trust-based consent models, while France faced public backlash over the Health Data Hub's potential partnership with Microsoft, highlighting sovereignty concerns. This underscores the importance of considering cultural sensitivities and trust, both with the public and among organisations managing health data.

- **Adam Rottenbacher from the European Institute of Innovation and Technology** emphasised the importance of striking a balance between innovation through technology and consumer protection through regulation. While early regulation can hinder innovation, delayed regulation may leave consumers vulnerable to risks. Mr. Rottenbacher also highlighted the complexity of EU regulations, which may act as a barrier to innovation. Serbia, however, might have the flexibility to implement initiatives that EU countries cannot pursue due to stricter regulatory frameworks. The representative stressed the importance of discussing the implications of the AI Act in this context.
- **Anne Geubelle from Prologica Portugal** emphasised the importance of involving all ecosystem stakeholders to ensure successful data governance. Mrs. Geubelle noted that in Portugal, the quality of data is poor, with a lot of missing data. Currently, the focus is on the sustainability of the system, but a major challenge is the lack of human resources. It was acknowledged that investments in digital transformation systems take time to yield a return, adding to the complexity of the situation. There is also uncertainty about data ownership. In Portugal, patients own their data, but hospitals are responsible for ensuring the security of these data. This raises critical questions, as insufficient communication with both citizens and hospitals has led to a lack of awareness about data governance processes. Stakeholders must clearly understand what data they can share, how they can share them, and under what conditions, emphasising the need for their involvement in the governance framework.

- **Bence Horvath from Spicy Analytics Hungary** shared an example highlighting the impact of data restrictions. He explained that in Hungary, 100 people die each day from cartilage disease, and half of these deaths could be prevented. However, GDPR regulations limit the use of data, hindering the implementation of targeted screening campaigns and patient advisories.
- **Ligia Kornowska from the Polish Hospital Federation** provided an overview of the progress in Poland's eHealth sector. Patients in Poland have online accounts that allow them to access prescriptions, referrals, and medical services through a mobile app. These accounts also enable self-registration for vaccinations and other medical services.

However, challenges remain regarding structured and unstructured data. One issue, referred to as „upcoding,” involves the inclusion of additional ICD-10 codes by doctors to increase payments from the National Health Fund. This issue requires resolution at a higher level, rather than at the level of individual doctors. Regarding unstructured data, the lack of a national or EU-wide standard for structuring medical notes limits consistency among doctors. Efforts have begun to address data structuring for radiological images through AI tools, but standardisation across the European Union is still lacking.

Poland also faces challenges in data sharing, similar to Portugal. Although GDPR is followed, hospitals are uncertain whether even anonymised medical data can be shared for research and development or patient benefit. As a result, no hospital shares anonymised data, reflecting organisational, interpretational, and regulatory challenges.

Efforts are underway to promote „data altruism,” encouraging citizens to voluntarily share their medical data for research purposes. This initiative aims to educate citizens about their role in advancing medical research, comparing their contribution to blood donation and encouraging them to become „citizen scientists.”

- **Marco Foracchia from the Italian Association of Information Systems in Healthcare** highlighted shared challenges across Europe regarding digital health projects and regulations. Mr. Foracchia noted that collaboration has significantly improved compared to a decade ago when challenges varied greatly between countries. In Italy, the healthcare system is fragmented into 21 sub-systems, each with its own digital strategy. While the Emilia-Romagna region has managed to store approximately 92% of clinical data in a structured format, the national average remains at 40%. Lessons learned from previous attempts have shaped Italy's current approach to avoid repeating past mistakes.

Initially, only 7% of the population used the EHR, as many clinicians found it unhelpful. The lack of value for different stakeholders led to a dual strategy: a top-down approach focused on population-wide insights and a bottom-up approach to address the needs of clinicians and patients. This shift in focus, along with rebuilding the system from scratch, resulted in over 70% regular usage by patients and clinicians. The key to this success was providing simple, valuable services beyond mere data collection, ensuring stakeholders benefitted directly from the system.

The region has since moved to leverage secondary data use, beginning with proactive public health efforts. For example, EHR data in Emilia-Romagna is used to identify patients for flu vaccinations and other screenings, such as breast cancer. Italy is now advancing toward more complex initiatives, such as research projects. At the regional level, AI is being used to analyse clinical information and create concise patient summaries to address the challenge of information overload. A clinical trial is currently underway to validate and certify this system as a medical device, which will provide clinicians with comprehensive summaries of relevant patient data derived from regional and national EHRs.

Data usage for commercial purposes is restricted to public entities. However, if public universities

collaborate with private organisations, such as pharmaceutical companies, in a consortium, they can participate. The underlying principle for secondary data use in Italy is that it must serve the public interest.

Conclusion ▼

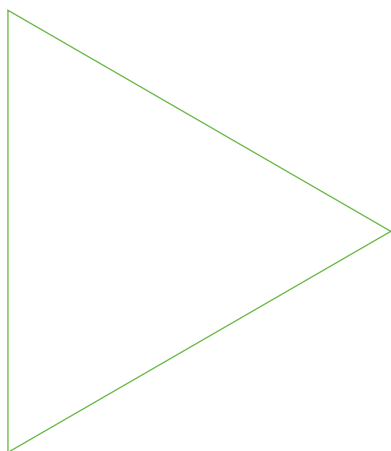
The EHDS is an ambitious initiative designed to transform cross-border access to health data for improved healthcare delivery and innovation. Serbia, as an EU candidate country with advanced public sector digitalisation, has established strategic and regulatory foundations for further healthcare digitalisation, that can make integration with the EHDS both feasible and smooth.

This study has identified key steps to advance healthcare digitalisation in a coordinated manner, strengthening Serbia's health data ecosystem. Achievements so far, along with discussions with representatives from public administration, healthcare institutions, patient associations, academia, and industry, have revealed a clear consensus on priorities. These include centralising health data to ensure they are accessible to healthcare professionals across the public, private, and military sectors, coordinating digitalisation efforts at the national level, and improving health data registries. The necessary actions to address these priorities are summarised in the set of proposed measures.

Lastly, the exchange of experiences between EU and Serbian stakeholders has shown that the challenges in developing a health data space are shared. By adopting best practices from EU countries and building on its existing strategies and regulations within the healthcare system, Serbia can implement agile and forward-looking approaches to contribute to the European digital health ecosystem. Through strong commitment and collaboration, Serbia has the potential to set an example for successful integration with the EHDS, paving the way for improved healthcare outcomes and enhanced regional cooperation in health data management.

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