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Summary

of key dimensions in digital healthcare

implementation

Deliverable D.1.1.1

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**Summary**

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**D.1.1.1**

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Introduction

*Bridging Innovations in Digital Health: A Collaborative Vision for the Danube Region*

Recent advancements and progress in digital technology and wireless networking, healthcare applications, and overall digital transformation process, are becoming key drivers in establishing a successful digital healthcare ecosystem. The efficient implementation of new-generation digital technologies, strategic planning, efficient resource allocation, and control and evaluation processes, are fundamental to reshaping the healthcare ecosystem. The World Health Organization (WHO) defines eHealth as “cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research” [1]. Digital healthcare refers to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health-related issues and to monitor and manage lifestyle-habits that impact health [2]. Healthcare technology includes all medical equipment, devices, and consumables, as well as the organizational, support, and information systems used at all levels of healthcare delivery.

By 2025, the digital health market is projected to reach 38 billion [3]. In recent years, Artificial Intelligence (AI) has been recognized as a strategic technology to improve access, quality, and efficiency of healthcare and services. It could contribute to numerous healthcare tasks and activities, such as clinical decision-making (e.g., diagnosis, screening, and treatment), service organization (e.g., flow optimization, triage, and resource allocation), and patient management and follow-up (e.g., drug administration and compliance) [4]. As part of the European strategy for AI, the EU published in April 2021, the proposal for a Regulation on the European approach, which resulted in the first European legal framework on AI. In March 2024, the EU Parliament adopted the regulation laying down harmonised rules on AI (AI Act) [5]. Although the field of AI has made major progress, there are still challenges and ethical concerns that must be fully addressed. Moreover, biological data elaboration still represents an open challenge.

The smart healthcare, as a promising application area, integrates novel Internet of Things (IoT) technologies, wireless networking and emerging 56/6G mobile networks, that will undoubtedly bring significant benefits to citizens. Such applications remotely deliver healthcare services, thus bringing significant cost savings as well as allowing patients to live independently in their own homes or in a family environment for longer periods of time.

These systems will also enable early detection and pre-emption of diseases and significant improvement of patients’ quality of life. Novel smart healthcare architectures will benefit from deep learning, big data, and high-performance computing to implement reliable Cloud/Edge/Fog network solutions [6]. The important aspect of digital healthcare implementation is the Health Technology Assessment (HTA) which refers to the systematic evaluation of properties, effects, and impacts of health technology [7]. This is a multidisciplinary process to evaluate the social, economic, organizational, and ethical issues of a health intervention or healthcare technology.

The DIGI4Care project, through its convergence of innovation and collaboration, seeks to redefine care pathways across the Danube region by strategically integrating digitalization and AI technologies.

A map of europe with different colored regions

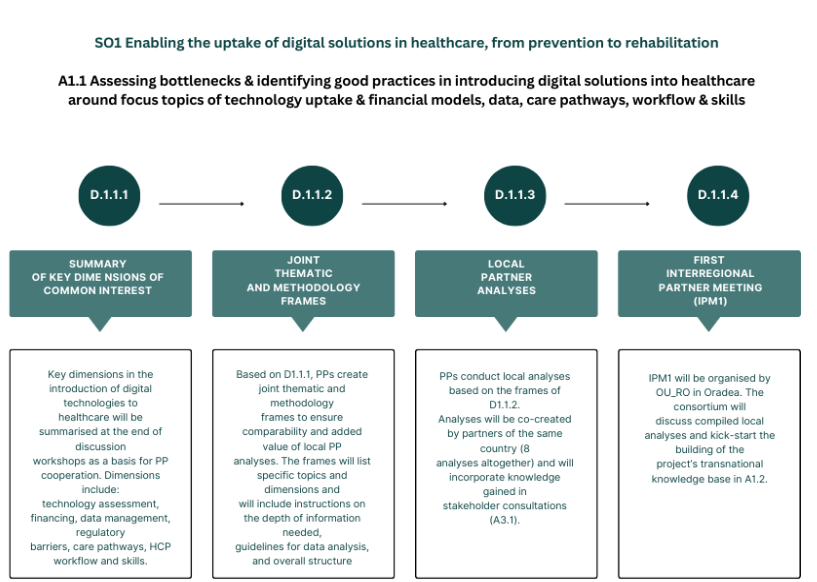
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**Fig.1. DIGI4Care ecosystem: 12 partners from 8 different countries**

Encompassing 12 partners from 8 different countries in one consortium, this initiative showcases the strength of transnational cooperation in addressing the dynamic challenges and seizing opportunities within the healthcare sector (see Fig.1). The Project’s ambition is to transform digital technologies from mere tools to foundational elements of healthcare delivery, thereby significantly enhancing patient care, operational efficiencies, and support for healthcare professionals.

The creation of this document (Deliverable D.1.1.1 – Summary of key dimensions of common interest) is a direct response to this ambition, aiming to capture and articulate the essence of our collective explorations and discussions into a unified narrative that highlights the key dimensions of digital healthcare.

This narrative is crucial as it conveys our shared insights, challenges, and innovative strategies identified through the consortium's dialogue. The goals are manifold, extending beyond identification and articulation to charting a comprehensive course through the intricacies of adopting and integrating digital health solutions across diverse healthcare systems. This deliverable unfolds within the framework of Specific Objective 1 (SO1) of the DIGI4Care project, titled "*Enabling the uptake of digital solutions in healthcare, from prevention to rehabilitation*" (see Fig.2).



**Fig.2. The structure of Specific Objective SO1of the DiGI4Care project**

SO1 is dedicated to promoting and facilitating the integration of digital solutions throughout the entire patient pathway, from prevention to rehabilitation. This objective culminates in the creation of a Digitally Enabled Integrated Care Model (ICM) Strategy (O1.31) and corresponding institutional-level Action Plans (O1.42), all of which are validated by tangible transnational uptake cases in SO2 pilots. These pilots cover the entire uptake process, addressing required skills, roles of participating actors, financial resources and models, and strategies for removing bottlenecks and overcoming potential obstacles.

1 O.1.3 Digitally Enabled Integrated Care Model (ICM)

2 O.1.4 Institutional-Level Action Plans to the ICM Strategy

In parallel, a transnational knowledge base, underpinned by continuous information exchange and sharing of good practices (A1.13, A1.24, A3.15), lays the groundwork for achieving this objective. This includes the development of a Knowledge Platform and Radar (O1.2) to support stakeholders across the Danube Region—primarily healthcare professionals (HCPs) and healthcare decision-makers—with technology assessment, uptake, and related decision-making processes.

Activity 1.1, titled "*Assessing Bottlenecks & Identifying Good Practices*" and coordinated by the Research and Technological Development Association in HEALTH RTD CLUSTER (HRTD\_BA), is instrumental in this process. It facilitates transnational cooperation among all Project Partners (PPs) through a series of online workshops and questionary designed to explore and define the key dimensions of common interest in facilitating digital technology uptake in healthcare. These dimensions, identified through preliminary evaluation, include technology readiness, technology assessment, financing models for digital technologies, data storage and management, regulatory and ethical barriers, integration of digital solutions into care pathways, embedding digital technologies into workflows, and ensuring necessary skills for healthcare professionals.

3 A.1.1 Assessing bottlenecks & identifying good practices in introducing digital solutions into healthcare around focus topics of technology uptake & financial models, data, care pathways, workflow & skills

4 A.1.2 Building a transnational knowledge base on digital health technologies and good practices and creating lasting cooperation frames at DR level

5 Pilot Preparation

Methodology

*The DIGI4Care project, with its ambition to reshape healthcare through digital innovation and AI, operates within a rich tapestry of knowledge brokers, academia, research institutions, civil society, and private sector actors across the Danube region.*

The collective DIGI4Care effort aims to strengthen synergies and foster cross-country cooperation thus narrowing the innovation gap between the older and newer Member States, as well as non-EU countries in the Danube Region. A critical aspect of this endeavour is the identification of key dimensions critical to digital healthcare transformation, as revealed in an in-depth territorial needs analysis conducted during the project's preparatory phase. These dimensions encompass:

1. *Technology Readiness,*
2. *Technology Assessment,*
3. *Financing Models for Digital Technologies,*
4. *Data Storage and Management,*
5. *Regulatory and Ethical Barriers,*
6. *Integrating Digital Solutions into Care Pathways, and*
7. *Embedding Digital Technologies into Workflow and Ensuring Necessary Skills for HCPs.*

Recognizing the diversity in development stages among countries and partners involved during the preparatory phase of the DIGI4Care project proposal, the project underscores the necessity of a unified approach to harmonize the innovation landscape. This approach is vital for reducing the innovation gap and facilitating critical impacts in areas such as data validation and test group piloting. The complex process of adopting digital and AI technologies in healthcare highlights the indispensable role of transnational cooperation as an enabling factor. Through joint piloting, knowledge sharing, and cooperation, the project seeks to expedite the transition towards digital healthcare and enable regions at varying levels of innovation to achieve higher preparedness for technological uptake.

The methodology for gathering and analyzing insights within the DIGI4Care project is encapsulated through a series of online workshops, tailored to foster comprehensive dialogue and exchange on the afore-mentioned key dimensions.

These key dimensions were analyzed in order to identify common challenges, barriers, and good practices thus creating joint macro-regional solutions to accelerate AI technology uptake and digitization of healthcare in the core phases of care. This methodological approach is premised on the principle that blending diverse perspectives from across the partnership can yield a richer, more nuanced understanding of the challenges and opportunities within digital health.



**Fig.3. Activity A.1.1 timeline**

The project’s Activity A1.1. (see Fig.3.) orchestrated two foundational workshops between consortium partners to spearhead this collaborative inquiry:

1. **First Online Workshop: "*Understanding and Assessing the Technology Landscape*"** - held on March 26th, 2024. This session, moderated by HRTD\_BA, delved into technological factors influencing digital healthcare, showcasing partner-level case studies and discussing regional specificities and gaps. Each consortium partner was allocated time to present, fostering a structured yet comprehensive exploration of technological challenges and innovations.
2. **Second Online Workshop: "*Financial Models and Data Management Strategies, Regulatory and Ethical Issues in Digital Healthcare*"** - held on April 12th, 2024, and moderated by HRTD\_BA. Building on the technological groundwork, this workshop shifted focus to financial models, data management, and the regulatory and ethical dimensions of digital healthcare. It aimed to elucidate strategies for overcoming financial and regulatory barriers, enhancing data management practices, and facilitating the ethical integration of digital solutions into healthcare.

Two coordinated online workshops explored dimensions of common interest concerning the facilitation of the uptake of digital technologies in healthcare. During the workshops, following presentations, discussions were structured around a carefully curated set of questions, drawing from the insights shared by partners. This approach was designed to facilitate an in-depth examination of each key dimension, enabling the identification of shared barriers, innovative solutions, and strategic opportunities for collaboration. The discussions were aimed at not only understanding the current landscape but also at identifying actionable paths forward to address the multifaceted challenges of digital healthcare transformation.

This methodological design reflects a commitment to a scientific and investigatory approach, where the diversity of development among countries and partners is not seen as a hurdle but as an opportunity for enriched collaboration. The insights and conclusions drawn from both workshops serve as the foundation for the D.1.1.1.

Additionally, a supplementary questionnaire was prepared and analyzed in Annex II of this report. This questionnaire aimed to further process and clarify obtained data, providing an even clearer picture where it was not possible through the organized workshops. The questionnaire covers 6 key dimensions since the Technological Landscape analysis is provided in detail within the Deliverable 1.2.1. Through structured engagement and analysis, the DIGI4Care project aims to harmonize the innovation landscape, ensuring that all partners, regardless of their developmental stage, can contribute to and benefit from the collective pursuit of digital healthcare excellence.

Overview of Key Dimensions

*DIGI4Care builds on available knowledge by ensuring continuous Q-Helix cooperation during implementation and by providing a comprehensive knowledge base on available technologies and best practices in the key dimensions of interest.*

The process of digital healthcare implementation involves various key dimensions that contribute to the success and effectiveness of digital health initiatives. In general, these dimensions encompass technological, organizational, regulatory, and societal aspects. The following key dimensions (see Fig.4) were identified and discussed by consortium partners in two workshops (see methodology above): (1) Technological Readiness, (2) Technology Assessment, (3) Financing Models, (4) Data Storage and Management, (5) Regulatory and Ethical Barriers, (6) Integrating Digital Solutions into Care Pathways, and (7) Embedding Digital Technologies into Workflow and Ensuring Necessary Skills for HCPs. These dimensions collectively contribute to improving healthcare access, efficiency, patient engagement, and outcomes while addressing challenges such as healthcare disparities, lack of standardized methodologies, rising equipment costs, etc.

Understanding key dimensions in digital healthcare is essential for leveraging technology to its fullest potential and addressing various aspects of healthcare delivery. For each key dimension, the objective, key considerations, and country-specific insights that were discussed during the workshops are presented in this document. According to the key dimensions of interest and joint thematic and methodology frames (A1.1), PPs will engage key players (such as SMEs, universities, clinics, regulators, patient representatives, and technology providers) and opinion leaders via their national network.

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**Fig.4. Key dimensions of digital healthcare implementation**

To efficiently measure the operational features of digital health systems, as well as transformation of digital care delivery that is focused on outcomes, quality of data and real-world evidence are of vital importance. The indicators for each of the key dimensions of digital healthcare have been developed under the methodology framework (D1.1.2 Methodology for local partner analysis). It facilitates a structured evaluation - based on the perception of project partners - of the maturity of national or regional contexts with respect to the introduction and use of digital health solutions.

By comprehensively addressing these key dimensions, stakeholders in digital healthcare can effectively harness technology to improve patient outcomes, enhance healthcare delivery, and advance the overall quality and accessibility of healthcare services.

Technological Readiness

*DIGI4Care project aims at providing technological readiness analysis, knowledge building, and stakeholder cooperation thus creating transnationally validated, dynamic, and openly accessible digital knowledge platform on available technologies and good practices.*

Technological Readiness addresses the availability and affordability of the required ICT, as well as the hardware and software needed to implement a proposed solution [8]. It also aims to determine the use of existing ICT infrastructure, networks and available electronic resources, as well as IT support personnel and healthcare providers’ past IT experience [9,10,11]. A robust technological infrastructure ensures smooth data transmission, secure storage, and seamless integration of various healthcare systems and devices. Technological Readiness is a strategic exercise that facilitates long-term innovation planning by providing a broad overview of a relevant technology space. This process is focused on surveying technology landscapes and developing a comprehensive understanding of what’s possible. The benefit of Technological Readiness lies in shaping innovation strategy by identifying current and future competing technologies. Also, it will define opportunities and areas of potential technological disruptions and identifies different targets for acquisition of potential complementary technologies. This process requires diverse skill sets that depend on experience with and access to complementary knowledge bases, such as intellectual property, peer-reviewed literature, conference presentations, start-up investments, etc.

Countries in the Danube region have diverse approaches to technological readiness, reflecting their unique healthcare environments and policies, as well as their level of technological development. Austria and the Czech Republic have robust national programs and strategies, such as Austria’s ELGA system and the Czech Republic’s Digital Czechia.

These initiatives focus on integrating telemedicine, electronic health records (EHRs), and AI-driven diagnostic tools. Slovakia and Hungary are also making strides, with Slovakia emphasizing eHealth services and Hungary exploring health information systems and the introduction of AI solutions. However, countries like Romania and Ukraine face significant challenges due to regulatory barriers and IT infrastructure limitations. Bulgaria and the Republic of Srpska (BiH) are in the early stages of digital healthcare adoption, focusing on integrated health information systems and telemedicine. The most significant challenges in implementing digital healthcare infrastructure in Austria include regulatory complexities, the siloing of health data, resistance from health professionals, and resource limitations. Special efforts are directed towards ensuring interoperability, maintaining data security, managing change resistance among healthcare providers, and securing adequate funding.

Digital technologies impact medical education and create new opportunities for practitioners. Digital healthcare applications allow patients to participate in decision-making regarding their healthcare and access information through the internet and mobile applications. Information technology can benefit hospitals by improving service procedures and enhancing service innovation processes. Moreover, technological capability positively influences patient service and innovation in the service process. The DIGI4Care project addresses these technological gaps by fostering collaboration between regions with varying levels of technological advancement. By leveraging the experiences and best practices from more advanced regions, the project aims to elevate the technological readiness of all participating countries, facilitating a smoother and more effective adoption of digital health technologies.

Key considerations

* Identifying and addressing technological gaps to enhance healthcare delivery.
* Encouraging the system-level adoption of emerging technologies like AI, telemedicine, and wearable health devices.
* Developing national strategies and programs tailored to local healthcare environments and technological readiness.

Main barriers

* Selected countries are still facing low budgets for acquisition or purchase of most advanced healthcare technologies.
* Advanced technologies require advanced knowledge and skills to use the technology in most adequate way.
* The countries have lack of skilled healthcare staff that would be able to use advanced technology.

Recommendations

* To use advanced technology, like AI based equipment, further education efforts are required. Advanced diagnostic equipment is a priority, as it can significantly influence other elements of value chain in healthcare.
* To further enhance the digital security and technological information systems.

Technology Assessment

*DIGI4Care assesses and validates the feasibility, benefits, and added value of integrating digital technologies into healthcare processes and workflows. These activities will result in enhancing financing models and cooperation with technology providers, introducing developments supporting the integration of care pathways*.

Technology assessment relates to evaluation of current technologies in use and identify emerging trends. This process encompasses various aspects of identification of required technology assets for optimal use, selection of technologies that no longer meets the needs of the health service, implementation of methods to track and manage all assets in a digital and cost-effective, selection of the purchasing strategy for technologies, as well as data security and privacy solutions. Health Technology Assessment (HTA) is a systematic and multidisciplinary evaluation of the properties of health technologies and interventions covering both their direct and indirect consequences. It is a multidisciplinary process that aims to determine the value of a health technology and to inform guidance on how these technologies can be used in health systems around the world. HTA is a transparent and accountable process that can be used by decision makers and other stakeholders to support the decision-making process in health care at the policy level by providing evidence about given technologies It has been described as a bridge that connects the world of research to that of policy making [12].

First Online Workshop: "*Understanding and Assessing the Technology Landscape - introducing digital technologies and AI into healthcare*" which was held on March 26th, 2024, focused on technological aspects of digital healthcare implementation, such as availability and trustworthiness of technologies, The IT capability dimension represents the extent to which the organization has implemented infrastructure, digital systems, technologies, and services that are usable and effective. This dimension comprised three indicators: systems and services, IT infrastructure, and technical quality.

Partners provided overview of these aspects in their regions using the standardized template. Facilitated group discussions on technological readiness and technology assessment provided an important insight into the stages of implementation of digital technologies as well as barriers and gaps in this process. Additionally, all project partners subsequently provided more detailed review based on defined questionnaires and elaborated what the national landscape looks like in the field of digital health.

Austria leads in technology assessment with its real-world evidence collection and patient-reported outcomes. MySugr (Austria) is a digital diabetes management platform that helps patients track blood sugar levels, manage medication, and receive personalized insights. The Czech Republic follows with its HTA system managed by SÚKL, focusing on pharmaceuticals and AI solutions. Slovakia and Bulgaria are developing their HTA methodologies, emphasizing patient screening and personalized medicine. Romania and Ukraine have limited HTA activities, primarily focused on drugs and medical devices, while Hungary faces challenges due to limited resources and experience concerning digital technologies. Republic of Srpska has very recently initiated the activities in the field of digital healthcare and technology assessment.

The DIGI4Care project contributes to tackling these challenges by creating a Knowledge Platform and Radar (O1.2), This platform should provide a transnationally validated, dynamic, and openly accessible digital knowledge platform on available technologies and good practices. The platform will support healthcare professionals to make informed decisions about new technologies, thus facilitating better technology assessment and adoption processes.

For policy makers in resource-limited countries (Balkan region countries), where HTA is relatively new or where there may not be the necessary supporting institutional mechanisms or resources, it is of crucial importance to conduct an overall study of digital healthcare key dimensions. A detailed study on HTA in selected 29 countries (among which 14 are in Europe) indicate that there are challenges driven by a lack of awareness of the HTA process, limited involvement of experts involving relevant stakeholders, and limited participatory processes [13].

Key Considerations

* Implementing real-world evidence and patient-reported outcomes to complement traditional clinical trials.
* Developing standardized HTA methodologies tailored to local needs.
* Enhancing HTA capabilities to support digital health integration across all countries.

Main barriers

* Infrastructure and technical barriers were the most frequently described barriers among included reviews, relating to issues with a limited or insufficient network, lack of existing technologies, lack of devices, compatibility with daily workflow, connectivity speed, healthcare capacity of technology integration, interconnectedness, absence of standardized/harmonized systems at different facilities, etc.
* Lack of digital technology awareness, disparities in access to digital healthcare technologies, healthcare workforce - training and skills gap, tech enabled models for patient engagement, lack of integration of technologies in outpatient care, lack of innovation ecosystem, lack of chronic diseases management, patient safety and quality of care.

Recommendations to overcome the barriers [14]:

* The idea of HTA and institutionalization should be promoted to decision-makers, ensuring links with the most important decision- and policymakers.
* Support for an action roadmap should be encouraged.
* Raising awareness and gaining trust among the public and health experts should be pursued. This should involve identifying and building relations with key stakeholders (including experts, academia, industry and patients).
* Discussions should be started to review the options and needs of policymakers and key stakeholders.
* Options and remits for HTA frameworks, as well as capacity- and network-building, human resources and communication strategies should be presented. Time should be allowed for policymakers and key stakeholders to understand the concepts and form opinions.
* National public health and medicines plans should be developed.

Financing Models

*DIGI4Care assesses and validates the feasibility, benefits of financing models and cooperation with technology providers, introducing developments supporting the integration of care pathways.*

Financial models play an important role in digital healthcare, helping organizations and investors assess the viability and potential profitability of various initiatives. Various budgeting and financial planning models are essential tools for stakeholders in digital healthcare, including healthcare providers, technology companies, investors, and policymakers. They provide insights into financial feasibility, risk management, and strategic decision-making in an evolving healthcare landscape.

Second Online Workshop: "*Financial Models and Data Management Strategies, Regulatory and Ethical Issues in Digital Healthcare*" which was held on April 12th, 2024. This was an opportunity for the DIGI4Care project partners to share their experiences and elaborate on different approaches on key strategic dimension related to various national financial models, data management systems, as well as regulatory and ethical dimensions of digital health.

In addition, all project partners subsequently provided additional clarifications based on defined questionnaires and elaborated what the national landscape looks like in the field of digital health.

Based on the discussion that was conducted between the project partners at the 2nd workshop itself, as well as based on submitted questionnaires in which additional clarifications were given and key barriers were identified, certain conclusions can be drawn for each country.

However, to supplement these resources, a diverse range of financial mechanisms are being explored still in the beginning stage, including official development assistance such as the EU IPA III, syndicated loans, tax incentives, private capital infusion, and social performance bonds. Despite these efforts, challenges persist, particularly in allocating adequate resources for cybersecurity and data protection measures. Establishing a dedicated fund for scientific research work and innovative activities, a science and technology park, and a digital innovation hub reflects the government's commitment to fostering innovation in healthcare.

Austria employs diverse financing models, including public-private partnerships, outcome-based funding, and crowdfunding. The Czech Republic, Hungary and Slovakia rely on public health insurance and EU grants, but face challenges in securing sustainable funding for digital health initiatives. Romania needs alternative financing mechanisms, such as venture capital and public-private partnerships, to drive digital health adoption. Bulgaria and the Republic of Srpska (BiH) primarily rely on public funding, with limited private investment and innovative financial models.

The DIGI4Care project addresses these financing challenges by facilitating structured, large-scale stakeholder cooperation (A3.1). This cooperation clears the pathway for AI and digital health technologies from idea/concept to validation and adoption. By developing a collaborative approach to financing, the project ensures that resources are effectively allocated to support the integration of digital health solutions.

Key considerations

* Encouraging public-private partnerships and innovative financing models to support digital health initiatives.
* Exploring outcome-based funding and social impact bonds to ensure accountability and effectiveness.
* Securing sustainable funding sources, including EU grants and private investments.

Main barriers

* Insufficient funding provided for healthcare systems.
* Outdated financial models for funding of healthcare systems.
* Effectiveness of the healthcare system strongly depends on available budgets.

Recommendations

* Necessity to ensure sufficient funding for healthcare systems is of ultimate importance.
* Necessity to improve financial models in line with the overall country situation.
* Necessity to have more accountability in spending to increase effectiveness of use of funds.
* Strengthening public-private partnerships is important to relax overstretched healthcare systems.

Data Storage and Management

*The co-developed and co-tested Model will present data management and storage practices and principles to ensure comparability of data produced in a variety of transnational settings and thus facilitating the production of analogous transnational-level results. The Model will serve as a general framework for future transnational cooperation among and beyond the DIGI4Care partnership.*

In the healthcare industry, various sources for big data include hospital records, medical records of patients, results of medical examinations, and devices that are a part of Internet of Things. These devices are generating a huge amount of data that can be analyzed to provide real-time clinical or medical care. The exponential growth of medical data from various calls for design innovative strategies to analyze and interpret such enormous amount of data within a given timeframe [15].

Based on the Second Online Workshop: "*Financial Models and Data Management Strategies, Regulatory and Ethical Issues in Digital Healthcare*" conclusions, the DIGI4Care partners have observed some similarities and quite important differences in daily practices relevant to the data storage and management.

Data management practices vary widely across the region. Austria and the Czech Republic have advanced systems like ELGA and standardized frameworks for data interoperability. Slovakia uses the national e-Identity Framework to ensure secure data handling. Hungary and Romania face challenges in data privacy, interoperability, and IT infrastructure. Ukraine and Bulgaria grapple with data governance, sharing, and cybersecurity issues. The Republic of Srpska (BiH) focuses on integrating health information systems but faces significant challenges due to limited ICT infrastructure.

Recognizing the challenge of large-scale interregional data standardization and interoperability, the DIGI4Care project implements a collaborative data storage and management plan. This plan facilitates systematic analysis and evaluation via comparability, resulting in credible validation of outputs and results. The project’s Data Management Guidelines (O2.2) serve as a blueprint for future collaboration among project partners, setting a positive precedent for interregional cooperation.

Key considerations

* Implementing advanced encryption, secure storage solutions, and role-based access controls to protect health data.
* Ensuring compliance with GDPR and local data protection regulations.
* Promoting interoperability through standardized frameworks and national health information systems.

Main barriers

* Insufficient funding creates a problem for implementation of most advanced IT systems supporting data storage and management.
* The existing procedures for data storage and management should be renewed or updated to comply with GDPR and other regulatory requirements.
* E-health systems are not fully in place thus jeopardising the quality of services that are available.
* Citizens are not well informed about the advantages and benefits of digital healthcare services.

Recommendations

* Further education of staff in charge of data storage and management is of ultimate importance to prevent data corruption or losses.
* Further equipping with advanced security systems and encryption.
* Make healthcare information systems more resilient to possible unexpected events, such it was COVID-19 pandemics.

Regulatory and Ethical Barriers

*DIGI4Care co-designs, tests, and validates a number of solutions to tackle this challenge. Comprehensive guidance, user-friendly visualisation, and strategic road mapping contribute to the successful introduction of digital technologies in healthcare provision within the Danube region. This approach, paired with unique, validated solutions, is relatively new and sets a higher standard for innovation in the region.*

Regulatory and ethical barriers in digital healthcare are significant considerations due to the intersection of technology, patient care, and privacy. Some of the key barriers are related to privacy and data security, interoperability, regulatory compliance, ethical use of AI and big data, quality and safety of digital healthcare technologies, etc. Concerns can be addressed with the adoption of appropriate technologies, monitoring and evaluation of security systems, transparency and accountability mechanisms such as legal remedies and compensation for privacy harms resulting from security breaches [16].

Regulatory barriers are a significant challenge across the region. Austria and the Czech Republic face complex approval processes and cross-border data transfer issues. Slovakia and Hungary find challenging the lack of sufficient safeguards or policy measures for implementing new digital tools in the provision of health services, along with the need to align national regulations with the evolving and promising yet unsettled EU framework for years now, while the development of ICT devices in the healthcare sector is rapidly accelerated.

Romania and Ukraine need comprehensive regulatory reforms to address GDPR compliance and ethical considerations. Bulgaria and the Republic of Srpska (BiH) are developing regulations but face resistance from healthcare providers and stakeholders.

DIGI4Care co-designs, tests, and validates a number of solutions to tackle regulatory challenges, including the Knowledge Platform and Radar (O1.2), the Dashboard (O3.2), and the Digitally Enabled ICM Strategy (O1.3) and Action Plans (O1.4). These solutions, developed and validated through transnational collaboration, promote inclusion, universality, and adaptability, setting a higher standard for regulatory and ethical practices in the region.

Key Considerations

* Developing clear guidelines and comprehensive regulations for digital health technologies.
* Harmonizing national regulations with EU frameworks to facilitate cross-border data sharing.
* Addressing ethical considerations such as data privacy, consent, and security.

Main barriers

* Regulations within the region are diverse and unharmonized and not facilitating cross-border collaboration.
* In some cases, privacy of collected data within the healthcare system is not sufficiently supported.
* Guidelines and manuals for implementation of best working practices are often avoided in daily work and can cause significant problems.
* Significant resistance among healthcare professionals with imposing different rules and regulations that are overwhelming their daily work and require additional education or training.

Recommendations

* Good practices in regulatory frameworks and ethics considerations have to be more precise and detailed.
* All practitioners and providers should be educated in detail to understand their importance for all.
* Strengthening mutual collaboration for exchange of good practices especially in ethics in Danube region.
* Further strengthening of regulations and guidelines for electronic health records (EHR) to provide ultimate security and data protection, as well as to prevent any form of data misuse or fraud.

Integrating Digital Solutions into

Care Pathways

*Transnational good practices can be adapted in fields too complex for individual organisations to solve enhancing financing models and cooperation with technology providers, introducing developments supporting the integration of care pathways.*

To design and implement digital health pathways at scale, enterprise health care systems need to develop capabilities and partnerships in human-centred design, operational workflow, clinical content management, communication channels and mechanisms, reporting and analytics, standards-based integration, security and data management, and scalability [18].

Austria is proficient in incorporating digital technologies into healthcare pathways, effectively using telemedicine and electronic health records (EHRs) throughout the patient journey. Additionally, AI-driven diagnostics are increasingly being adopted and implemented. Slovakia and Hungary are also making progress, focusing on telemedicine, e.g. remote monitoring and chronic disease management, and in Hungary the testing of different AI-based decision support algorithms is relevant as well. The Czech Republic and Romania need to enhance their integration efforts, particularly in telemedicine and AI applications. Bulgaria and Ukraine face significant barriers in achieving seamless integration due to IT infrastructure limitations and regulatory challenges. The Republic of Srpska (BiH) is in the early stages of integration, focusing on primary and outpatient care.

The DIGI4Care project integrates digital solutions into care pathways by developing a Digitally Enabled ICM Strategy (O1.3) and institutional-level Action Plans (O1.4). The project’s transnational pilots validate key outputs in different care levels, covering the integrated patient pathway and contributing to improved quality of care and better patient outcomes.

Key Considerations

* Mapping patient journeys to identify opportunities for digital solutions at each stage.
* Utilize digital integration to improve coordination among healthcare providers for timely access to patient records and personalized care delivery.
* Enhancing telemedicine platforms and remote monitoring technologies for real-time tracking of patients' health metrics, enabling early intervention and tailored treatment plans.
* Addressing IT infrastructure and regulatory challenges to achieve seamless integration.

Main barriers

* Complex healthcare systems require additional efforts in creating seamless integration.
* Funding models often prevent this seamless integration as they are not flexible enough to accommodate sudden changes and real situations.
* Insufficient skills and knowledge of users prevents some parts of healthcare systems to advance their services.
* Quality of services depends on qualifications of practitioners, and, in some cases, this quality is undermined with lack of highly skilled practitioners.

Recommendations

* Ensure robust data security measures to protect patient information from cyber threats and maintain confidentiality.
* Provide ongoing workforce training programs to equip healthcare professionals with the skills necessary to effectively utilize digital tools and technologies.
* Form multidisciplinary teams comprising experts in healthcare IT, clinical practice, data analytics, cybersecurity, and technical development to address digital healthcare challenges effectively.

HCP Workflow and Skills

*DIGI4Care aims at designing integrated care management models, proposing optimal processes for implementing and scaling-up the tested solutions in core phases of care. The integration of digital technologies in HCP workflow is facilitated by jointly designed training materials for practising medical professionals along with improved university curricula for medical students, including innovation in medicine, the use of technology, best practices in telemedicine.*

In digital healthcare, healthcare professionals (HCPs) utilize various workflows and skills to deliver care efficiently and effectively. Workflow in digital healthcare refers to patient engagement and communication, clinical decision support, treatment and care coordination, documentation and reporting, patient follow-up and remote support. The broad range of necessary skills include technological proficiency, communication skills, clinical decision making, adaptability and flexibility.

Austria and the Czech Republic have established training programs for healthcare professionals to use digital technologies effectively. Slovakia and Hungary are developing similar initiatives, focusing on continuous professional development. Romania and Bulgaria face challenges due to limited resources and resistance from healthcare providers. Ukraine and the Republic of Srpska (BiH) need to invest in training and support for HCPs to ensure successful adoption and integration of digital solutions.

A detailed study on barriers and facilitators to utilizing digital health technologies by HCP has been conducted in [14]. The study reveals that infrastructure and technical issues, psychological barriers, and workload-related concerns are relevant barriers to comprehensively and holistically adopting digital health technologies by HCPs.

The DIGI4Care project tackles these challenges by designing a comprehensive Training Toolbox (O3.1), which goes beyond traditional training materials to foster technology adoption. The project also supports the development of educational podcasts (D3.2.4) and curriculum development for medical students (A3.3), facilitating continuous learning and the incorporation of digital technologies in healthcare education. The Dashboard (O3.2) supports evidence-based decision-making for HCPs and healthcare institutions, promoting the acceptance and integration of digital technologies into workflow.

The DIGI4Care project addresses these key dimensions through collaborative efforts, innovative strategies, and transnational cooperation. By focusing on technology landscaping, assessment, financing, data management, regulatory and ethical considerations, integration into care pathways, and workforce training, the project aims to transform healthcare delivery and improve patient outcomes across the Danube region. This state-of-the-art approach sets a new standard for innovation in the region, promoting sustainable and effective healthcare solutions that benefit patients, healthcare providers, and the overall healthcare system.

Key Considerations

* Investments in infrastructure and resources are necessary to support digital healthcare initiatives.
* Evaluation is vital to measure the impact of programs on patient care and outcomes.
* Workforce Training: Addressing the workforce training needs and bridging the skills gap is essential for successful implementation of digital health initiatives.

Main barriers

* Cultural and Organizational Barriers: Creating a culture that values innovation, encourages collaboration, and empowers staff is crucial to overcoming cultural and organizational resistance to digital transformation.
* Resistance to Change: Overcoming resistance among healthcare professionals to adopt new digital workflows requires effective change management strategies, training programs, and ongoing support.

Recommendations

* Implementing continuous professional development programs to train healthcare professionals in digital technologies.
* Collaborate with higher education institutions to expand and enhance programs and courses on digital healthcare implementation, ensuring alignment with evolving healthcare needs.
* Overcoming resistance to change by demonstrating the benefits of digital solutions.
* Ensuring necessary skills and support for HCPs to adapt to technological advancements.
* Collaboration among stakeholders is essential for designing and implementing effective programs.

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Annex I

Questionnaire

|  |  |  |
| --- | --- | --- |
| Section | Question | Response Options/Notes |
| 1. Technology Assessment | Does your country/region have an established programme for introducing digital technologies and AI into healthcare? What is the main aim of the established program/strategy? |  |
|  | Does your country has a formalized HTA (Healthcare Technology Assessment) system to support its population’s access to health services? Who is the formal decision maker of the HTA system(s) e.g., who decides on acting or implementing recommendations (nationally or regionally)? |  |
|  | What type of technologies are in scope for advanced digital healthcare solutions in your country? |  |
|  | What do you consider to be the most important technologies that should be in focus for successful digital healthcare implementation? |  |
|  | Has your organization identified specific types of patients or clinical needs that may benefit from using digital technologies? |  |
|  | What are the specific integration requirements for the new digital technology/AI tool? What type of permissions are required to integrate the digital tool into the existing healthcare IT infrastructure? |  |
|  | What methodologies are used in your country for evaluating digital health technologies? | Standard frameworks; Unique methodologies; Please specify |
|  | How do these methodologies align with your healthcare system's needs? | Fully aligned; Partially aligned; Not aligned; Please explain |
|  | Describe any innovative approaches to technology assessment in your country. | List innovative methodologies; Describe their impact |
|  | What are the main challenges in technology assessment in your region? | Resource limitations; Regulatory complexities; Lack of expertise; Other; Please specify |
|  | Please, specify the most important challenges in the process of implementing digital healthcare infrastructure? |  |
| 2. Financing Models | What types of financing models support digital health in your country? | Public funding; Private investments; Partnerships; Grants; Other; Please specify |
|  | Has your practice considered how it will fund any capital costs (e.g., equipment, software, licensing) needed to start a digital healthcare program? |  |
|  | Describe any particularly innovative financing models used in your country. | List models; Describe innovations and impacts |
|  | How are funding mechanisms structured for digital health in your country? | Discuss models for resource-constrained settings; Explain upfront costs and sustainability issues |
| 3. Data Management | What are the primary challenges in data management in your country? | Data privacy; Security; Interoperability; Consent process; Other; Please specify |
|  | What strategies are adopted to manage these data challenges? | Regulations; Technology solutions; Training programs; Other; Please specify |
|  | How is data interoperability managed in your healthcare system? | Standards adoption; Custom solutions; Partnerships; Other; Please specify |
|  | Identify and address potential risks, particularly with respect to physical infrastructure. |  |
|  | What measures ensure data privacy and cybersecurity in your country? | Technology solutions; Training and awareness; Regulatory compliance; Other; Please specify |
| 4. Regulatory Barriers | What are common regulatory hurdles for digital health in your country? | Approval processes; Guidelines clarity; Cross-border issues; Other; Please specify |
|  | Share examples or lessons from your country's regulatory approach. | Provide examples; Discuss impacts |
|  | What collaborative actions could address these regulatory barriers? | Joint advocacy; Guideline development; Transnational agreements; Other; Please specify |
| 5. Care Pathways | How are digital technologies integrated into care pathways in your country? | Prevention; Diagnosis; Treatment; Follow-up; Please specify |
|  | What impact has digital integration had on healthcare in your country? | Improved outcomes; Increased efficiency; Challenges; Please specify |
|  | Provide examples of successful digital integration into care pathways. | Describe technology used; Process; Outcomes |
| 6. HCP Workflow and Skills | What are the personnel and technical expertise requirements for training, integration, and information-security activities? | Technical training; Data management; Ethical training; Other; Please specify |
|  | Do institutions (higher institutions and/or universities) provide a minimum education regarding digital healthcare implementation? |  |
|  | Have you considered how clinical workflows (e.g., taking vital signs, ordering labs, doing diagnostics, writing prescriptions) will need to change to incorporate digital healthcare services? |  |
|  | What are the main challenges related to adjusting workflows for digital health? | Staff resistance; System integration; Cost; Other; Please specify |
|  | Describe any innovative training programs or workflow adjustments. | List programs; Describe adjustments and impacts |

Annex II

Results Report

Technology Assessment

Technology assessment relates to evaluation of current technologies in use and identify emerging trends. This process encompasses various aspects of identification of required technology assets for optimal use, selection of technologies that no longer meets the needs of the health service, implementation of methods to track and manage all assets in a digital and cost-effective, selection of the purchasing strategy for technologies, as well as data security and privacy solutions.

First Online Workshop: "Understanding and Assessing the Technology Landscape - introducing digital technologies and AI into healthcare" which was held on March 26th, 2024, focused on technological aspects of digital healthcare implementation, such as availability and trustworthiness of technologies, acceptance by workforce, integration of technologies in patient pathways. Technology assessment supports the evaluation of medical, social, economic, and ethical implications of using a health technology to inform decision-making and improve healthcare outcomes. ​It aims at supporting healthcare decision-makers, such as policymakers, healthcare providers, and payers, in making informed decisions about the adoption, reimbursement, and use of health technologies. The IT capability dimension represents the extent to which the organization has implemented infrastructure, digital systems, technologies, and services that are usable and effective. This dimension comprised three indicators: systems and services, IT infrastructure, and technical quality.

Partners provided overview of these aspects in their regions using the standardized template. Facilitated group discussions on technology landscaping and technology assessment provided an important insight into the stages of implementation of digital technologies as well as barriers and gaps in this process. Additionally, all project partners subsequently provided more detailed review based on defined questionnaires and elaborated what the national landscape looks like in the field of digital health.

Based on the discussion that was conducted between the project partners at the 1st workshop and after reviewing submitted questionnaires, summary conclusions are presented for each country.

AUSTRIA

As an experienced DIGI4Care partner, Austria has established programs for introducing digital technologies and AI into healthcare. The main aim is to enhance patient care, improve efficiency, and integrate advanced technologies to support prevention, diagnosis, treatment, and rehabilitation. Moreover, Austria has a formalized HTA system where the main decision-makers are national bodies, such as the Austrian Federal Ministry of Health or the Austrian Institute for Health Technology Assessment (AIHTA), formerly known as the Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA). Technologies that are in scope for advanced digital healthcare solutions include telemedicine, electronic health records (EHR), AI-driven diagnostic tools, wearable health devices, and mobile health applications. Particularly, AI in diagnostics, telemedicine platforms, EHR systems, and patient monitoring devices are considered crucial for successful digital healthcare implementation. LBI\_AT partner has identified patients with chronic diseases, elderly patients, and those requiring remote monitoring as key groups that can benefit from digital technologies. To establish specific integration requirements for the new digital technology/AI tool, interoperability with existing EHR systems, compliance with data privacy laws (GDPR), and obtaining necessary regulatory approvals are required, as well as permissions from healthcare authorities and IT departments.

Regarding the methodologies for technology assessment, standard frameworks such as the **European Health Telematics Observatory (EHTO)** and unique methodologies tailored to local needs are used in Austria. These methodologies are fully aligned with local regulatory, clinical, and operational requirements.

Austria adopts some innovative approaches to technology assessment:

1. **Real-World Evidence Collection**:

* Methodology: Real-world evidence (RWE) involves collecting data from actual patient experiences rather than controlled clinical trials. This includes data from electronic health records (EHRs), patient registries, and wearable health devices.
* Impact: RWE provides a more accurate picture of how technologies perform in everyday settings. It helps in understanding the long-term effectiveness and safety of digital health tools. This approach has been particularly useful in assessing the impact of telemedicine and remote monitoring tools during the COVID-19 pandemic (Inits) (LBI for Digital Health and Prevention).

1. **Patient-Reported Outcomes (PROs):**

* Methodology: Patient-reported outcomes are collected directly from patients through surveys and health apps, focusing on their experiences, quality of life, and satisfaction with the healthcare services they receive.
* Impact: PROs offer valuable insights into the patient perspective, which is crucial for evaluating the efficacy and acceptability of new technologies. This approach ensures that patient needs and preferences are central to the assessment process, leading to more patient-centered care (ICLG Business Reports) (International).

1. **Digital Health Pilots and Sandbox Environments:**

* Methodology: Austria employs pilot programs and sandbox environments where new digital health technologies can be tested in a controlled yet flexible regulatory framework. This allows for real-time feedback and iterative improvements before wider implementation.
* Impact: These pilots enable rapid innovation and adaptation, ensuring that only the most effective and user-friendly technologies are scaled up. They also help identify potential regulatory hurdles early, allowing for smoother integration into the healthcare system (LBI for Digital Health and Prevention).

**4. Multidisciplinary Assessment Teams:**

* Methodology: Multidisciplinary teams comprising clinicians, data scientists, regulatory experts, and patients are involved in the technology assessment process. This ensures a holistic evaluation that considers clinical effectiveness, usability, regulatory compliance, and patient perspectives.
* Impact: This approach leads to more comprehensive and balanced assessments, facilitating the adoption of technologies that are not only effective but also practical and well-received by end-users (ICLG Business Reports) (International).

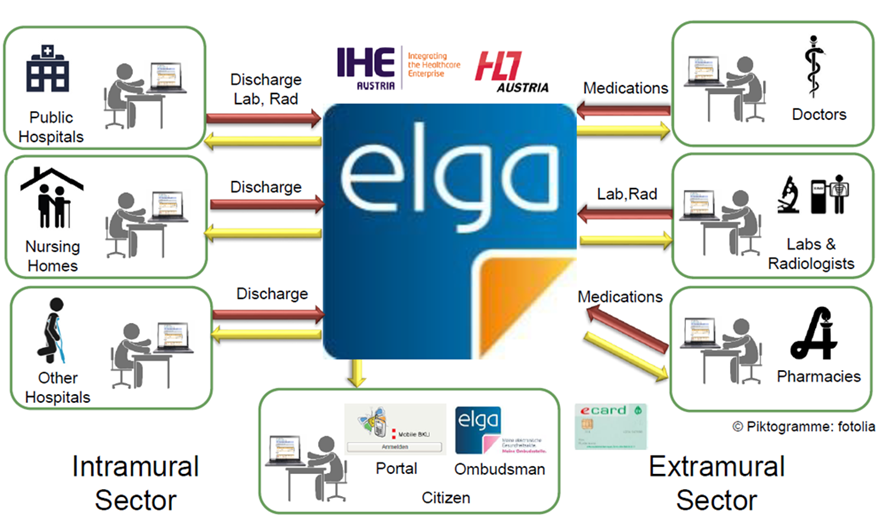
1. **Health Technology Reassessment (HTR):**

* Methodology: HTR involves the periodic review of existing health technologies to ensure they continue to meet current clinical and economic standards. This includes technologies that have already been implemented but require re-evaluation due to new evidence or changing healthcare landscapes.
* Impact: HTR helps maintain high standards of care by ensuring that outdated or less effective technologies are identified and phased out, making room for newer, more effective solutions (International).

**Case study on technology use**

The Austrian health data infrastructure: National electronic health records through ELGA (see Fig.1).

ELGA is an information system that simplifies the process of accessing the health records for the patient and the doctors, as well as other health care professionals at hospitals, care facilities and pharmacies [1]. The health data are not stored centrally, but just the information that the respective health data are available and can be accessed by authorised health service providers (general practitioners, hospitals, laboratories etc.).



**Fig.1. ELGA system**

This makes information available to doctors for optimum treatment and double or even multiple examinations can be avoided. Part of ELGA will be e-medication. Prescribed and obtained medicine is recorded to detect and prevent contraindications (interactions between several drugs taken) as well as double prescriptions. ELGA thus mainly aims at the patients’ safety and the improvement in treatment quality. Moreover, ELGA makes it possible for patients to access their own data. ELGA is a joint project of the Federal government, the provinces and Austrian social insurance.

**Key challenges and barriers**

The most significant obstacles to implementing digital healthcare infrastructure in Austria include regulatory complexities, the siloing of health data, resistance from healthcare professionals, and constraints on resources. Special efforts are directed towards ensuring interoperability, maintaining data security, managing change resistance among healthcare providers, and securing adequate funding.

Regional specificities:

1. Pseudonymization of health data for systems planning (bPK)

2. Telemedicine: Telemedicine and Telecare (1450), poison information centre (VIZ)

3. National (quality) registries

4. Digital health applications (DiGAs) – pilot project”

CZECH REPUBLIC

The Czech Republic has an established programme for introducing digital technologies into healthcare. The main government document that focuses on digitalization process is called Digital Czechia (Digitální Česko). This is the main strategic document of the Czech government that sets out goals and measures for the digital transformation of the country. The document focuses on areas such as eGovernment, digital infrastructure, cybersecurity, digital economy, and education in digital skills. National eHealth Center (Národní centrum elektronického zdravotnictví) is a center responsible for coordinating and implementing eHealth projects in the Czech Republic, as well as for developing and maintaining electronic health records (EHR), telemedicine services, and other digital health solutions. This center is responsible for releasing strategic documents such as Implementation plan – Health 2030. The eHealth in CZ aims to enhance patient care, improve data management, and increase the efficiency of healthcare services. The programs include projects like electronic prescriptions (ePreskripce, eRecept) and electronic sick certificates (eNeschopenka).

The Czech Republic has a formal HTA system managed by the State Institute for Drug Control (SÚKL). The system is still not fully operable, but there should be innovation focused on unification of HTA. The formal decision-makers are national authorities within the Ministry of Health, focusing primarily on pharmaceuticals. Methodologies introduced by SÚKL are generally focused on drugs and medical devices, but not on software solutions. During the evaluation of AI solutions, the medical device approaches are usually used.

The advanced technologies have been already applied and include telemedicine, electronic health records (EHRs), AI for diagnostics and treatment, wearable health devices, and health information systems. Other advanced technologies in scope are VR for rehabilitation or robotics used in surgery. In the focus should be telemedicine and technologies using AI due to benefits such as more efficient operations, reduced costs for treatment, etc. The actual problem in Czech healthcare system is the lack of doctors causing inaccuracy of diagnosis. The modern technologies can effectively use digital data, can be effectively implement into digital processes in practice and can help improve the quality of healthcare in Czech Republic.

FMVŠE\_CZ as a DIGI4Care partner organization has identified specific types of patients or clinical needs that may benefit from using digital technologies. These are: medical students, GPs, the radiology and oncology departments in hospitals and patients, mammography patients, doctors etc. Integration requirements include interoperability with existing systems, data security measures, and compliance with national health IT standards. Permissions required include approval from the Ministry of Health and the State Institute for Drug Control (SÚKL) and approval by the MDR (EU). For using AI in practice in CZ, the most challenging barrier is undergoing the MDR certification, that approve the clinical validity and safety of the product, but the efficiency of the company’s process as well.

Regarding the methodologies for technology assessment, Czech Republic is using the standard frameworks for evaluation. According to EU legislation, the evaluation should be done by the EUnetHTA [2] methodology.

The Czech Republic, as a country implementing HTA, applies a flexible model of network cooperation of several smaller institutions of state, academic and non-profit character, which use a common methodology and are coordinated from one center – the local HTA agency. Institute for Health Economics and Technology Assessment (iHETA) is the reference body for these technology evaluation standards. The observation is that these methodologies are partially aligned with our healthcare system’s needs by ensuring that digital health technologies are safe, effective, and provide value for money.

The technology assessment in the Czech Republic adopts some innovative approaches, such as: the use of real-world evidence and patient-reported outcomes to complement traditional clinical trials, the implementation of adaptive pathways for faster access to promising technologies, etc. There are no specific approaches that may differ from EU legislation. Main challenges in this ongoing process include resource limitations, regulatory complexities, and a lack of expertise in new digital technologies. Methodologies in the Czech Republic should be modified for the SW/AI approach to reach its full potential.

Key milestones of telemedicine in Czech Republic can be summarized as follows:

* Remote monitoring of implantable devices (since 2004 – Biotronik, …)
* Telemonitoring of ECG recording (since 2008 – 35 000 patients evaluated)
* Telemonitoring of blood pressure (since 2010 - Stabil-o-graph mobil)
* Telemonitoring of diabetes (since 2014)

**Case study (Pilot 4) – Focus is on dementia and cognitive disorders in Alzheimer home settings**

The main activities within the Pilot 4 will be monitoring of patients’ vital functions and movement, social activities and cognitive training (see Fig.2 and 3). Various equipment will be used for that purpose, such as Philips transcription system, TELMED monitoring system, ROBIN social robot, PROXYQB for cognitive training,

A diagram of a patient needs

Description automatically generated

**Fig.2. Groups of technologies in the care of people with Alzheimer's disease**

A table with text and numbers

Description automatically generated

**Fig.3. The use of technology in nursing care facilities with a special regime**

**Key challenges and barriers**

The most important challenges are related to regulatory barriers. Achieving the MDR certification is a very expensive, long-term and complex process. For smaller companies, it is quite difficult to finalize the process. Another challenge relates to the current state of digitalization and data sharing. In general, medical facilities are not using cloud infrastructure, which make it difficult to implement advanced software solutions for healthcare applications.

SLOVAKIA

The introduction of digital technologies and AI into healthcare in Slovakia is regulated by a national Strategy for Digital Transformation to implement digital technologies in various domains of government. A national healthcare strategy for digital transformation is yet to be introduced.

National Institute for Value and Technologies in Health Care (Národný inštitút pre hodnotu a technológie, NIHO, www.niho.sk) acts as a national HTA institute based on Act 358/2021 of Slovak Republic. The methodological manual of the Ministry of Health of the Slovak Republic for Decree No. 422/2011 defines requirements for pharmacoeconomic analyses in submitted dossiers. Digital technology in healthcare is pioneered by National Health Information Centre (www.nczisk.sk, Národné centrum zdravotníckych informácií, NCZI). NCZI is responsible for implementing eHealth systems, as well as to monitor and support implementation of global and European standards, facilitate communication between digital technology interest groups and set or recommend standards for Slovak Healthcare. Decisions are made on government level (strategy), ministerial level (Ministry of Finance for electronic communication and data standards for eGovernment, Ministry of Healthcare for health-related standards). Ministry of Health State acts as HTA assessor on all drugs, while Institute for Drug Control is responsible for registration of drugs and their oversight.

To support the advanced digital healthcare solutions in Slovakia, the focus is on online distributed services for eHealth – electronic health records, ePrescription, eBirth, eSickLeave, eExamination, eBooking, eVaccination, My Health personal health management app, Patient Summary, eAlerts, eLab to capture, share and analyse data created in healthcare process. The most important technologies are those enabling automation of routine tasks to unburden medical personnel and medical doctors to allow more time to focus on problems requiring highly skilled medical professionals. The priority areas are automation of health administration, health checkup processes, payment settlements, patient management on side of improving processes, access to healthcare innovations for improved quality of care and lowering false positivity and negativity of examinations. Cost reduction is another important factor to consider.

Digital technologies, once successfully implemented, are offering benefits across the whole framework of healthcare process. CEE HPN also organizes 2 specialized annual workshops where specific topics are discussed – recently topics of ophthalmology (example of AIREEN AI diagnostic tool for diabetes patients), oncology workshop (low level of public awareness on available preventive measures prevents reduction of oncological cases), covid-19 workshop (20+k avoidable deaths caused by poor management and coordination) – all areas where digital technologies provided / could have provided benefits on large scale. Specifically, in AI, there are three main priority areas: patient screening, personalized medicine and fraud detection.

Regarding the integration requirements for the new digital technology/AI tool, Slovakia follows European standards, regulations and recommendations, and there are no country specific regulations. Medical devices must be validated and certified before they are introduced into the market. Medical devices are regulated in the EU in a similar manner to consumer products.

European Medicines Agency oversees the evaluation and supervision of medicinal products, in Slovakia there is the Slovak Authority for normalization, metrology and testing – approves aids, diagnostics, implants, etc. Devices can be legally marketed in the EU after receiving a CE Mark from a Notified Body (NB), a private, for-profit organization based in a member state that specializes in evaluating medical devices or other consumer products. In addition to pre-market approval, each EU Member State also has a governmental Competent Authority (CA), which oversees the NBs and has primary responsibility for post-approval surveillance. In Slovakia, the Slovak Institute for Drug Control (SIDC) has responsibility for post-approval surveillance of medical devices.

Methodologies that are used in Slovakia for evaluating digital health technologies are based on Standard frameworks; EUnetHTA. The SIDC is a primary point of contact for adverse event reporting in Slovakia, defined by the MDR (Medical Device Regulation), AIMD (Active implantable medical devices) a IVDD (In-vitro Diagnostic Directive). For this purpose, SIDC has a centralized system which collects reports from manufacturers, and processes to receive event reports submitted directly by patients or providers to manufacturers. SIDC also undertakes active surveillance, based on randomly selected medical devices and audited conformity.

**Key challenges and barriers**

The main challenges in technology assessment are resource limitations, lack of expertise; national institute is still new and cooperation networks still being implemented, low availability of data in digital format (administrative and clinical data are digitized since 2017), technological complexity, diversity of players, conflicting interests, low level of interest and acceptance among senior medical personnel, implementation mistakes in national level projects. Furthermore, health registries are incomplete, and data is not filed in a timely manner, there is no central storage or large scale annotated diagnostic image datasets in Slovakia, determinants of health data are not yet machine friendly. SIDC has limited capabilities regarding surveillance of medical software.

HUNGARY

The implementation of digital healthcare framework in Hungary is based on the publicly available strategies covering AI and digital health technologies. These include strategies covering digitalization, AI and healthcare. Most of these documents do not contain a detailed action plan, except for the AI strategy.

**The most relevant documents are as follow**:

1. National Digitalisation Strategy 2022-2030 (HUN) Published by the Cabinet Office of the Prime Minister

* Further development of the “EESZT” (EHR cloud) with focus on training of personal, interoperability and infrastructure.
* Implementation and support of population prevention, screening, disease and health management programs supported by digital tools and based on artificial intelligence.
* Smart hospital system development
* Concrete action plan is not included.

1. Hungary’s Artificial Intelligence Strategy 2020-2030 (EN)

* Published by Minister for Innovation and Technology
* The aims are to achieve, in agreement and cooperation with all stakeholders, the responsible use of the continuously expanding health data assets available in Hungary, to strengthen the diagnostic and curative use of artificial intelligence, to develop and introduce AI-supported medical decision-making and medical devices, and to contribute thereby to an effectively and efficiently operating healthcare sector in accordance with the e-Health strategy.
* Preparing citizens to accept the benefits of digital health preservation schemes and the use of AI-supported proposals and help them steer around possible dangers.
* Concrete action plan is included.

1. "Healthy Hungary" Health Sector Strategy 2021-2027 (HUN)

* Published by the ministry responsible for healthcare (currently the Ministry of Interior)
* Planned actions: Human-centred e-Health, data-driven decisions based on real-time data, unification of the IT system, digitization of supply processes, connection to electronic administration, creation of an e-Health institutional system.
* Concrete action plan is not included.

1. Hungary's competitiveness Strategy 2024-2030 (HUN)

* Published by the Ministry of National Economy
* Developing a business model for data and artificial intelligence, connecting "EESZT" (EHR cloud) data with the hospital database and NEAK (National Health Insurance Fund) reimbursement data within the limits of the data protection rules. Switching to BNO11 for more accurate data.
* Development of a financing program supporting the acquisition of certifications (MDR / IVDR).
* Concrete action plan is not included.

The evaluation of digital health technologies is based on the general HTA framework. Hungary has adopted a guideline for preparing and appraising HTA that is published in the gazette. The current version is available in Hungarian [3]. The guideline is published by the minister in charge of health care.

The process of the HTA is the following: the National Health Insurance Fund of Hungary (NEAK) sends the reimbursement submission to the Division for Health Technology Assessment at the National Centre for Public Health and Pharmacy (NNGYK). Based on the cost-effectiveness analysis submitted by the applicant and the relevant literature, the NNGYK prepares a critical appraisal of the submission. After that, the NEAK sends the reimbursement submission and its critical appraisal to the relevant section of the College of Health Professionals for an opinion and may also send it to the Medical Research Council. In the light of these opinions, the NEAK seeks the opinion of the Health Technology Assessment Committee, which is a proposal and opinion making panel run by the Director-General of NEAK. Then the NEAK - with the assistance of the Health Technology Assessment Committee - evaluates the submission based on the opinions received, with a score based on the professional criteria set out in Annex 1 of Decree No. 28/2010. (V.12.) EüM of the Minister of Health. If the NEAK decides that the technology is suitable for reimbursement, it will take a decision and make a proposal to the Minister responsible for health. For more details see [4,5,6].

The Hungarian National E-health Infrastructure, the EESZT was launched on November 1st, 2017, electronically storing information about the patients from publicly funded hospitals, outpatient care providers, general practitioners and in-house paediatricians. By November 2018, private providers were asked to contribute by reporting to different implant registers and divulging the same information. The enhanced exchange of information between private and public service providers, would allow for patient data to be assessed from different providers, which is essential for diagnosis and therapy. E-prescription has already been introduced as the default way of prescribing medicine within the system of EESZT. There are also different pilot programs in the area of patient monitoring (e.g. CGM-s), telemedicine solutions, to be scaled up and included in this central cloud. Online appointment booking system is being introduced in outpatient care. It is also being examined how these solutions can be financed through public funds. The AI-based decision support algorithms are also in the focus of different pilots (e.g. the National Centre for Public Health and Pharmacy plans to introduce AI in the national screening programmes in the future, first in the breast cancer screening programme, and there is a pilot project testing a deep-learning algorithm for decision support in pathology diagnostics).

Successful digital healthcare implementation relies on a variety of technologies that work together to improve patient outcomes, enhance healthcare delivery, and optimize operational efficiencies.  The Health Services Management Training Centre as an institution of the Semmelweis University (SOTE\_HU) does research in the area of AI and machine learning, developing AI solutions in different areas (the most developed is digital pathology) in order to pilot and later scale them up to healthcare system level use in Hungary, which is of utmost importance. They are also working with big data analytics, it supports evidence-based medicine, population health management, and operational efficiency improvements. EHRs are crucial facilitators of digital health implementation by providing a comprehensive, real-time patient history to healthcare providers and decision-makers and to patients.

Telemedicine and telehealth are also important areas to mention, during COVID and since then a huge progress has been observed in its use, there are different programs running in this area in Hungary and its regulation is in progress.

Mobile health apps and devices monitoring the status of e.g. chronic patients (such as CGMs and different wearables) are also important to be used and properly assessed and regulated, as data provided by them can support considerably the treatment and monitoring of such patients/diseases. Their integration to EESZT is initiated.

There are many other technologies which can support the success of digital health implementation (robotics, AR and VR solutions, etc.). The successful implementation also necessitates to focus on cybersecurity, secure IT solutions (encryption, multi-factor authentication, and regular security audits, use of blockchain technology, etc.) and the hardware infrastructure.

Digital technologies can greatly benefit various types of patients and clinical needs by enhancing the quality of care, improving access to healthcare services, and enabling more personalized treatment plans. The areas where the most benefits can be gained are:

1. Chronic disease management, as wearable devices and remote patient monitoring (RPM) systems can track vital signs and other health metrics continuously, allowing healthcare providers to monitor patients' conditions in real-time and intervene when necessary. Continuous glucose monitors are good examples here.
2. Elderly care: elderly people often have multiple health issues, where telemedicine and RPM can be useful solutions, similarly to the above example.
3. Post-surgical recovery: telehealth platforms for follow-up consultations, remote monitoring tools can track the recovery progress of these patients, detect complications early, and provide data to healthcare providers for better post-operative care management.
4. Oncology patients: remote monitoring of their condition, managing side effects of treatments, and maintaining communication with their healthcare team is also an opportunity, and in addition, AI-driven analytics can help in tailoring personalized treatment plans for these patients and cancer diagnosis can be supported by AI algorithms (one of the main focus areas of our institution is this one).
5. Patients in remote or rural areas: telemedicine bridges the gap for patients in remote or rural areas who have limited access to healthcare facilities. It allows them to consult with specialists and receive medical advice without traveling long distances. This is crucial for timely diagnosis and treatment of various health conditions.

To integrate a digital tool into the existing healthcare IT infrastructure in Hungary, several types of permissions and approvals are necessary. These permissions ensure compliance with regulatory, legal, and operational standards. Regulatory approvals for medical devices, integration permissions, and interoperability are the most relevant to mention here.

Under EU law, which applies to Hungary, the medical device regulation (MDR) and the in-vitro medical device regulation (IVDR) govern the clinical investigation, production and distribution of medical devices in Europe. If the digital tool qualifies as a medical device (including AI-based tools), it must be approved by the National Centre for Public Health and Pharmacy (NNGYK, Nemzeti Népegészségügyi és Gyógyszerészeti Központ), the authority responsible for this decision in Hungary.

Furthermore, for most medical devices, obtaining CE mark certification is also necessary to demonstrate compliance with EU health, safety, and environmental protection standards. In addition to the EU-level regulations mentioned above, some Hungarian rules regulate the detailed processes leading to medical device approval [7, 8]. In accordance with EU regulations, a device authorized or notified under the MDR/IVDR regulation can be used (also a boxed device with a CE mark) during health care provision. This regulation also applies to medical devices using AI methods. There are no special domestic regulations for AI tools under development. The inclusion of the data coming from the use of these devices into the central Hungarian EHR cloud (EESZT) is currently carried out concerning a few solutions.

The most important challenges in the process of implementing digital healthcare infrastructure are the following:

* **Legal issues**: navigating the complex landscape of healthcare regulations and ensuring compliance with various laws at EU and national/regional levels
* **Data-protection, cybersecurity**: protecting sensitive patient data from breaches, cyber-attacks, and unauthorized access, compliance with regulations such as GDPR
* **Data quality and management**: ensuring the accuracy, consistency, and completeness of

healthcare data is critical for effective digital health solutions, data from multiple sources and systems must be carefully managed

* **Interoperabilit**y: ensuring that different systems, platforms, and devices can communicate and share data seamlessly, lack of standardization in data formats and protocols
* **Availability of appropriate infrastructure**: rural and underserved areas may lack the necessary infrastructure to support these technologies
* **Costs of digital technologies**: initial investment and maintenance, upgrades, and cybersecurity measures
* **HR:**
* Shortage of data scientists and IT specialists especially who are familiar with the specific nature of the healthcare sector (therefore Semmelweis University Health Services Management Training Centre is launching a Master programme in health data science). Healthcare organizations face also challenges in recruiting and retaining skilled IT professionals as available compensation is often under the market salary range
* Engagement of healthcare professionals: resistance to change among healthcare providers and staff can impede the adoption of new technologies; effective training and change management strategies are needed
* Patient engagement and digital literacy: ensuring that patients are engaged, educated and capable of using digital health tools. Addressing disparities in digital literacy and access to technology among different patient populations often lacks resources.

ROMANIA

As a part of digital healthcare implementation process, Romania has accessed PNRR (National Recovery and Resilience Plan) fund for digitalization. The digitalization component of the PNRR programme includes optimization of the health insurance platform, investment in informatic systems for public hospitals and the digitalization of the institution that are under the surveillance of the Health ministry. All of these represent only projects and are not established programmes.

In 2024, the projected revenue in the Digital Health market in Romania is expected to reach US$440.00m. Looking ahead, the market is anticipated to show an annual growth rate of 7.44%, resulting in a projected market volume of US$586.20m by 2028.

The Digital Health market is divided into three markets:

* Digital Fitness & Well-Being: This market includes fitness trackers, health and wellness coaching, and tools that help individuals monitor and improve their health and well-being.
* Online Doctor Consultations: This market includes telemedicine and other digital tools that allow patients to consult with doctors remotely.
* Digital Treatment & Care: This market includes digital tools that are used to diagnose, treat, and manage medical conditions. It includes the Connected Biosensors and Digital Care Management markets.

The growth of the Digital Health market is driven by factors such as increasing smartphone penetration, improved internet connectivity, and the growing need to curb healthcare costs. The market is also supported by government initiatives to spread digitalization across the healthcare sector. Key players in the market are introducing advanced applications to enhance the user experience and integrate with other digital platforms. The COVID-19 pandemic has accelerated the adoption of digital health solutions, particularly in the Online Doctor Consultations market [9].

According to [10], HTA-related activities in Romania appears to be limited and has been largely confined to research and spread across several institutions. The MoH has promulgated several iterations of national HTA guidelines and established an HTA Unit in 2013 that conducted evaluations of manufacturers’ formulary listing submissions, in collaboration with the Ministry’s clinical advisory commissions. However, the limited expertise that previously existed within the ministry of Health was lost with the transfer of the HTA unit to the National Agency for Medicines & Medical Devices (NAMMD) in 2014”. As a result, the NAMMD is currently the only public institution with a remit to undertake HTA, and with any capacity to do so. The most important technologies that should be in focus for successful digital healthcare implementation are cloud technology, artificial intelligence diagnosis in radiology and laboratory medicine, telemedicine. There is an ongoing WB project to implement HTA in 2024 – 2025, but only for medicines.

Particular attention is given to data governance & data interoperability (EHRs), data security and privacy, integration of IoT, telemedicine and telehealth solutions, AI and ML, digital capabilities - workforce training and skills gap, digital health awareness.

In terms of exclusions/exemptions applicable regarding liability, it should be noted that Romanian law does not set out any specific legal regime regarding the liability relating either to the software in digital health apps or to medical devices in general.

Technologies that are in scope for advanced digital healthcare solutions telemedicine in imaging, PACS - data storage and archiving system, FRAX for osteoporosis, triple test, automated microbiology instruments, home care - monitoring system.

Technologies that should be in focus for successful digital healthcare implementation are advanced patient monitoring applications and platforms; diagnostic systems with AI/ML technology, management systems and interconnected database systems between public authorities and healthcare providers; operation of the Romanian HIS (integrated health information system) patient identification, online verification of insured status, electronic patient health record with data collection from both state and private systems.

**Case study on technology use - partner level**

In University of Oradea digitalisation is used for e-learning, online lectures for students, online catalogue for monitoring the grades of students, online library where students can read online different books.

In the case of hospitals and private clinics electronic record of consultations are kept for each patient.

The National eHealth Platform in Romania is the nation’s Ministry of Health initiative to improve access to healthcare and provide better services. It is designed to enable the secure transfer of healthcare data between healthcare institutions and includes an integrated system for managing patient records, prescriptions, and lab results. The platform also provides access to a range of patient-centric services, including online appointment scheduling and ePrescribing.

**Key challenges and barriers**

Technological factors influencing digital healthcare in Romania are IT infrastructure limitations, budgetary limitations lead to maintenance issues, lack of redundancy in the IT infrastructure, bandwidth limitations, security issues, GDPR- related constraints, server uptime deficiencies, lack of data validation, lack of IT support, lack of legal support. Moreover, the issues related to successful implementation of digital healthcare are also related to non-transparent County Health Insurance Funds website, lack of structure of published information, presence of old/outdated information, lack of efficient search engines on these pages.

The main challenges in technology assessment are the following: public health system in Eastern Europe is underdeveloped in comparation with Western Europe; private health system (voluntary/ out- of - pocket payments) is highly developed in Romania in comparation to neighbouring countries; lack of unified centralization of collected data; restricting access to public data even for a fee; many doctors are not used to using the computer for keeping the record of patients; the National eHealth Platform in Romania has many delays and function quite hard; online consultations are still very rarely used and look out with suspicion; transmission of patients lab results or clinical markers (blood pressure, pulse etc.) to the doctor via online health digital apps is almost non-existed; hospitals and private clinics have multiple financial difficulties that do not permit them to invest in buying digital apps.

UKRAINE

The digital health landscape in Ukraine has witnessed significant transformations, especially in the wake of the COVID-19 pandemic and subsequent military conflicts. These events have catalyzed the expansion of telemedicine services, leading to innovative approaches in healthcare delivery. In recent years, alongside significant health finance reforms, Ukraine has made strides in advancing digital healthcare solutions, notably an eHealth system and the burgeoning field of digital health, encompassing telemedicine and telerehabilitation. Telemedicine offers potential benefits by enhancing efficiency, transparency, and access to quality healthcare services, while concurrently reducing corruption opportunities.

Still, Ukraine doesn’t have any established program for digital technologies. The current situation in the country generates the following obstacles:

* Shortfall of over 10 million family doctors internationally according to the WHO
* Only 40% of medical students in Ukraine can access teaching offline
* Danger of closing medical faculties for foreign students
* Some medical faculties in “hot regions” of Ukraine are closed or have online education.

The HTA (Healthcare Technology Assessment) system is still in the early phase of implementing to provide Ukraine population’s access to health services [11]. It is in a process of piloting the assessment system of andragogy in family medicine teaching with the use of healthcare technologies. The pilot of using healthcare technologies in medical education was supported by the authorities of Uzhhorod National University and is being conducted by the trainers of the family medicine and the Outpatient Care Department who are also general practitioners of the “InterFamily” clinic. Five other departments of family medicine of the other Ukrainian universities from the regions affected by war are invited to participate in the VCE project.

The department of Family Medicine and Outpatient Care of Uzhgorod National University together with “InterFamily” clinic first in Ukraine developed a teaching project for using technologies (virtual clinical environment (VCE) of the family doctor as well as a simulation center with e-mannequins) for hands-on teaching of internal medicine, paediatrics, point of care ultrasound and emergency medicine skills for medical Ukrainian and foreign students, residents and doctors and also non-medical population. The aim is to develop a new system of distant practical teaching medicine in a clinical setting of a family doctor and to implement a hands-on training of practical skills with a help of e-devices.

Regarding the technologies that are in scope for advanced digital healthcare, virtual clinical environment (VCE) of a family doctor in distant practical medical education is set up and includes: smart glasses, e-stethoscope, e-dermatoscope, e-ophtalmoscope, angled video camera, ultrasound, e-mannequins simulators for hands-on training (for emergency care at the battle field cyborg named “Cezar”, for internal medicine skills training cyborg named “Istan”, for pediatric skills training – 2 cyborg kids mannequins).

They also use the newly developed web-based program named “Evidence based screening adviser” to be implemented both in medical education of students and doctors and in practical work of the family doctors.

Ukraine partner has identified specific types of patients or clinical needs that may benefit from using digital technologies: students, residents and GPs, IDP patients and local citizens from the rural parts of Transcarpathea. Recently they have received letters of request for such educational activity from 5 FM departments of universities of Ukraine asking for digital training during the war in Ukraine as a valuable option for the practical medical education.

With the absence of state rules as to the digital technologies they do not need any specific integration requirements for the new digital technology. Though, they have got a concern of the local authorities of Uzhgorod National University to use these technologies. For future development, based on the results of their research in andragogy by applying digital technologies in clinical teaching, the Ministry of Science and Education and Ministry of Health Care of Ukraine will consider this initiative to introduce these activities into the teaching curriculum.

Ukraine is developing the platform of assessment of the skills, knowledge and attitude changes of the trainees before and after VCE session in a form of surveys to assess the knowledge and attitude changes. Moreover, practical skills self-assessment questionnaires as well as hands-on skills assessment by two independent experts during module sessions will be designed.

**Possible envisioned solutions are:**

* International collaboration – British Ukrainian project
* Program of simultaneous translation of virtual consultation
* Use of smart glasses and e-devices during VCE: stream to different parts of the country and abroad
* Innovative remote-teaching technology can develop the knowledge and skills of medical students

Assessment of the knowledge and motivation for screening based on the program “EB screening advisor” is being used in a form of the survey among medical students, doctors and patients. A lack of practical medical education in the FDs offices because of the old academic education system and because of the war in Ukraine needs this system to be changed by means of new distant technologies of practical medical education like VCE.

The system of screening in Ukraine has not been developed yet and is not a priority of the Ministry of Health Care due to the war but remains a curtail for the population’s health. The designed web-based program “EB screening advisor” can make a significant change during the transitional period.

**Case study technology - Virtual Clinical Placements – Using technology to overcome challenges and enhance medical education**

* International Ukrainian-British project: Uzhgorod National University, “InterFamily” Clinic, British team Esseter UK

VCE is a tool that allows learners to experience and participate in clinical environments from a remote location. The aim of this solution is to evaluate the effectiveness of virtual clinical placements in medical education of senior medical students and FDs and to establish and test a pedagogical framework for virtual clinical teaching. Virtual clinical placement using smart glasses will be tested in addition to the standard teaching (see Fig.4).

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**Fig.4. - Virtual Clinical Placements – Using technology to overcome challenges and enhance medical education**

**Key challenges and barriers**

The main challenges in providing technology assessment are human and financial resource limitations; regulatory complexities; lack of expertise. The challenging task is to develop new teaching technology with a lack of finance and human resources. As they are teaching foreign students whose Ukrainian language skills are sometimes insufficient, a language barrier appears as a problem.

BULGARIA

Bulgaria has an approached National Strategy for eHealth and Digitalization of the Health System 2030 and Action Plan for Implementation of the National Strategy for eHealth and Digitalization of the Health System 2030. This document also includes a model for managing the eHealth Digital Services Infrastructure (eHDSI), which will enable Bulgarian citizens to exercise their patient rights in cross-border healthcare (Directive 2011/24/EU).

The main aim of the strategy is to support the development of healthcare in Bulgaria by developing and implementing data-driven solutions that meet local needs and provide citizens with tools and services for a healthier life. Strategic priorities (SP) of the National eHealth and Digitalization Strategy:

* SP1: Development of the organizational model for eHealth and capacity building for stakeholders.
* SP2: Developing the regulatory framework for eHealth.
* SP3: Seamless access to health data across the healthcare ecosystem by ensuring interoperability of eHealth systems
* SP4: Ensuring adequate cybersecurity measures for eHealth systems and confidentiality of health data
* SP5: Implementation, development and upgrading of the National Health Information System (NHIS) and other IS in the health sector.
* SP6: Introduce education and training to support eHealth skills development.
* SP7: Developing telemedicine, large data sets, innovative solutions and new health technologies.

The backbone of the National strategy for eHealth and Digitalization in terms of technology is the NHIS. According to the legal framework, the NHIS is established by the Health Act, which is maintained by the MoH and aims to collect, process and store information on the health status of the population as a whole and for everyone. The NHIS includes electronic health record data for all citizens, as well as information obtained from registries, databases and systems maintained by the MoH, its sub-national budget holders, health care facilities, NHIF, insurance companies, etc.

Bulgaria has a National AI Strategy that outlines policy initiatives for AI development until 2030, but there is crucial need for improvement and adoption.

The strategy emphasizes areas such as infrastructure, research capacity, knowledge, skills, and building trust in society. However, the strategy is still on paper and should be adapted to continue in execution in alignment with the new EU policies. The other pillar for adoption is the funding for all these technologies. There is no clear vision how the healthcare facilities in outpatient and inpatient care can access and implement technologies within their structures because of budget limitations and lack of local strategies for improvement.

Bulgaria has also taken steps toward implementing HTA, but there is room for further improvement to ensure equitable access to health services based on evidence-based assessments. The formal decision-making process for HTA recommendations in Bulgaria involves various National Health Insurance Fund (NHIF) as the single payer administering social health insurance and plays a crucial role in implementing HTA recommendations nationally. Other stakeholder is the National Council for pricing and reimbursement where currently is the HTA process for access of new therapies. It is important to note that despite the introduction of HTA, the Bulgarian health system still faces challenges related to centralization, stakeholder resistance and regional inequities, and is still waiting the application of the telemedicine regulation.

**Technologies in scope for advanced digital healthcare solutions in your country are**:

* National Health Information System – NHIS (it is centralize date from the healthcare system – hospitals, outpatient care, laboratories, etc.),
* Insurance companies’ applications

**Solutions** that are provided by private companies:

* Advances telemedicine and remote patient monitoring solutions – HUBIS, Check Point Cardio, Concento, Diasyst,
* Integrated care solutions – Haelan
* EHRs solutions
* Thermography solutions – Kelvin Health
* Outpatient care solutions
* AI analytics and big data
* Clinical trial management solutions
* Information management system solutions
* Cybersecurity Solutions
* Complex IT & Cloud Based Solutions
* Analytics and big data

Technologies that are considered as the most important for successful digital healthcare implementation are paperless healthcare, viable HER, telemedicine and telehealth, home care, analytics and big data (incl. ML and AI), health information exchange, cloud computing, genomics and precision medicine, solutions for self-management and self-care,

Moreover, specific types of patients or clinical needs that may benefit from using digital technologies are identified: chronic patients, non-communicable diseases patients, diabetes, CVD, oncology, respiratory disease, rare disease patients, risk patients.

The methodologies for evaluating digital health technologies are in development phase. Bulgaria is in development of strategy and methodology for MDR and HTA assessment. But there is still missing the main link between the healthcare needs, regulation and adoption of health technologies.

The National Council on Prices and Reimbursement of Medicinal Products (NCPRMP) in Bulgaria is ranked among the few EU countries that collect and analyze data from real-world practice. NCPRMP is leading the country on the path of evidence-based medicine by embracing digital solutions, including AI, to integrate and process real-world data (RWD) from electronic health records. The software extracts medical statistical data from hospital information systems with the aim of aggregating and harmonizing it and analyzing clinical treatment outcomes and clinical survival rates, comparing them with clinical trials. These analyses help health authorities understand how patients respond in real-world practice and, therefore, facilitate efficiency in public spending. This could empower value-based payment models for better use of government spending while improving patient healthcare quality and outcomes.

**Case study 1 - empower patients to better own and manage their chronic CVD, and support Interdisciplinary Care teams to provide coordinated and holistic care (see Fig.5)**

The concept represents a transformative approach to healthcare, emphasising continuous, integrated, and tech-enabled patient care. This innovative model aims to enhance the overall healthcare experience, improve health outcomes, and streamline the delivery of healthcare services in a way to provide continuous patient care, integration of the healthcare ecosystem, tech-enabled healthcare, better patient engagement, remote monitoring and home care, enhanced care coordination, and data security and privacy.

**A screenshot of a computer

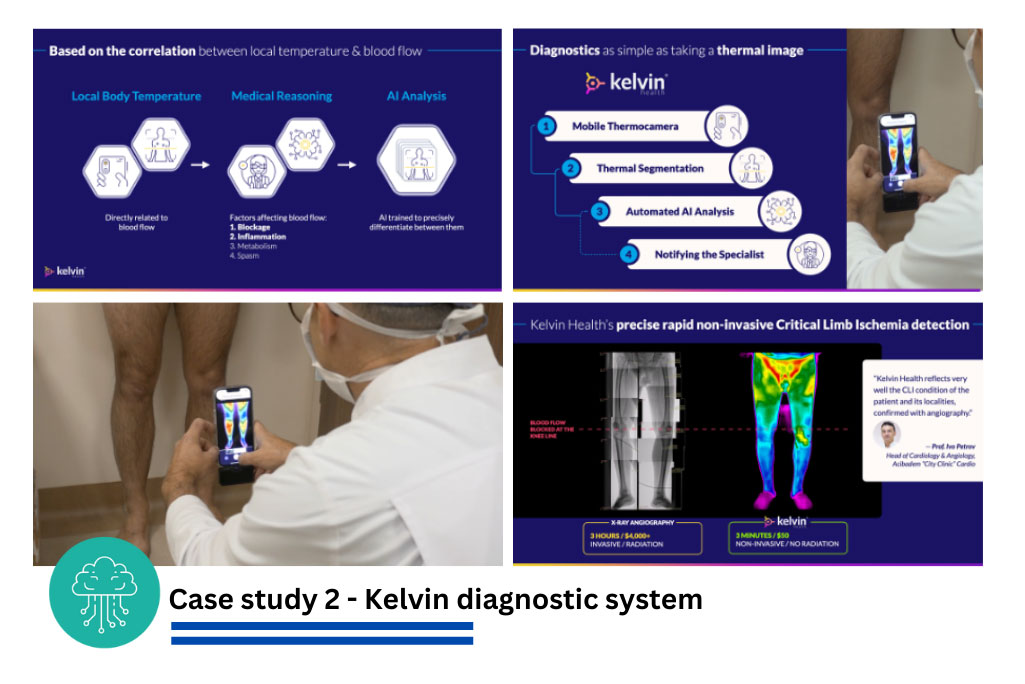
Description automatically generated**

**Fig.5. E-care platform**

**Case study 2 - Kelvin diagnostic system (see Fig,6)**

This diagnostic assistive solution provides the following benefits:

* replaces part of the current workflow (ABI and, in some cases, Doppler)
* powerful rapid triage and healing capabilities
* leading to substantial cost saving for the hospital
* time and documentation saving for the clinician
* cost, limb, and life saving for the patient

****

**Fig.6. Kelvin diagnostic system**

**Key challenges and barriers**

The main challenges in technology assessment are regulatory framework, IT infrastructure limitation, lack of data governance, interoperability immaturity, resistance of technology adoption and integration, lack of digital technology awareness, disparities in access to digital healthcare technologies, healthcare workforce - training and skills gap, tech enabled models for patient engagement, lack of integration of technologies in outpatient care, lack of innovation ecosystem, lack of chronic diseases management, patient safety and quality of care.

Analysis of the health-specific governance current state indicates a low to medium maturity level and readiness for digital transformation.

The most important challenges in the process of implementing digital healthcare infrastructure are the fragmentation of the data, lack of consistent communication between healthcare institutions, lack of IT infrastructure, HCPs resistance, political instability and will for effective digital transformation, focus on IT rather that cultural transformation.

**Policy and Low:**

* A national strategy on healthcare digitalization for 2021-2030 is drafted but not yet finalized
* The basic principles of processing of health data for primary and secondary uses are secured in the Health Act in accordance with GDPR, but specifications of level of access to health data are lacking
* The Health Act stipulates the creation of a National Health Information System (EHR), but details about its functioning are not yet specified in secondary law (Regulation on EHR)
* Regulations on data transfer, security, and standards are missing or outdated

**Institutions / stakeholders:**

* The key governing bodies (Ministry of Health, National Center for Public Health Analysis, Ministry of e-Government) lack specified roles and functions to enable the process of digital transformation
* The national strategy on healthcare digitalization is expected to streamline the functions of these bodies and to identify potential partnerships with private companies and NGOs with domain expertise

**Funding**

* + - The healthcare budget has dedicated BGN 3.8m (EUR 2m) to digital healthcare, with a vague formulation of the use of the funds
    - Several European funding programs exist for strengthening of healthcare systems and use of digital technologies

**Resistance:**

HCPs are not ready to adopt healthcare solutions. They resist because of lack of proper education programs, awareness of the benefits and they don’t want to change their work flow.

REPUBLIC OF SRPSKA

As a resource-limited and developing country with many obstacles and barriers in adopting digital healthcare regulations and without the necessary supporting institutional mechanisms, an additional problem connecting digital healthcare development, is the relatively low level of ICTs indicators (computer technology and networking, connection speed, Internet usage, level of education and ICT knowledge) as well as the importance of ICTs to government vision of the future. Research and development are key components for improving competitiveness and innovation. However, RS investment in research and development is significantly lower compared to global standards, which limits its ability to compete globally. Namely, business expenses for research and development in RS amount to only 0.01% of gross domestic product (GDP), compared to 2% of GDP allocated by the European Union, as well as an average of 0.32% for candidate countries in 2019. Innovations are not common in the RS at the enterprise level, and only 24.3% of the total of 1,850 surveyed enterprises reported having some kind of innovative activity.

Statistics related to technological adoption, availability of latest technology as well as capacity for innovation in RS are still far away from desired. The multiple-step interactive processes of technology innovation and adoption require constantly changing resources and skills, needing a broad scope of actors and interests operating under different goals, incentives, and timelines. Thus, a set of recommendations which should be addressed by government participation in health ICT development and deployment can be specified [12]: define unique criteria for the continuous and uniform implementation of the information system for all institutions alongside the unique quality control of work and services; increase the efficiency of health service delivery using assessment, but also the utilization of advanced technology, which should provide communication and data exchange between healthcare institutions accompanied with data transparency and guaranteed privacy issues; perform a financially sustainable healthcare system by coordinating the costs of the health sector with incomes; redesign the basic package of healthcare that is financed from social and health insurances to obtain the cost effective use of digital healthcare services.

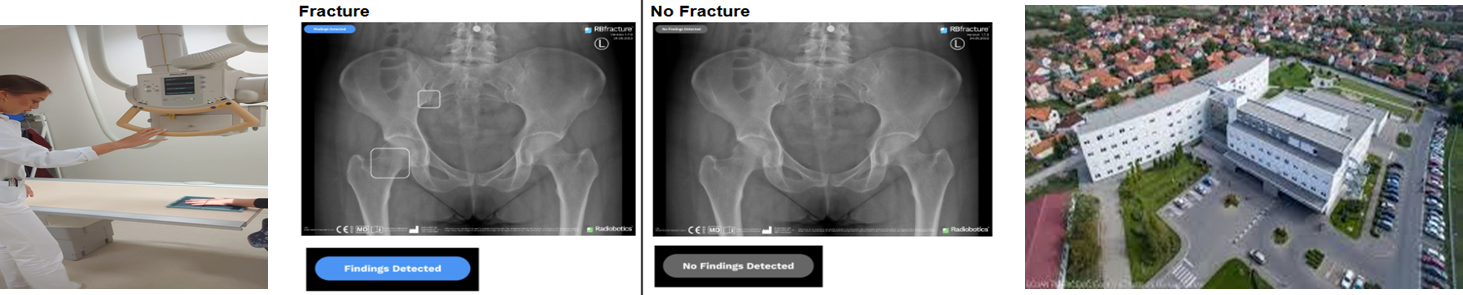
In September 2023, the Strategy for the Development of Science and Technology, Higher Education and Information Society in the Republic of Srpska for the period 2023-2029 was published. The concept of developing a sustainable smart specialization strategy was introduced, the process of which is intersectoral and includes not only the sectors of scientific and technological development, higher education and the information society, but also a number of other sectors. The development involves a series of coordinated phases and the interaction of many interested actors from the public, private, non-governmental sector and the academic community.

The first working meeting related to the development of the five-year digitalization strategy in healthcare was held on March 27, 2024. The areas in healthcare where AI is already most present is radiology, but its application in other areas such as physical medicine and rehabilitation is accelerating.

**Case study 1**

**Diagnostics**: Software RBfracture in radiology by Image biopsy lab (Braincon Technologies) in PHH “Sveti Vračevi”

Device enables additional quantitative analysis and enrichment of medical data, which can be valuable for research and development of new diagnostic algorithms or therapeutic strategies – providing equal measurement of distance between bones and joints (see Fig.7).

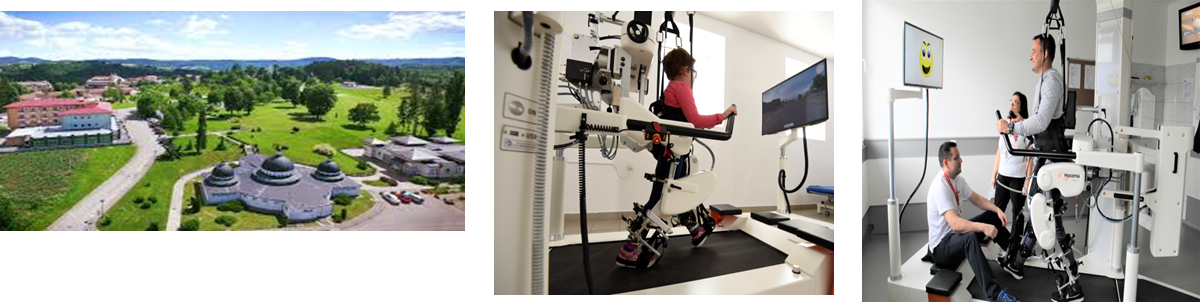


**Fig.7. Software RBfracture in radiology by Image biopsy lab (Braincon Technologies) in PHH “Sveti Vračevi”**

**Case study 2**

**Treatment:** Advanced software in rehabilitation Lokomat by Hocoma in the PHI “dr Miroslav Zotović”

Device enables computer-controlled walking movements while taking over the patient's body weight, providing various degrees of relief. A combination of a dynamic suspension system and adjustable orthoses, along with sensory-motor stimulation, ensures walking training that closely resembles physiological walking (see Fig.8).

 **Fig.8. Advanced software in rehabilitation Lokomat by Hocoma in the PHI “dr Miroslav Zotović”**

Integrated health information system (IZIS) implies complete integration, i.e. informational connection of all institutions of the health system of RS, and the use of electronic referrals, prescriptions, electronic health records (HER), e-cards instead of health booklets since 2023. It is regulated by three laws: the law on health care, the law on health insurance and the law on health documentation and records in the field of health. Benefits that such a system can provide are information exchange among healthcare professionals, more coordinated and efficient care delivery, and comprehensive data analysis for strategic decision-making. The impact of such a system reflects on improved patient safety and confidentiality, streamlined administrative processes, and reduced paperwork burden on healthcare providers.

Implementing digital technologies and AI in healthcare brings a number of challenges and barriers based on conclusions from the international conference Future vs. Present in medicine, Digitalization - Artificial Intelligence, in Bijeljina September 2023 [13]. In 2024, The cardiology clinic at the University Clinical Center of the Republika Srpska in Banja Luka has acquired one of the most modern devices that will significantly improve diagnostics and examinations in this area. The device has excellent features, some of which are high image resolution and software supported by artificial intelligence that will help in obtaining more information about the condition of the heart muscle and valves. Essentially, the device will make diagnoses much faster, especially in severely hospitalized patients, and in addition, it will affect the more precise preparation of patients from the cardiac surgery department.

**Key challenges and barriers**

Technological factors influencing digital healthcare in Republic of Srpska are lack of governmental support through strategies, programs or action plans; insufficient technical IT infrastructure that requires networks, hardware and software; lack of trained and supportive human resources; lack of financial support from various funding sources; lack of implementation of AI into work process and integrating AI with existing systems; lack of investing in security measures and data protection; lack of ethical and regulatory guidelines.

Financing Models

Financial models play an important role in digital healthcare, helping organizations and investors assess the viability and potential profitability of various initiatives. Various budgeting and financial planning models are essential tools for stakeholders in digital healthcare, including healthcare providers, technology companies, investors, and policymakers. They provide insights into financial feasibility, risk management, and strategic decision-making in an evolving healthcare landscape.

Second Online Workshop: "*Financial Models and Data Management Strategies, Regulatory and Ethical Issues in Digital Healthcare*" which was held on April 12th, 2024 provided the opportunity for DIGI4Care project partners to share their experiences and elaborate on different approaches on key strategic dimension related to various national financial models, data management systems, as well as regulatory and ethical dimensions of digital health.

In addition, all project partners subsequently provided additional clarifications based on defined questionnaires and elaborated what the national landscape looks like in the field of digital health.

Based on the discussion that was conducted between the project partners at the 2nd workshop itself, as well as based on submitted questionnaires in which additional clarifications were given and key barriers were identified, certain conclusions can be drawn for each country.

However, to supplement these resources, a diverse range of financial mechanisms are being explored still in the beginning stage, including official development assistance such as the EU IPA III, syndicated loans, tax incentives, private capital infusion, and social performance bonds. Despite these efforts, challenges persist, particularly in allocating adequate resources for cybersecurity and data protection measures. Establishing a dedicated fund for scientific research work and innovative activities, a science and technology park, and a digital innovation hub reflects the government's commitment to fostering innovation in healthcare.

AUSTRIA

Based on the presented experiences and examples of good practice, it is evident that the national health system of Austria has a quite developed diverse financial systems and support programs for digital health initiatives. In addition to public programs for financing and supporting the development of digital health, the national health system of Austria has experience in using various EU funding models (e.g., joint actions, grants, cross border collaboration, etc.). It is important to mention that there are positive examples in Austria of private investments in the digital health system which generates a significant interest of private investors. Thus, different innovative financial models and initiatives aimed at improving digital health should be highlighted.

**Funded mechanism is implemented through different innovative financing models**, such as:

* public-private partnerships (share of costs, risks, and benefits)
* outcome-based funding (ties financial support to achieving specific health outcomes) which ensures investments are directed towards effective technologies that improve patient care.
* crowdfunding and social impact bonds (raising funds from a number of small investors and ties returns to social outcomes) which ensures accountability by linking returns to health improvements.

Public-Private Partnerships (PPPs) emerge as a strategic approach in Austria to leverage shared resources and expertise, particularly in the healthcare sector. These partnerships facilitate collaboration between the public and private sectors, enabling accelerated research, enhanced production capabilities, and streamlined administrative processes. The COVID-19 pandemic further underscored the importance of PPPs, particularly in the health sector, where rapid response and resource mobilization are critical.

Funding Mechanisms are structured like resource-constrained settings (model of flexible funding like PPPs and EU grants mitigate resource limitations by bringing in external expertise and financial support) and upfront costs (including equipment, software, training, and system integration) and under governance of the Federal Target-Based Governance Commission.

CZECH REPUBLIC

Although there is effective public funding focused on different R&D projects (grants) in Czech Republic, but still there is no effective focus on implementation of new digital health technologies. Private investments from Business Angels and VCs are more focused on introducing the technologies into the hospitals and medical practice rather investment or developing of new financial models or initiatives for new digital health technologies.

Czech healthcare financing system primarily relies on public health insurance, supplemented by some innovative digital initiatives such as *e-recept* (remote prescriptions) and platforms like Moje VZP and *VITAKARTA*, *Zdraví v mobilu*, *Zdraví na klik* offering benefits like reimbursement reporting and compatibility with smartwatches.

Despite efforts to embrace telemedicine, robotics, and electronic cards, progress in digitalization remains limited due to financial constraints including a lack of local and national Research and Development grants and limited health insurance companies, with the country ranking below the EU average in the Digital Economy and Society Index (DESI) 2021. Private sources and initiatives play a crucial role in driving innovation, exemplified by projects like EPIDIS, Carebot, Aireen, and virtual clinics like EUC.

There are grant opportunities for medical facilities to update or renew standard medical equipment or medical hardware and purchasing medical software as well. On the other side, the public funding through health insurance should work more efficiently, to develop new model for medical facilities to buy digital health technologies when they need it. So, innovative financial models for new digital health technologies in Czech Republic are still not enough for further improvement of new digital health technologies.

SLOVAKIA

Slovakia's eHealth services have the potential to revolutionize healthcare delivery by leveraging digital technologies to enhance efficiency, accessibility, and patient care. Key components of Slovakia's eHealth infrastructure include national eHealth services (ePrescription, eLab, eSickLeave, eBirth, EHR, eVaccine, eExamination, eBooking, Patient Summary), national health insurance providers, third-party health services, hospital information systems, private labs, and primary care facilities. However, the successful implementation and sustainability of these services hinge upon effective financing models, robust data management practices, and navigating regulatory barriers.

Slovakia's eHealth financing models encompass a mix of EU/state budget allocations and contributions from the Resilience & Recovery Plan. Both public and private funding sources are instrumental in driving innovation and sustaining eHealth initiatives. Private sector involvement in financing underscores the importance of collaboration between public and private entities in advancing eHealth infrastructure. However, challenges such as effective allocation and utilization of funds persist, necessitating strategic planning and coordination to maximize the impact of financial resources.

HUNGARY

Digital health in Hungary, like in many other countries, is supported by a variety of financing models. These models can be broadly categorised into public, private, and hybrid financing mechanisms. Although there is a growing private sector of service providers in Hungary, since Hungary has a single-payer system based on a risk pool, public funding plays a significant role in the healthcare sector.

Public funding can be government grants and programs. The Hungarian government provides grants and funding programs to support developing and implementing digital health initiatives.

These can include funding for research and development, infrastructure, and pilot projects. The Hungarian government has launched several initiatives to support digital health. These include strategic plans such as the “Digital Success Program 2.0,” which outlines goals and provides funding for digital transformation in healthcare.

Specific projects, such as the National eHealth Infrastructure (EESZT), are government-funded and aim to integrate various digital health services into a single platform.

Another type of public funding is the European Union Funds. As an EU member, Hungary has access to various EU funds and programs to promote digital innovation and healthcare improvements. The Horizon Europe, and the Digital Europe Programme are examples of EU funding sources that support digital health projects.

In their own institutional level practice, Semmelweis University Health Services Management Training Centre is initializing digital healthcare programs based on a national research programme called the network of national laboratories. Among these there is the Health Security National Laboratory, within which SOTE\_HU is leading the Division on Data-Driven Health. Within this project starting a digital healthcare initiative (they are working on different solutions including development of AI and scaling it up to national level) is fully funded by the state. The focus is mainly on AI-based solutions for the possible financing models. Questions arise whether HTA (financial analysis based on medical aspects) is a useful tool to assess whether a digital/AI solution should be reimbursed from public financing.

ROMANIA

Romania's health system is based on a combined or mixed system, pooling of financial resources, from premiums paid by taxpayers and funds collected by the Romanian Government through various taxes and contributions, which are then channelled into the Unique National Social Health Insurance Fund (UNSHIF). The financial resources collected in this way include various sources: health insurance premiums, budget transfers from state institutions for certain categories of the population, local budgets, special taxes, loans and international grants, as well as the Fund's own income.

The financing model in Romania's healthcare system revolves around the electronic reporting of medical services, with each service assigned a monetary value based on a points system. This system allows for the financial analysis of services rendered, with hospitals and clinics receiving reimbursement from the National Health Insurance House accordingly. However, challenges persist, including the need for improved financial transparency, training for medical professionals on financial management, and addressing errors in reporting and reimbursement.

The example of innovative financing models used in Romania is Primary care – FRAX system. Romanian Healthcare System needs to reinvent itself by using innovative financing mechanisms coupled with electronic information and communication systems, while offering greater transparency, flexibility and choice and increasing access to the services available.

It is obvious that the health system rests on public financing with the central role of the National Social Health Insurance Fund. Healthcare facilities and key medical infrastructure are highly dependent on public funds as well as available EU funds, which slows down the introduction of advanced digital medical technologies and innovative funding models.

There are very few examples of public-private partnership, which face Romania's health system with significant challenges. Within the strategic and program documents, there are no costs or resources have been identified to facilitate the development of digital health solutions.

UKRAINE

The Ukrainian health system has preserved the fundamental features of the Soviet system against a background of other changes, which are developed on market economic principles. The transition from centralized financing to its extreme decentralization is the main difference in the health system in comparison with the classic Soviet model.

A series of health system reforms were introduced in Ukraine in 2015 and launched two years later. In January 2018, the Ministry of Health of Ukraine began a fundamental transformation of the national healthcare system. The health care reforms initiated in 2015 culminated in the Law on Financial Guarantees for Health Care Services, which define a guaranteed benefit package—the PMG—for all Ukrainians and created the National Health Services of Ukraine (NHSU) to serve as the strategic purchaser for this program. The PMG transformed the previous vague constitutional commitment to free health care for all into an entitlement to a defined package of health services. It reduced the fragmentation of health financing and shifted responsibility for government spending from hundreds of subnational governments which were previously responsible for most operational costs, to the national government.

National Health Service of Ukraine is the central body of the executive power, which implements state key health reform principle “money follows the patient” and other policies in the field of state financial guarantees of medical care.

NHSU is a national insurer that concludes contracts with health care institutions and purchases medical services from them. Additionally, it monitors compliance with the terms of contracts and makes direct payments to institutions for services provided.

The adoption of digital healthcare services in Ukraine hinges on viable financing models that balance accessibility and sustainability. Several models, including subscription-based, pay-per-use, value-based, and hybrid models, offer varying benefits and challenges. While subscription-based models foster patient loyalty and financial predictability, they may face resistance in regions with lower disposable incomes. Pay-per-use models offer flexibility but may deter patients due to cost concerns. Value-based models align incentives but can be complex to implement. A hybrid approach may offer the flexibility needed to cater to diverse patient needs but requires careful management to strike the right balance. The digital health landscape in Ukraine has witnessed significant transformations, especially in the wake of the COVID-19 pandemic and subsequent military conflicts. These events have catalysed the expansion of telemedicine services, leading to innovative approaches in healthcare delivery. The Ukrainian national strategy underscores the necessity for human-centric and accessible telemedicine, reinforced by technological neutrality, and harmonization with global standards.

BULGARIA

Bulgaria's healthcare system is undergoing significant transformation, fuelled by digitalization efforts aimed at enhancing patient care and research capabilities. However, amidst these advancements, the country faces a multitude of regulatory, ethical, and financial challenges that impact the adoption and implementation of digital health solutions.

Financial initiatives in digital health in Bulgaria is a complex endeavour, compounded by financial inequality and limited funding sources. While traditional insurance models play a role, disparities in access to healthcare services persist. Innovative financing models, such as grants from non-governmental organizations and the European Union provide alternative funding avenues but may not be sustainable in the long term. Operationalizing digital health solutions entails significant costs, including data collection, annotation, and maintaining patient registers. While some activities may be undertaken pro bono, others require substantial investment. The lack of standard funding sources exacerbates financial constraints, necessitating creative approaches to secure funding for essential activities.

REPUBLIC OF SRPSKA

Bosnia and Herzegovina is organized as a decentralized state which, based on the provisions of the Constitution of BiH, is administratively divided into two entities: the Republic of Srpska (RS) and the Federation of Bosnia and Herzegovina (FBiH). Because of complex constitutional arrangement, healthcare system of Republic of Srpska operates as a fully independent and autonomous.

The healthcare system of the Republic of Srpska is centralized, and the system's holders are the Ministry of Health and Social Protection and the Health Insurance Fund. The Republic of Srpska is undergoing a transformative journey in healthcare digitalization, propelled by various financing models, data management strategies, and regulatory initiatives. While progress is evident, challenges persist, necessitating concerted efforts to overcome barriers and realize the full potential of digital healthcare.

In the Republic of Srpska health services are mainly financed through the compulsory health insurance fund (HIF); annual budgets of the health institutions, based on tax projects and donations; local self-government units; health care users (via out-of-pocket payments). Digitalization initiatives in the Republic of Srpska rely predominantly on public funding from the budget.

The Solidarity Fund for the diagnosis and treatment of diseases, conditions and injuries of children abroad was founded at the end of 2017. It was established with the aim of raising additional financial resources to enable the diagnosis and treatment of children abroad, when this is not possible in health institutions in the Republic of Srpska or in other health institutions with which the Republic of Srpska’s HIF has a contract.

Medicines are procured by the HIF, health institutions and pharmacies. Medical devices are procured by the Ministry of Health, the HIF or health institutions. Priority criteria for reimbursement/public financing are based on priority-setting in the Republic’s hospital sector development plan and situation analysis and capital investment plan. Priorities for medicines are determined in accordance with the rules on conditions and procedures for placing medicines on the HIF positive list. Reimbursement decisions are made by Ministry of Health, the HIF and/or health care institutions.

However, to supplement these resources, a diverse range of financial mechanisms are being explored still in the beginning stage, including official development assistance such as the EU IPA III, syndicated loans, tax incentives, private capital infusion, and social performance bonds. Despite these efforts, challenges persist, particularly in allocating adequate resources for cybersecurity and data protection measures. Establishing a dedicated fund for scientific research work and innovative activities, a science and technology park, and a digital innovation hub reflects the government's commitment to fostering innovation in healthcare.

Data Storage and Management

In the healthcare industry, various sources for big data include hospital records, medical records of patients, results of medical examinations, and devices that are a part of Internet of Things. These devices are generating a huge amount of data that can be analyzed to provide real-time clinical or medical care. The exponential growth of medical data from various calls for design innovative strategies to analyze and interpret such enormous amount of data within a given timeframe [15].

Based on the Second Online Workshop: "Financial Models and Data Management Strategies, Regulatory and Ethical Issues in Digital Healthcare" conclusions, the DIGI4Care partners have observed some similarities and quite important differences in daily practices relevant to the data storage and management.

Data management practices vary widely across the region. Austria and the Czech Republic have advanced systems like ELGA and standardized frameworks for data interoperability. Slovakia uses the national e-Identity Framework to ensure secure data handling. Hungary and Romania face challenges in data privacy, interoperability, and IT infrastructure. Bulgaria has one of a kind National health Information Systems which is an advanced national developed solution for centralization of health data form all stakeholders and providers. The NHIS complained with all the standards and protocols as HL7, FHIR and OpenEHR. Bulgaria already has an EHR with regulated access for GPs and constat access for patients. However, Ukraine and Bulgaria grapple with regulation issues, data governance, sharing, and cybersecurity issues. The Republic of Srpska (BiH) focuses on integrating health information systems but faces significant challenges due to limited ICT infrastructure.

Recognizing the challenge of large-scale interregional data standardization and interoperability, the DIGI4Care project implements a collaborative data storage and management plan. This plan facilitates systematic analysis and evaluation via comparability, resulting in credible validation of outputs and results. The project’s Data Management Guidelines (O2.2) serve as a blueprint for future collaboration among project partners, setting a positive precedent for interregional cooperation.

AUSTRIA

When it comes to Data Management as one of the key dimensions in digital health, the key challenges of the Austrian Health System have been identified as follows:

1. **Data Privacy:** Ensuring compliance with GDPR and other local regulations to protect patient data.
2. **Data silos and data storage.**
3. **Security:** Protecting health data from cyberattacks and unauthorized access.
4. **Interoperability:** Integrating diverse data systems and formats across various healthcare providers.
5. **Consent Process:** Managing patient consent for data usage in compliance with strict regulatory requirements.
6. **Fragmented Data:** Dealing with data that is duplicated, stored in multiple formats, and spread across various systems.

Austria employs several strategies to address these data management challenges, such as:

* regulations: strict adherence to GDPR and the Austrian Data Protection Act to ensure data privacy and security.
* technology solutions: implementing advanced encryption, role-based access controls, and secure data storage solutions to protect health data.
* training programs: conducting regular training for healthcare professionals on data protection and cybersecurity best practices.
* standard frameworks: utilizing standards like the (ELGA) to ensure uniform data handling and interoperability across healthcare systems​.

Data interoperability in Austria's healthcare system is managed through several channels like **Standards Adoption** (using standardized systems like ELGA for electronic health records to ensure data can be shared seamlessly across different platforms), **Custom Solutions (**developing tailored integration solutions to connect diverse healthcare IT systems) and different **Partnerships** (collaborating with technology providers and other healthcare entities to develop interoperable solutions that facilitate data exchange​).

Austria's healthcare system is managed through several solutions (standard and custom adoption such as ELGA for e-health records or tailored developed integration solution for connection of diverse e-health IT systems) or different partnerships (collaboration with technology providers and other healthcare entities) which provide efficiency, timely and secure access and full integration.

Nevertheless, there is certain potential risks in Austria's healthcare data management including Data Breaches, System Downtime and Data Loss. To mitigate and address these risks, Austria implements Data Resiliency (redundant storage systems and regular data backups) and Standardised Security Protocols (robust cybersecurity measures including encryption and access controls).

One of the important issues is data privacy and cybersecurity in data health system, in order to prevent adverse events, Austria’s NHS employs different technology solutions, training and awareness programme, audit trail, etc.

**A case study of telehealth data management** exemplifies these principles in practice. Ultrasound images are collected and annotated using standardized formats such as DICOM for data and OMOP CDM for findings. Anonymous patient data is shared responsibly, adhering to data security protocols, and ensuring accessibility through public databases. Clear delineation of responsibilities ensures the quality and integrity of curated data.

CZECH REPUBLIC

When it comes to Health Data Management, primary challenges in Czech Republic include ensuring data privacy, maintaining security, achieving interoperability and managing the consent process.

The current state of data management in the Czech Republic is characterized by inadequacies in legislative frameworks and national infrastructure. The Alliance Pro Telemedicinu (ATDZ) aims to address these challenges by bringing together key stakeholders and advocating for improved digitization of healthcare and social services. Barriers and challenges include clinical data management, security concerns, the need for increased funding and reimbursement for digital health initiatives, and ability of patients and staff to adapt to digital solutions. Strategic objectives focus on enhancing patient engagement, supporting scientific research, and improving legislation to facilitate data sharing between healthcare providers, interoperability, cybersecurity, data anonymization, and repositories.

In order to achieve of full interoperability in the healthcare system, it will be necessary to plan and implement a national-scale project in cooperation and with the support of Czech Government.

In order to manage these data challenges, several strategic documents need to be implemented focusing on robust regulations, deploying advanced technology solutions, and providing training programs for healthcare professionals, mostly within EU frameworks. Data interoperability in the Czech healthcare system is managed through the adoption of international standards such as HL7 and FHIR, as well as custom solutions developed to ensure seamless data exchange between different healthcare providers and systems. In recent years focus has been not only on the technology side but also on the communication side of interoperability.

There are some potential risks to physical infrastructure such as cybersecurity threats and hardware malfunctions. These risks are addressed in Czech’s health system by implementing robust cybersecurity protocols, regular maintenance and updates of hardware systems, and having disaster recovery plans in place. The infrastructure in medical facilities is moving from the local on-premise way to the cloud way, so the cybersecurity is becoming the main goal.

Czech’s Health system implementing different measures to ensure data privacy and cybersecurity, including compliance with GDPR and using advanced encryption methods, conducting regular security audits, and providing ongoing training and awareness programs for healthcare professionals on data security practices. Beside this, companies that implementing health AI products usually have to be aligned with local cybersecurity regulations (ISOs).

SLOVAKIA

Data management lies at the core of Slovakia's eHealth services, facilitated by the national e-Identity Framework “Slovensko.sk”. The integration of asymmetric cryptography within the National ID chip ensures secure and GDPR compliant handling of sensitive health data. Additionally, the use of private and public APIs enables seamless data exchange across healthcare entities while maintaining data privacy and integrity. Internal solutions further enhance data management practices, contributing to the interoperability and accessibility of healthcare information. However, ongoing efforts are needed to address data quality issues and optimize data management processes to realize the full potential of eHealth services.

HUNGARY

Effective data management is essential for successfully integrating digital solutions into healthcare pathways. Data management practices in Hungarian health system are hindered by privacy concerns, lack of transparency, and accessibility to data. The General Data Protection Regulation (GDPR) provides a regulatory framework for data protection, but compliance with GDPR requirements poses challenges for healthcare organizations. Furthermore, the fragmented nature of healthcare data silos impedes interoperability and data sharing, limiting the potential benefits of digital solutions such as AI-based decision support algorithms.

**The primary challenges in data management** in Hungary can be summarized as follows:

* **Data privacy and security**: Balancing the need for data analysis with strict data protection regulations like GDPR is a challenge.
* **Data quality and interoperability**: Inconsistent data collection methods and fragmented healthcare IT systems can lead to inaccurate or incomplete data. This makes it difficult to share information effectively between healthcare providers.
* **Standardization and regulation**: A lack of clear regulations for digital health solutions makes it hard to distinguish between trustworthy tools and unreliable apps.

**Strategies** adopted to manage these data challenges are the following:

* **Strengthening data governance**: Implementing a robust data governance framework can help ensure data privacy, security, and quality. This includes defining clear roles and responsibilities for data management, establishing data access controls, and implementing data quality monitoring processes.
* **Promoting data standardization**: Standardizing data collection methods and formats across healthcare institutions allows for easier data sharing and analysis. Hungary can leverage existing international health data standards and promote their adoption within the country.
* **Investing in interoperable IT systems**: Upgrading healthcare IT infrastructure to facilitate seamless data exchange between different systems is essential. This allows for a more holistic view of patient data and improves care coordination.
* **Public awareness and education**: Building public trust requires transparency and clear communication. Hungary can launch initiatives to educate citizens about their data rights and how their health information is being used. This can involve public awareness campaigns and ensuring easy access to information about data security practices.
* **Collaboration and capacity building**: Collaboration between healthcare providers, policymakers, and technology companies is crucial. Investing in training healthcare professionals on data management best practices and fostering a data-driven culture within the healthcare system are important steps.

Although the healthcare system is centralized in Hungary, different bodies have different registries, and the data fusion is not yet accomplished. Data interoperability in Hungary is supported by the following: the EESZT (EHR cloud) allows for data sharing between healthcare institutions; specific technical standards used for data exchange (e.g. XML, HL7 FHIR); use of international code dictionaries (e.g. BNO); maintenance and publication of code dictionaries.

**Potential risks**, particularly with respect to physical infrastructure are also identified:

* **Aging infrastructure**: many healthcare facilities, especially in rural areas, may have aging buildings and equipment.
* **Maintenance and funding**: inadequate funding can hinder proper maintenance and upgrades to physical infrastructure.
* **Limited capacity**: the healthcare system might be overcrowded or lack specialized function.
* **Cybersecurity threats:** physical infrastructure like servers and data centres can be vulnerable to cyberattacks.
* **Vulnerability** to natural disasters: Natural disasters like earthquakes, floods, or power outages can disrupt healthcare services if facilities are not properly prepared.

Several measures that ensure data privacy and cybersecurity in Hungary have been adopted:

* **Regulatory compliance**:
* EU General Data Protection Regulation (GDPR): This overarching regulation sets the foundation for data privacy in the EU, including Hungary. It mandates strong data protection principles like transparency, purpose limitation, and data minimization for healthcare data processing.
* National Laws: Hungary has supplementary national laws like Act XLVII of 1997 on Processing and Protection of Medical and Other Related Personal Data, which specifically governs healthcare data. These laws define specific requirements for data security and access controls.
* **Technology solutions**:
* Access controls: Healthcare providers implement access control mechanisms like multi-factor authentication and user activity monitoring to restrict access to health data only to authorized personnel.
* Data encryption: Sensitive health data is often encrypted at rest and in transit to protect against unauthorized access.
* Audit logs: Audit logs track data access and usage, allowing for monitoring and accountability.
* Training and awareness:
* Healthcare professionals: Training programs for healthcare workers educate them on data privacy regulations, proper data handling practices, and how to identify and report cybersecurity threats.
* Patients: Public awareness campaigns can inform patients about their data privacy rights and how their health information is being used.

ROMANIA

In Romania, medical services are reported to the National Health Insurance House, with specific codifications assigned to each disease and procedure. Medical informatics programs like InforWorld facilitate the registration and reporting of services, tracking costs per patient, doctor, and department. However, gaps in data management, including the lack of connectivity between informatics systems, lead to limited cooperation between hospitals at the local and regional levels. Additionally, challenges such as the need for IT training for medical professionals, errors in codification, and compliance with GDPR regulations pose obstacles to effective data management practices.

The interoperability between private and public health sector refers mainly to economic data related to consultation done by ensured patients. Beside this, there also a problem concerning to data security. Cyber-attacks can be a serious threat for health system due to lack of money for maintains.

Set of procedures for data management including data collection, storage, cleaning, quality control, metadata requirements, analysis and presentation for target audiences have been developed and these are implemented throughout the whole country.

To manage these data challenges, the ongoing projects for investments in IT systems and digital infrastructure of public health units through Romania's National Recovery and Resilience Plan (PNRR) has been recently initiated.

UKRAINE

Effective data management is paramount for ensuring the confidentiality, integrity, and availability of patient data in Ukraine's digital healthcare landscape. Key strategies include data encryption, access controls, secure storage solutions, regular backups, and compliance with data protection regulations. By implementing these measures, healthcare organizations can safeguard patient data from unauthorized access, system failures, and cyber threats. However, challenges such as limited interoperability between healthcare systems and the need for standardized regulations for telemedicine services underscore the importance of proactive measures to address data management gaps. Furthermore, there is a lack of a unified architecture for the application of digital health technologies, and the technical requirements for its interaction with the Central Database Repository (CDBR) of the eHealth system have not been defined; the communication infrastructure in healthcare facilities is underdeveloped; there are no compatibility rules and insufficient standardization requirements for devices and digital health technologies; quality standards for providing medical assistance using telemedicine and digital health technologies are missing.

BULGARIA

The overall situation in Bulgaria regarding data management is curtail because of the lack of relevant regulation and policy. In terms of data centralization, Bulgaria has developed an advanced technological solution – National Health Information systems, which is gathering and centralizing all the health data from different sources - Electronic Health Records (EHRs) from hospitals, clinics, and general practitioners; Patient-generated data from wearable devices and mobile health applications; Health insurance data; National health registries (e.g., cancer, diabetes); Laboratory results. Implementation of internationally recognized data standards such as HL7, FHIR (Fast Healthcare Interoperability Resources), and ICD-10 for coding diagnoses and procedures are available in Bulgaria.

Bulgaria grapples with several issues such as data governance, data sharing, interoperability, as well as privacy and ownership issues. Ensuring seamless data exchange between healthcare providers while safeguarding patient privacy remains a priority. Data quality and ownership challenges further complicate efforts to harness the full potential of health data for research, development, and innovation. Furthermore, high-quality historical records and relevant data are missing in order to develop predictive models.

REPUBLIC OF SRPSKA

Effective data management is critical for the success of digital healthcare initiatives in the Republic of Srpska. However, challenges such as limited access by healthcare providers across various healthcare institutions and Insurance fund of Republic of Srpska – lack of interoperability, resistance to change among healthcare professionals and insufficient technical competencies related to electronic patient record management, standardization concerns regardingsecurity, privacy, and confidentiality, as well as legal barriers hinder progress. The Integrated Health Information System (IZIS) faces with specific implementation challenges at the primary healthcare level, such as non-operational laboratory and electronic prescriptions modules, and slow integration of primary healthcare clinics, including a crucial challenge of tertiary clinical centre integration into the IZIS framework. To facilitate data exchange and data management in general, specific strategies such as defining architecture, access and use methods, authorizations, communication and security standards, data exchange protocols and data protection mechanisms should be implemented. Additionally, assigning unique identifiers in healthcare ensures data integrity and security. Beside this, there is a substantial problem of IZIS concerning cyber security and data protection.

Regulatory Barriers

Regulatory and ethical barriers in digital healthcare are significant considerations due to the intersection of technology, patient care, and privacy. Some of the key barriers are related to privacy and data security, interoperability, regulatory compliance, ethical use of AI and big data, quality and safety of digital healthcare technologies, etc. Concerns can be addressed with the adoption of appropriate technologies, monitoring and evaluation of security systems, transparency and accountability mechanisms such as legal remedies and compensation for privacy harms resulting from security breaches [16].

Regulatory barriers are a significant challenge across the region. Austria and the Czech Republic face complex approval processes and cross-border data transfer issues. Slovakia and Hungary find challenging the lack of sufficient safeguards or policy measures for the implementing new digital tools in the provision of health services, along with the need to align national regulations with the evolving and promising yet unsettled EU framework for years now, while the development of ICT devices in the healthcare sector is rapidly accelerated.

Romania and Ukraine need comprehensive regulatory reforms to address GDPR compliance and ethical considerations. Bulgaria and the Republic of Srpska (BiH) are developing regulations but face resistance from healthcare providers and stakeholders.

DIGI4Care co-designs, tests, and validates a number of solutions to tackle regulatory challenges, including the Knowledge Platform and Radar (O1.2), the Dashboard (O3.2), and the Digitally Enabled ICM Strategy (O1.3) and Action Plans (O1.4). These solutions, developed and validated through transnational collaboration, promote inclusion, universality, and adaptability, setting a higher standard for regulatory and ethical practices in the region.

AUSTRIA

When it comes to matter of regulatory barriers, Austria’s digital health system faces with several regulatory hurdles and ethical considerations in advancing healthcare initiatives, such as approval processes **(**lengthy and complex procedures, involving multiple regulatory bodies, compliance with both national and EU regulations), lack of clarity in guidelines, particularly concerning the application of existing laws to new digital health technologies and additional regulatory challenges in cross-border issues. Ethical considerations extend to data management, where issues such as privacy, consent, and data security must be prioritized.

To streamline regulatory approval, several strategies are developed such as Joint Advocacy (collaboration of various stakeholders in digital health system), guideline development (comprehensive guidelines for the digital health technologies) and transnational agreements (aiming to harmonize regulations related to data protection, telemedicine, and digital health standards).

CZECH REPUBLIC

Several key regulatory barriers for digital health in the Czech Republic have been identified which including complex approval processes for new technologies, lack of clarity in guidelines, and cross-border data transfer issues. Beside this, issues like data sharing, interoperability, ethical frameworks, and cyber risks for digital healthcare solutions still remain as a serious challenge. These hurdles can delay the implementation of digital health solutions and create uncertainty for developers and healthcare providers. One example is the implementation of the “eRecept” system, which required significant regulatory adjustments to allow electronic prescriptions.

The absence of an effective reimbursement system, lack of methodologies for digital solutions, and insufficient focus on AI exacerbate these challenges. Proposed solutions include adopting European legislation, modifying existing eHealth laws, and prioritizing digitalization processes beyond data management. Emphasis is placed on unified data management, electronic health records, and legislation facilitating data exchange between healthcare institutions.

Obrázok, na ktorom je snímka obrazovky, text, rad, vývoj

Automaticky generovaný popis

**Fig.9. Access to e-health records**

Joint actions that could address or reduce the number of existing regulatory barriers should include joint advocacy by industry and healthcare professionals, development of clearer and unified guidelines, and transnational agreements to harmonize regulations. These efforts can simplify processes and facilitate the implementation of digital health technologies in the Czech Republic. The Fig.9. illustrates the current position of Czech Republic in terms of access to e-health records in comparison to other European countries.

SLOVAKIA

Regulatory barriers pose significant challenges to Slovakia's eHealth initiatives, stemming from both EU and Slovak legislation. Ineffective master plans, low data quality, and the implementation status of Diagnosis-Related Groups (DRG) are among the regulatory challenges that impede the progress of eHealth infrastructure. Harmonizing EU and national regulations is essential to streamline regulatory processes and ensure compliance with legal requirements. Addressing regulatory barriers through effective policy formulation and implementation strategies is crucial for overcoming obstacles and advancing eHealth objectives in Slovakia.

In conclusion, Slovakia's eHealth services hold promises in transforming healthcare delivery and improving patient outcomes. However, addressing challenges related to financing, data management, and regulatory barriers is imperative to realize the full potential of eHealth initiatives. Collaborative efforts between public and private stakeholders, strategic investments in digital infrastructure, and proactive regulatory reforms are essential for fostering innovation and driving sustainable progress in Slovakia's eHealth ecosystem.

HUNGARY

In Hungary, the regulatory landscape for digital health faces several common hurdles that stakeholders need to navigate. Addressing these regulatory hurdles requires a comprehensive understanding of both European and local Hungarian regulations, as well as proactive engagement with regulatory bodies and healthcare stakeholders. The regulatory hurdles for AI-based medical devices in Hungary mainly focus on compliance with European and local regulations, ensuring safety, efficacy, and ethical use. Moreover, issues such as algorithmic bias, accountability, and fairness pose ethical challenges that must be addressed in developing and deploying digital healthcare solutions.

As a first step, AI-based medical devices must comply with Medical Device Regulation (MDR) or In Vitro Diagnostic Regulation (IVDR). This involves a rigorous conformity assessment process, including clinical evaluations and obtaining a CE mark to demonstrate the device's safety and performance. However, besides MDR/IVDR, there is an ongoing and comprehensive regulatory effort in the EU concerning digitalisation, including data utilisation in the so-called big data era. The Data Governance Act (DGA) regulates „the reuse of publicly/held, protected data, by boosting data sharing through the regulation of novel data intermediaries and by encouraging the sharing of data for altruistic purposes” [14]. AI-based devices must comply with these regulations when handling and sharing data. The Data Act aims to make data - produced through their utilisation of smart objects, machines and devices - more accessible while maintaining privacy and security standards. Compliance is necessary for AI-based medical devices that utilise large datasets. The AI Act regulates AI systems based on their risk levels. AI-based medical devices will fall into high-risk categories, requiring stringent compliance with transparency, accuracy, and safety requirements. Beyond all these horizontal regulations, the European Health Data Space (EHDS) will facilitate the secure exchange of health data across the EU via primary and secondary use of those data. AI-based medical devices must ensure interoperability and data protection in compliance with EHDS standards.

Within the abundance of the new regulations mentioned, the main barrier is that this ongoing regulatory process has not yet been completed. However, the technological development of AI-based tools is not waiting for that. Thus, whilst the main objective is to build system capability for AI-based tools to get from artisanal manufacturing to production lines, it is hard to find a future-proof baseline, at least for the moment. Every actor is stumbling because there are no robust legal-ethical requirements for AI yet since the approved EU-level legal acts need to be implemented, and there also are ongoing transition periods for many.

Overall, there is a long way to go in integrating an AI-based tool as a nationwide solution, along with a publicly financed health insurance scheme supported by system-level data management for developing and deploying AI-based medical devices.

**National/Regional Specificities and Gaps:** Hungary's healthcare landscape exhibits unique national and regional specificities that influence the integration of digital solutions into care pathways. While there are common issues such as privacy, transparency, and algorithmic bias, the lack of robust legal-ethical requirements for AI poses significant challenges. Despite being pioneers in the integration of AI-based tools nationwide, stakeholders in Hungary struggle to establish a future-proof baseline for regulatory compliance and ethical governance.

In conclusion, the integration of digital solutions into healthcare pathways in Hungary presents both challenges and opportunities. Addressing issues related to financing, data management, and regulatory and ethical considerations is essential for realizing the full potential of digital health technologies in improving patient outcomes and advancing healthcare delivery in Hungary. Collaborative efforts among stakeholders are needed to navigate the complexities of integrating digital solutions into care pathways while upholding the highest standards of patient safety, privacy, and ethical conduct.

ROMANIA

Regulatory barriers in Romania's healthcare system include the lack of regulations regarding GDPR compliance, errors in disease and procedure codification, and challenges in meeting deadlines for service transmission to the National Health Insurance House. Additionally, there is a lack of financial transparency, with medical professionals often uninformed about the financial aspects of healthcare delivery, particularly in the public sector. Addressing these regulatory barriers requires comprehensive reforms, including the implementation of GDPR regulations, improved training for medical professionals on coding and reporting practices, and increased transparency in financial management.

In conclusion, Romania's healthcare system faces challenges in financing, data management, and regulatory compliance. While the electronic reporting system ensures transparency in healthcare financing, gaps exist in data management practices and regulatory compliance. Addressing these challenges requires coordinated efforts from healthcare stakeholders, including improved training for medical professionals, enhanced connectivity between informatics systems, and regulatory reforms to ensure compliance with GDPR regulations and improve financial transparency. By addressing these challenges, Romania can enhance the efficiency and effectiveness of its healthcare system, ultimately improving patient outcomes and quality of care.

UKRAINE

Ukraine faces regulatory barriers in digital healthcare, including issues related to data privacy and security, limited interoperability, and the absence of standardized regulations for telemedicine services. These challenges impede the seamless adoption and integration of digital healthcare solutions. To overcome regulatory barriers, concerted efforts are needed to promote data protection, establish clear guidelines for telemedicine practices, promote interoperability between healthcare systems, and foster collaboration between stakeholders. By addressing regulatory gaps and promoting regulatory alignment with evolving technology, Ukraine can create an enabling environment for digital healthcare innovation and adoption.

In conclusion, advancing digital healthcare in Ukraine requires a multifaceted approach that addresses financing challenges, enhances data management practices, and overcomes regulatory barriers. By embracing innovative financing models, implementing robust data management strategies, and fostering regulatory alignment, Ukraine can harness the transformative potential of digital technologies to improve healthcare delivery, enhance patient outcomes, and strengthen the resilience of its healthcare system. Collaboration between policymakers, healthcare providers, technology developers, and other stakeholders is essential to drive progress and ensure the successful integration of digital healthcare solutions into Ukraine's healthcare ecosystem.

BULGARIA

Regulatory frameworks governing telemedicine, cybersecurity, and secondary use of health data pose significant challenges. Establishing clear guidelines for telemedicine regulations and reimbursement models is essential to ensure patient safety and equitable access to healthcare services. Additionally, ethical considerations, such as obtaining informed consent and protecting patient privacy, are paramount in the digital health landscape.

**The Case of Kelvin Health:** Kelvin Health is an intelligent solution for detection and monitoring of various abnormalities and inflammation processes in different stages and conditions, using AI analysis applied to mobile-based digital thermal imaging. The AI-powered platform which allows you to daily monitor your body for early and hidden signs of various thermally verifiable diseases. Its main focus and goal are in making the home preventive medicine the new cornerstone of the modern and personalized healthcare. Kelvin Health's operational and financial setup exemplifies the challenges and complexities inherent in Bulgaria's digital health landscape. Engaging clinician champions, developing clinical protocols, and obtaining ethical approvals are critical to navigating regulatory and ethical requirements. However, sustaining operations and covering costs remain ongoing, highlighting the need for sustainable funding mechanisms.

In conclusion, Bulgaria's healthcare system faces multifaceted regulatory, ethical and financial challenges. Addressing these challenges requires collaborative efforts from policymakers, healthcare providers, researchers, and funding agencies. Establishing clear regulatory frameworks, promoting ethical practices, and diversifying funding sources are essential to fostering innovation and advancing digital health in Bulgaria. By addressing these challenges, Bulgaria can harness the transformative potential of digital health to improve patient outcomes and enhance healthcare delivery for all citizens.

REPUBLIC OF SRPSKA

The Republic of Srpska grapples with regulatory and ethical challenges in digital healthcare. The absence of comprehensive regulations and legal frameworks for digitalization, privacy policies, data sharing protocols and data protection mechanisms poses hurdles to implementation. While efforts such as the introduction of Smart Digitalization concept (within the Strategy of the Ministry of Science and Technology, 2023) and formulation of the inaugural Strategy for Digitalization in Healthcare of the Ministry of Health are underway, guidelines pertaining to digital healthcare, health insurance, and documentation remain unpublished. Ethical committees play a crucial role in overseeing ethical considerations and regulatory compliance, but comprehensive regulations are imperative to effectively address ethical and legal considerations.

In conclusion, the Republic of Srpska's journey towards digital healthcare transformation is marked by progress, challenges, and opportunities. By leveraging diverse financing models, implementing robust data management strategies, and addressing regulatory and ethical barriers, the Republic of Srpska can accelerate its digital healthcare agenda. Collaborative efforts between government agencies, healthcare providers, technology developers, and regulatory bodies are essential to navigate challenges, foster innovation, and ensure the delivery of efficient, accessible, and ethical healthcare services to all citizens

Integrating Digital Solutions into Care Pathways

To design and implement digital health pathways at scale, enterprise health care systems need to develop capabilities and partnerships in human-centered design, operational workflow, clinical content management, communication channels and mechanisms, reporting and analytics, standards-based integration, security and data management, and scalability [18].

Austria is proficient in incorporating digital technologies into healthcare pathways, effectively using telemedicine and electronic health records (EHRs) throughout the patient journey. Additionally, AI-driven diagnostics are increasingly being adopted and implemented. Slovakia and Hungary are also making progress, focusing on telemedicine, e.g. remote monitoring and chronic disease management, and in Hungary the testing of different AI-based decision support algorithms is relevant as well. The Czech Republic and Romania need to enhance their integration efforts, particularly in telemedicine and AI applications. Bulgaria and Ukraine face significant barriers in achieving seamless integration due to IT infrastructure limitations and regulatory challenges. The Republic of Srpska (BiH) is in the early stages of integration, focusing on primary and outpatient care.

The DIGI4Care project integrates digital solutions into care pathways by developing a Digitally Enabled ICM Strategy (O1.3) and institutional-level Action Plans (O1.4). The project’s transnational pilots validate key outputs in different care levels, covering the integrated patient pathway and contributing to improved quality of care and better patient outcomes.

AUSTRIA

Austria has made significant advancements in integrating digital technologies into its healthcare pathways, enhancing patient care, operational efficiency, and coordination of services. These technologies are employed at various stages of patient care, including prevention, diagnosis, treatment, and follow-up.

**Integration of Digital technologies:**

1. **Prevention:** Digital health tools are extensively used to monitor patient health and provide preventive care. Wearable devices and health apps track vital signs and lifestyle habits, enabling early detection and intervention for potential health issues. These tools empower patients to take a proactive role in managing their health.
2. **Diagnosis:** AI and machine learning technologies are utilized to enhance diagnostic accuracy, particularly in radiology and pathology. AI algorithms help in early detection of anomalies in imaging scans, leading to timely diagnosis of conditions such as cancer. Additionally, telemedicine platforms enable remote consultations and second opinions, making specialized healthcare accessible to a broader population.
3. **Treatment:** Electronic Health Records (EHR) systems, like the Elektronische Gesundheitsakte (ELGA), play a crucial role in facilitating comprehensive treatment plans. These systems provide healthcare professionals with complete patient histories, laboratory results, and therapy details, allowing for personalized and coordinated care. Digital therapeutics are also employed to manage chronic conditions such as type 2 diabetes and chronic heart failure, offering personalized treatment plans and continuous monitoring.
4. **Follow-up care:** Telemonitoring and remote patient management systems ensure continuous monitoring and follow-up care for patients with chronic illnesses. These systems reduce the need for frequent hospital visits by enabling healthcare providers to monitor patients remotely, providing timely interventions when necessary. This approach is particularly beneficial for managing chronic diseases, where ongoing monitoring is crucial.

The integration of digital technologies has led to significant improvements in Austria's healthcare system:

1. **Improved Patient outcomes:** Enhanced diagnostic accuracy and timely interventions through AI and telemedicine have substantially improved patient health outcomes. Early detection and intervention result in better management of diseases and overall health improvement.
2. **Increased Healthcare efficiency:** Digital tools streamline workflows and reduce administrative burdens, allowing healthcare providers to focus more on patient care. EHR systems eliminate the need for repetitive documentation and facilitate quick access to patient information, improving the efficiency of healthcare delivery.
3. **Reduced costs:** The use of telemedicine and remote monitoring reduces hospital admissions and the need for in-person consultations, leading to cost savings for both healthcare providers and patients. By minimizing unnecessary hospital visits, these technologies also alleviate the burden on healthcare facilities.

Several notable examples highlight the successful digital integration in Austria:

1. **AI for Early Diagnosis:** AI algorithms are employed in radiology to detect anomalies in imaging scans. This technology allows for early diagnosis of conditions such as cancer, leading to timely and effective treatment.
2. **Telemedicine:** Services like 1450 facilitate remote consultations, enabling patients to receive medical advice and care without visiting healthcare facilities. This service has been particularly beneficial during the COVID-19 pandemic, ensuring continuous access to healthcare while minimizing the risk of infection.
3. **Remote Monitoring:** Chronic disease management programs utilize remote monitoring devices to track patient health metrics continuously. These programs provide ongoing care and timely interventions, reducing the need for frequent hospital visits and ensuring better disease management.

CZECH REPUBLIC

Digital technologies are integrated into care pathways in the Czech Republic primarily through electronic health records (EHRs), telemedicine services, and mobile health applications provided by health insurance companies. These technologies are used for prevention, diagnosis, treatment, and follow-up care. For example, telemedicine platforms enable remote consultations, which are especially useful for patients in rural areas.

Digital integration has led to improved patient outcomes, increased efficiency in healthcare delivery, and better data management. The use of EHRs has reduced paperwork and made patient data more accessible to healthcare providers, leading to faster and more accurate diagnoses and treatments.

A successful example of digital integration is the eRecept system, which allows for electronic prescriptions, making it easier for patients to get their medications without physical visits to healthcare providers. Another example is the use of telemedicine platforms for remote consultations, which has been particularly beneficial during the COVID-19 pandemic, although their use has unfortunately decreased post-pandemic.

SLOVAKIA

Slovakia has embraced the integration of digital technologies at various levels of healthcare, with the extent of integration often depending on the specific provider. These technologies are used to enhance different stages of patient care, including diagnosis, treatment, and follow-up.

The integration of digital technologies in Slovakia's healthcare system has led to improved patient outcomes, faster access to data, and increased efficiency. These advancements streamline workflows, reduce the burden of paperwork, and ensure that healthcare providers can make more informed decisions quickly.

**Examples of successful digital integration:**

1. **eRecept – ePrescription:** The eRecept system allows for electronic prescriptions, facilitating the daily process of prescribing and dispensing medications without the need for physical visits to healthcare providers.
2. **AIREEN in Ophthalmology:** AIREEN technology is employed in ophthalmology to enhance diagnostic accuracy and treatment planning.
3. **AI in Radiology:** Tools such as IcoBrain (IcoMetrix), Brainomix (e-Stroke suite), and AI RAD Companion are used regularly for radiological assessments, improving the precision and speed of diagnoses.
4. **AI in Cardiovascular Research:** At VUSCH, research is being conducted on AI-assisted stratification of patients with cardiovascular diseases, aiming to optimize treatment plans and improve patient outcomes.
5. **AI for COVID-19 Diagnostics:** Several state hospitals utilize the EIhealth Huawei platform for AI-assisted CT screening services to diagnose COVID-19, demonstrating the role of AI in managing the pandemic.
6. **AI in Transplantation and ECG Evaluation:** At UN Kosice, AI-assisted programs are being developed for transplantation procedures and ECG evaluations, enhancing the accuracy and efficiency of these critical processes.
7. **AI in Brain Health:** At OU SA in Bratislava, the AI-supported solution from Brainit is being used to advance brain health diagnostics and treatments.
8. **AI for Fraud Detection:** Private health insurers Dôvera and Union are testing AI-based fraud detection routines and protocols, aiming to identify and prevent fraudulent activities within the healthcare system.

HUNGARY

In Hungary, digital technologies are integrated into care pathways in the following approaches:

* Prevention;
* The use of digital health technologies in prevention is not well-organized or widespread inthe country. There are some general practitioners and healthcare institutes utilizing applications or self-developed programs. Hungary also has a new application called “Egeszsegablak,” (the official patient-app of EESZT) which includes a special section dedicated to information about prevention. However, this application is still under development.
* Diagnosis;
* “EESZT” since 2017 - which is a general medical cloud, where all registered doctors and all patients can follow their medical documentation
* hospital information systems (HIS) different programs (primary care, outpatients and inpatients) that are used by HCP’s - they generate documents, EHRs which are sent to the medical cloud (EESZT)
* the results of tests (lab, microbiology, pathology, etc.) are sent electronically
* images from Xray, CT, or MRI can be seen on the monitor of the attending physician (or it can be sent electronically or on a cd)
* wearable devices, which are on the patients and the measured parameters can be seen by their doctors (SpO2, HR, BP, ECG) - it is not common, but there are some specific institutes or physicians who use these tools already
* telemedicine is also available in different part of the healthcare system, and there are some new, specific fields (teleradiology, telepathology,) or programmes (e.g. Attila Naszlady health promotion programme, offering complex telemedicine healthcare services in remote, under-developed areas [15].
* Treatment;
* prescriptions of drugs (not otc)
* telemedicine

The direct impacts of digital integration within the healthcare system in Hungary are:

* Improved outcomes
* The available documents in ” EESZT” provides effective help during the diagnosis and care of the patients.
* Data driven healthcare development
* Increased efficiency:
* The access of EHR documents can prevent unnecessary repetition of tests or treatments
* The availability of e-prescriptions can reduce dispensable doctor-patient visits
* Challenges:
* Training of healthcare personal
* Lack of infrastructure in some areas (e.g. stable internet connection)
* Increased administrative burden in cases of parallel existing registries (e.g. screening programs, cancer registries)
* Separate systems form the EESZT: There are numerous digital health technologies with their own digital ecosystem. For example, specific blood glucose monitoring systems, blood pressure monitors, pulse-oximeters have the function to connect data to health applications and web pages. It is also important to note that HIS systems with EESZT have limited data exchange. For example, primary care documentations are not integrated into the patient’s eHistory, and the EESZT is operating with pdf format, pictures and radiology recordings are not yet included.

The steps taken for the successful digital integration into care pathways are as follows:

* Technologies:
* The implementation of EESZT and its functions is considered a successful implementation. These are: eMedical History, ePrescription, eReferral, eProfile.
* Interoperability: many systems are already integrated into EESZT [14]. The EESZT is able to communicate and integrate data from HIS systems, from some remote patient monitoring systems , and a patient pathway management system is also able to communicate with the EESZT, among other solutions regarding financing, pharmaceuticals, etc.
* Process: The process took place after a long development period and numerous stakeholders were included in the process. The fact that Hungary already had one ID for each individual was beneficial.
* Outcomes:
* The EESZT system is in use in the state and private healthcare sector. The continuous development is supported by the government.

ROMANIA

In Romania, digital technologies are integrated into healthcare pathways primarily through electronic health records (EHRs), telemedicine services, and specialized applications developed by IT companies such as Pharmec and DigiWorld. All medical services must be reported to the National Health Insurance House (Casa Nationala de Asigurari de Sanatate), with each disease and procedure assigned specific codifications. However, there is currently no interoperability between different informatic systems, which limits local and regional cooperation between hospitals.

**The example of successful digital integration into care pathways is BIOdyssey MedTech Hub l**aunched in September 2022 as Romania's first dedicated MedTech innovation center. It supports the development of health technologies by providing training, mentorship, and resources to aspiring entrepreneurs. The hub aims to transform innovative ideas into practical healthcare solutions, thereby enhancing the overall healthcare ecosystem in Romania.

UKRAINE

In Ukraine, digital technologies are integrated into healthcare pathways primarily through telemedicine services, electronic health records (EHRs), and mobile health applications. The introduction of the national e-portal for vaccinations and other initiatives during the COVID-19 pandemic marked significant progress in digital health transformation. Telemedicine platforms have been particularly instrumental in providing remote consultations and medical examinations, especially in conflict-affected areas in Eastern Ukraine​​.

**Examples of successful digital integration into care pathways:**

1. **Telemedicine platforms:** UNICEF and the Ukrainian medical technology company Giva Care Group have implemented telehealth platforms in Eastern Ukraine. These platforms allow remote medical examinations and the sharing of multimedia files and lab data with health professionals located elsewhere. This initiative has greatly enhanced access to healthcare for over 400,000 children and their families in conflict-affected areas​.
2. **Skin Cancer Recognition App:** Ukrainian engineers have developed an app for skin cancer recognition, which uses machine learning algorithms to assess skin anomalies. Users can take pictures of suspicious areas and receive a preliminary diagnosis, which can then be sent to doctors for further evaluation. This application demonstrates the innovative use of AI in healthcare to enhance diagnostic capabilities​.

BULGARIA

Currently Bulgaria is up to adopt a regulation for Telemedicine integration and reimbursement. The idea is to change the regulation for dispensaries of chronic conditions. This will enable the implementation of digital solutions within the care pathways of chronic patients for continuous medical care.

Bulgaria has a very well-developed digital health industry in terms of innovative healthcare solutions. The primary issue is the adoption of regulations that will permit the reimbursement of these technologies for the average patient. At present, access to all new solutions is out of pocket. Bulgaria has the first telemonitoring center for continuous medical care, although the services there are still not reimbursed at the national level.

Currently, all successful digital integrations into care pathways are developed within Patient Support Programs (PSPs) from the pharmaceutical industry. These PSPs cover access to new therapies and effective patient monitoring. Various hospitals and healthcare providers (HCPs) are working with different digital solutions for effective decision-making in early diagnostics and treatment. However, there is no integration at the national level. Bulgaria uses Electronic Health Records (EHRs) to store patient data from inpatient, outpatient, and laboratory care, providing a very clear picture of healthcare pathways.

The National Council on Prices and Reimbursement of Medicinal Products is leading the country on the path of evidence-based medicine by embracing digital solutions, including AI, to integrate and process real-world data (RWD) from EHRs. The software extracts medical statistical data from hospital information systems, aiming to aggregate, harmonize, and analyze clinical treatment outcomes and survival rates, comparing them with clinical trials. These analyses help health authorities understand how patients respond in real-world practice, facilitating efficiency in public spending. This could empower value-based payment models for better use of government spending while improving patient healthcare quality and outcomes.

REPUBLIC OF SRPSKA

The Republic of Srpska, digital technologies, particularly electronic health records (EHRs), are deeply integrated into healthcare pathways across primary, secondary, and tertiary levels. EHRs serve as centralized databases for comprehensive patient information, including medical history, test results, and treatment plans. This accessibility enhances decision-making, care continuity, and efficiency by automating documentation tasks.

* **Improved Outcomes**:
* Enhanced Patient Care: Digital integration enables better coordination among healthcare providers, leading to timely access to patient records and personalized care.
* Remote Monitoring: Real-time tracking of patients' health metrics allows for early intervention and tailored treatment plans.
* **Challenges:**
* Data Security: Protecting patient data from cyber threats is crucial for safeguarding sensitive medical information.
* Infrastructure: Limited internet connectivity and technical resources in rural areas pose challenges to implementing digital healthcare systems.
* Workforce Training: Healthcare professionals require adequate training to utilize digital tools effectively, necessitating continuous education programs.

To address these challenges, multidisciplinary teams with expertise in healthcare IT, clinical practice, data analytics, cybersecurity, and technical development are essential. Higher education institutions in the Republic of Srpska offer programs and courses on digital healthcare implementation, but there's a need to expand and enhance these offerings to meet the demand for skilled professionals. Collaboration between academia, healthcare organizations, and industry stakeholders is key to ensuring educational programs align with evolving healthcare needs.

HCP Workflow and Skills

In digital healthcare, healthcare professionals (HCPs) utilize various workflows and skills to deliver care efficiently and effectively. Workflow in digital healthcare refers to patient engagement and communication, clinical decision support, treatment and care coordination, documentation and reporting, patient follow-up and remote support. The broad range of necessary skills include technological proficiency, communication skills, clinical decision making, adaptability and flexibility.

Austria and the Czech Republic have established training programs for healthcare professionals to use digital technologies effectively. Slovakia and Hungary are developing similar initiatives, focusing on continuous professional development. Romania and Bulgaria face challenges due to limited resources and resistance from healthcare providers. Ukraine and the Republic of Srpska (BiH) need to invest in training and support for HCPs to ensure successful adoption and integration of digital solutions.

A detailed study on barriers and facilitators to utilizing digital health technologies by HCP has been conducted in [14]. The study reveals that infrastructure and technical issues, psychological barriers, and workload-related concerns are relevant barriers to comprehensively and holistically adopting digital health technologies by HCPs.

The DIGI4Care project tackles these challenges by designing a comprehensive Training Toolbox (O3.1), which goes beyond traditional training materials to foster technology adoption. The project also supports the development of educational podcasts (D3.2.4) and curriculum development for medical students (A3.3), facilitating continuous learning and the incorporation of digital technologies in healthcare education. The Dashboard (O3.2) supports evidence-based decision-making for HCPs and healthcare institutions, promoting the acceptance and integration of digital technologies into workflow.

The DIGI4Care project addresses these key dimensions through collaborative efforts, innovative strategies, and transnational cooperation. By focusing on technology landscaping, assessment, financing, data management, regulatory and ethical considerations, integration into care pathways, and workforce training, the project aims to transform healthcare delivery and improve patient outcomes across the Danube region. This state-of-the-art approach sets a new standard for innovation in the region, promoting sustainable and effective healthcare solutions that benefit patients, healthcare providers, and the overall healthcare system.

AUSTRIA

To effectively integrate digital healthcare technologies and maintain information security, healthcare professionals in Austria need extensive training and expertise, though in practice, much of this learning occurs on the job:

1. **Technical training**: Healthcare professionals need to be proficient in using various digital health tools, including Electronic Health Records (EHR) systems, telemedicine platforms, and AI diagnostic tools. This technical training ensures that they can effectively operate these technologies to enhance patient care and healthcare delivery.
2. **Data Management Skills**: Expertise in handling and analyzing health data is crucial. Healthcare professionals must ensure data accuracy and maintain data integrity, which involves skills in data management. This expertise helps in better decision-making and improves overall healthcare outcomes.
3. **Ethical training**: Understanding data privacy regulations, such as the General Data Protection Regulation (GDPR), and ethical considerations in digital health is essential. Healthcare professionals must be trained to handle patient data responsibly and comply with legal standards to protect patient privacy.

In Austria, universities and higher education institutions provide courses and programs focused on digital healthcare implementation. These programs cover essential topics such as health informatics, data analytics, and telemedicine. By offering these educational opportunities, institutions prepare healthcare professionals for the digital transformation in healthcare, equipping them with the necessary skills and knowledge to utilize digital health technologies effectively.

Clinical workflows in Austria are being redesigned to efficiently incorporate digital tools. For example, the use of EHRs streamlines processes like ordering labs and writing prescriptions. Telemedicine platforms facilitate remote diagnostics and consultations, allowing for more flexible and accessible patient care. These adjustments ensure that digital health services are seamlessly integrated into routine clinical practices, improving efficiency and patient outcomes.

Several challenges are associated with adjusting workflows to integrate digital health technologies:

* **Staff Resistance**: Healthcare professionals may be resistant to adopting new technologies due to their comfort with traditional methods. Overcoming this resistance requires effective change management and continuous education. Often, training courses on new technologies are elective and optional, leading to situations where staff or students may choose not to participate, which hinders widespread adoption and proficiency.
* **System Integration Issues**: Integrating new digital tools with existing systems can be technically challenging and time-consuming. Ensuring compatibility and smooth integration is essential for successful implementation.
* **Cost of Implementation**: The financial investment required for new technologies and training can be significant. Securing funding and managing costs are critical components of the implementation process.

Austria has developed several innovative training programs and workflow adjustments to support the integration of digital healthcare technologies:

* **Simulation-Based Training**: Healthcare professionals undergo simulation exercises to familiarize themselves with new digital tools and scenarios. This hands-on approach helps them gain practical experience and confidence in using digital technologies.
* **Continuous Professional Development Courses**: Ongoing education programs focus on the latest developments in digital health technologies. These courses ensure that healthcare providers stay updated with current trends and advancements, enabling them to integrate new tools and methods into their practice effectively.

CZECH REPUBLIC

Personnel and technical expertise requirements for training, integration, and information-security activities in the Czech Republic include:

1. **Technical Training in Healthcare IT Systems**: Healthcare professionals must be proficient in using electronic health records (EHRs) and telemedicine platforms. This includes understanding how to navigate and utilize these systems effectively to enhance patient care.
2. **Data Management Skills**: Expertise in handling and analyzing health data is essential. Professionals need to ensure data accuracy, maintain data integrity, and facilitate efficient data retrieval and entry.
3. **Cybersecurity Knowledge**: With the increasing reliance on digital health technologies, understanding cybersecurity principles is crucial. Healthcare professionals must be trained to protect sensitive patient data and comply with data security protocols.
4. **Ethical Training**: Healthcare providers need to be aware of patient data privacy regulations, particularly the General Data Protection Regulation (GDPR). Ethical training ensures that they handle patient information responsibly and comply with legal standards.

Higher institutions and universities in the Czech Republic offer comprehensive education programs focused on digital healthcare implementation. These programs cover a range of topics, ensuring that healthcare professionals are well-equipped to handle digital health technologies. Examples include:

* **Healthcare Management**: Courses offered at institutions like VŠE (University of Economics, Prague).
* **Medical Informatics and Healthcare IT**: Specialized programs at universities such as the Czech Technical University in Prague, which offers degrees in biomedical engineering and health informatics.
* **Data Science**: Programs that equip healthcare professionals with skills in data analysis and management.

Clinical workflows need significant adjustments to incorporate digital healthcare services. Key changes include:

* **Integration of EHRs**: Ensuring seamless data entry and retrieval to improve the efficiency of clinical processes.
* **Digital Tools for Diagnostics and Lab Orders**: Utilizing advanced digital tools for diagnostic imaging and lab orders to streamline these processes.
* **Electronic Prescribing Systems**: Implementing electronic prescribing to reduce errors and improve medication management.

These adjustments aim to streamline clinical processes, enhance efficiency, and reduce the time burden on healthcare professionals.

The main challenges related to adjusting workflows for digital health include:

* **Staff Resistance to Change**: Some healthcare professionals may be resistant to adopting new technologies due to familiarity with traditional methods.
* **System Integration Issues**: Integrating new digital tools with existing systems can be technically challenging and time-consuming.
* **Cost of Implementation**: The financial investment required for new technologies and training can be substantial.
* **Maintaining Data Privacy and Security**: Ensuring the security of patient data during the transition to digital systems is a significant concern.

The Czech Republic has developed several innovative training programs and workflow adjustments to support the integration of digital healthcare technologies:

* **Simulation-Based Training for EHRs**: Healthcare professionals undergo practical training using simulations to familiarize themselves with EHR systems.
* **Virtual Reality Modules for Surgical Training**: Utilizing virtual reality to provide immersive training experiences for surgical procedures.
* **Online Courses in Cybersecurity**: Offering courses to enhance the knowledge of healthcare professionals in protecting digital health information.
* **Interdisciplinary Teams**: Implementing teams that facilitate better communication and collaboration among healthcare professionals.
* **Mobile Health Applications**: Using mobile apps to streamline patient monitoring and follow-up care, improving overall patient management.

SLOVAKIA

To ensure effective training, integration, and information-security activities in Slovakia, healthcare professionals need a range of skills and qualifications:

1. **Information Security Professionals**:
   * **Educational Background**: A degree in computer science, information technology, cybersecurity, or a related field is often required.
   * **Certifications**: Highly valued certifications include CISSP (Certified Information Systems Security Professional), CISM (Certified Information Security Manager), CEH (Certified Ethical Hacker), and CompTIA Security+.
   * **Understanding of Regulations**: Knowledge of Slovak national regulations regarding data protection and cybersecurity, as well as EU directives, is essential.
2. **Technical Experts**:
   * **Educational Background**: Similar educational background as information security professionals.
   * **Certifications**: Certifications in network security (e.g., Cisco Certified Network Associate Security, CCNA Security) and system administration (e.g., Microsoft Certified Solutions Expert, MCSE) are important.

Higher institutions and universities in Slovakia offer education programs related to digital healthcare implementation:

* **University of Žilina**:**Faculty of Management and Informatics**: This faculty offers a study program focused on biomedicine informatics, which includes the basic analysis of medical and biomedical data using machine learning methods and the creation of semi-automatic diagnostic systems to support decision-making in medicine. The program has a capacity of 20 students per year and is currently the only program in Slovakia combining advanced informatics with a health specialization.
* **KInIT**: The Kempelen Institute of Intelligent Technologies (KInIT) is an independent, non-profit institute dedicated to intelligent technology research. KInIT brings together and nurtures experts in artificial intelligence and other areas of computer science, with connections to other disciplines. More information can be found on their website ([KInIT](https://kinit.sk/" \t "_new)).

Business leaders in Slovakia's healthcare system are continuously improving workflows, although these initiatives are primarily driven by private efforts:

* The largest radio diagnostics company, PDG, uses AI to support diagnostic results and provides these results on a specialized, closed-in website where patients can access their results immediately and in electronic format ([eradiologia.sk](https://www.eradiologia.sk/)).

Several challenges hinder the adjustment of workflows to incorporate digital health in Slovakia:

* **Legislator Support**: Current laws are written for an analog, rather than a digital, environment.
* **Regulated Availability**: Health records are electronically stored, but their availability is strictly regulated.
* **Limited Secondary Use**: The secondary use of health data is limited to statistical purposes.

Innovative initiatives in Slovakia include:

* **KInIT**: The Kempelen Institute of Intelligent Technologies (KInIT) provides training and research opportunities in intelligent technologies, including AI.

HUNGARY

To achieve successful digitalization in healthcare, it is essential to shift perspectives in education, integrate digital knowledge into training programs in a structured way, and strengthen a multidisciplinary approach for future successful collaborations. Technical training is vital for understanding and operating new digital tools and systems. Data management training ensures that healthcare professionals can effectively handle, analyse, and interpret large volumes of healthcare data. Ethical training is crucial for addressing issues related to data privacy, security, and the responsible use of artificial intelligence in healthcare. Additionally, training should encompass communication and collaboration skills to facilitate interdisciplinary cooperation between various fields such as medicine, data science, and information technology. Leadership and change management skills are also important to prepare healthcare professionals to lead and adapt to the continuous changes brought by digital advancements. This holistic educational approach is crucial for preparing healthcare professionals to navigate and thrive in an increasingly digitalized healthcare environment.

In Hungary, there are different subjects taught in order to develop digital health skills and improve the understanding of digital health technologies for the different health professional groups, however these are not well-coordinated.

Semmelweis University offers different courses, by different institutions to support the development of digital skills and competences of the different health professional groups.

The Digital Health Sciences Institute offers essential courses in medical informatics, which are mandatory elective subjects. These include the "Introduction to Medical Informatics" course for medical students (taught in English). Additionally, the institute provides elective courses for medical students such as "Biostatistics in Clinical Medicine" (taught in Hungarian) and "Medical Informatics" (taught in Hungarian and German).

For dental students, medical informatics is also taught, while pharmaceutical students can - in addition to medical informatics - study also pharmaceutical informatics, providing an overview of the life cycle of medicines and the related legislation, and then describe in detail the IT tools that can be used at each step, from drug development through regulatory approval to the marketing of medicines.

Semmelweis University Health Services Management Training Centre is offering the course "Medicine in the Present and Future: Data-Driven Health and Artificial Intelligence", which aims to prepare future healthcare professionals for the ongoing digital revolution in medicine. It introduces the directions of digital development in healthcare, the increasing role of digital solutions in future treatments, the significance of data application, and the importance of data-driven decision-making. Participants are familiarized with the types of data generated in healthcare delivery, opportunities for data utilization and the application of artificial intelligence, as well as basic legal, data security, and cybersecurity concepts. The course provides insights into the practical application of artificial intelligence, including demonstrations in various diagnostic modalities. With this knowledge, participants will understand the necessity of digital skills and competencies, the importance of their continuous development, and will become open to applying digital solutions throughout their careers.

Semmelweis University Health Services Management Training Centre is currently launching a Master’s program in Health Data Science, which is a comprehensive, 120-credit, four-semester course. It prepares students to utilize modern data science techniques in healthcare, emphasizing data processing, analysis, and AI solutions. The curriculum includes hands-on projects and covers Python programming, quantitative research methods, database management, data visualization, and AI applications in diagnostics. Designed for medical professionals, IT specialists, and data scientists, the program blends health sciences, mathematics, and informatics. It offers both state-funded and self-financed study options with the aim of connecting IT and data-science.

The improvement of HPC workflow and skills is an ongoing process in Hungary. Based on the above mentioned pilot activities, system-level solutions are systematically building. One of the most developed areas is the e-prescription, which is already the default way of prescribing medicine, integrated into the EHR cloud EESZT [16].

Adjusting workflows for digital health presents several key challenges:

1. **Shortage of personnel**, which can strain existing staff as they try to adapt to new digital tools and systems.
2. **Lack of comprehensive information and the education** required to effectively use these technologies can be time-consuming, further burdening healthcare workers.
3. **Staff resistance to change** is another significant obstacle, as many healthcare professionals may be hesitant to adopt new methods and workflows, preferring traditional practices. There are sporadic initiatives and pilot programmes in this area, where the processes are tested and adjusted.

ROMANIA

To ensure effective training, integration, and information-security activities in Romania, healthcare professionals need a comprehensive set of skills:

1. **Technical Training**: Healthcare professionals must be proficient in using digital health tools, including electronic health records (EHRs), telemedicine platforms, and other digital healthcare technologies. This technical training ensures that they can operate these systems effectively to enhance patient care.
2. **Data Management**: Expertise in handling, analyzing, and managing health data is crucial. Professionals need to ensure data accuracy, integrity, and efficient data retrieval. This includes understanding how to work with large datasets and ensuring the security of patient information.
3. **Ethical Training**: Healthcare providers must be trained in ethical considerations related to patient data privacy. This includes understanding and adhering to data protection regulations, such as the General Data Protection Regulation (GDPR).
4. **GDPR Training**: Specific training on GDPR compliance is essential due to the strict data privacy and security requirements. Healthcare professionals need to be aware of the legal implications and best practices for handling patient data under GDPR.

While medical institutions in Romania offer bioinformatics courses, these are not sufficient to meet the comprehensive needs of medical digitalization. There is a need for more specialized and extensive education programs focused on digital healthcare implementation to better prepare healthcare professionals for the digital transformation in healthcare.

Clinical workflows in Romania need significant adjustments to incorporate digital healthcare services. An example of such an adjustment can be seen in Bihor County, where the Clinical County Hospital Bihor has digitalized its laboratory activities. However, this seems to be a unique local experience, indicating that broader implementation across other healthcare settings is necessary.

Several challenges hinder the adjustment of workflows to incorporate digital health in Romania:

* **Staff Resistance**: One of the biggest challenges is resistance from healthcare staff who may be reluctant to adopt new technologies due to comfort with traditional methods.
* **System Integration Issues**: Integrating new digital tools with existing systems can be technically challenging and time-consuming.
* **Financial Investment**: The cost of implementing new technologies and training staff can be significant, requiring substantial financial resources.

Romania has initiated several innovative training programs and workflow adjustments to support the integration of digital healthcare technologies:

* **Training of Trainers Program**: The Ministry of Health, INMSS, and WHO have marked the completion of a “training of trainers” program aimed at improving health management skills through the National Recovery and Resilience Plan (PNNR).

More than 120 trainers participated in this program, which was organized by the Ministry of Health and the National Institute for Health Services Management (INMSS) in partnership with WHO. Participants were provided access to the latest practices and methods in health management through six modules conducted by 16 world-renowned professors. Representatives of the G6 (the group of Romanian universities of medicine and pharmacy) supported this program.

* **Health Management Training Program**: On 11 January 2024, the Ministry of Health and the National Institute of Health Services Management (INMSS) marked the national launch of the health management training program. The event, organized with the support of the WHO Romania Office and the WHO Regional Office for Europe, celebrated a crucial achievement for health services management as part of the Health component of the National Recovery and Resilience Plan (NRRP).

UKRAINE

To ensure effective training, integration, and information-security activities in Ukraine, healthcare professionals need a variety of skills and qualifications:

1. **Training of the Trainers**:
   * Developing a robust training program for trainers who will then educate healthcare professionals.
   * Ensuring trainers are well-versed in digital health tools and teaching methodologies.
2. **Developing the Platform on the Website**:
   * Creating an online platform for training modules and resources.
   * Ensuring the platform is user-friendly and accessible to all trainees.
3. **Developing and Validating Teaching Modules**:
   * Creating comprehensive teaching modules that cover all aspects of digital healthcare implementation.
   * Validating these modules to ensure they meet educational standards and effectively convey the necessary information.
4. **Advertising Teaching Activities**:
   * Promoting the training programs to ensure wide participation and awareness among healthcare professionals.
5. **Data Management of Trainees**:
   * Managing trainee information securely, ensuring data privacy and compliance with relevant regulations.
   * Keeping accurate records of training progress and assessments.
6. **Assessment of Trainees’ Knowledge**:
   * Developing robust assessment tools to evaluate the knowledge and skills acquired by trainees.
   * Providing feedback and support to ensure continuous improvement.

In Ukraine, higher institutions and universities provide education regarding digital healthcare implementation. Simulation centers have been developed in various universities, offering hands-on training with digital health tools. Notable initiatives include:

* **Virtual Clinical Environment (VCE)**: A unique initiative in Ukraine that provides advanced simulation training for healthcare professionals.
* **Web-Based Program “Screening Advisor”**: An innovative program implemented into the training curriculum of senior students and practical work of the InterFamily clinic, enhancing the digital literacy of future healthcare providers.

To incorporate digital healthcare services, clinical workflows in Ukraine need to be adjusted. One innovative approach involves the use of a set of virtual equipment, including smart glasses, e-stethoscopes, e-dermatoscopes, e-otoscopes, e-ophthalmoscopes, angled video cameras, and ultrasound devices. This equipment allows family doctors to stream their workflows to trainees, providing a practical and immersive learning experience.

Several challenges are associated with adjusting workflows to integrate digital health technologies:

* **System Integration**: Ensuring that new digital tools can be seamlessly integrated with existing healthcare systems is a significant technical challenge.
* **Cost**: The financial investment required for new technologies and training programs can be substantial.
* **Staff Training**: Comprehensive training programs are necessary to equip healthcare professionals with the skills to use new digital tools effectively.
* **Changes in the Teaching System**: Adapting the existing teaching system to include digital health training requires significant effort and coordination.

Ukraine has implemented several innovative training programs and workflow adjustments to support the integration of digital healthcare technologies:

* **VCE in Family Medicine**: Six modules are being developed within the Virtual Clinical Environment (VCE) for Family Medicine. These modules include an andragogical framework for assessment and self-assessment, ensuring that trainees can evaluate their progress and competencies effectively.
* **Screening Advisor Program**: This web-based program has been incorporated into the training curriculum of senior students and the practical work of the InterFamily clinic, providing advanced training in digital health screening and diagnostics.

BULGARIA

In Bulgaria, there isn't a comprehensive national approach to training healthcare professionals (HCPs) in digital skills. The NGO sector, including associations like the DHI Cluster, is stepping in to provide specific training programs for HCPs, but these efforts are not sufficient to meet the nationwide need for improved digital skills. Various national associations, such as those focused on cardiovascular diseases (CVD), are offering specialized training for HCPs in their fields.

Medical universities in Bulgaria offer various training programs on innovative topics such as telemedicine, big data, software systems, decision support tools, and artificial intelligence (AI). These universities have well-developed centers of competence and excellence, as well as simulation centers where medical students can learn about new technologies and their integration into the healthcare system. The DHI Cluster has been leading a course on Digitalization and Innovations in Healthcare at Medical University-Sofia since 2019, educating over 750 medical students to date.

Private healthcare structures in Bulgaria are continuously improving their workflows to incorporate digital healthcare services, but these are largely private initiatives. There is a pressing need for a national campaign to raise awareness about the digital health transformation process. This campaign should aim to foster understanding and adoption of new technologies among HCPs, who often perceive this transformation as challenging, expensive, and feel unprepared to work with new health technologies.

Several challenges hinder the adjustment of workflows to incorporate digital health in Bulgaria:

* **Regulatory and Access Issues**: While electronic health records (EHRs) are stored electronically, access is strictly regulated. Only general practitioners (GPs) have access, limiting the utility for other HCPs. Additionally, the secondary use of health data is restricted to statistics, with no access for research and development (R&D).
* **Fragmentation of Information Systems**: The main challenge is the fragmentation of information systems implemented in healthcare workflows. The lack of interoperability and the multitude of different solutions, portals, and systems that need to be managed is a significant barrier to adopting new workflows. There is a need for unification in data management and clinical information systems to streamline processes.

To ensure the smooth adoption of digital solutions within the healthcare landscape, a structured and comprehensive implementation process is necessary. This should include:

1. **Public Implementation Process by the Government**:
   * **Digital Health Landscape**: Understanding the current state of digital health technologies, trends, and disruptions.
   * **Design Thinking and Innovation**: Applying design thinking principles to healthcare challenges and identifying opportunities for innovation and transformation.
   * **Change Management and Leadership**: Strategies for driving organizational change and leading teams through digital adoption.
   * **Patient-Centric Approaches**: Enhancing patient experiences through technology and leveraging data for personalized care.
   * **Healthcare Analytics and Data Science**: Using data analytics for informed decision-making and implementing data-driven solutions.
   * **Legal and Ethical Considerations**: Navigating privacy, security, and regulatory issues, and ensuring compliance with healthcare laws.
2. **Local Program for Adoption of New Technologies**:
   * **Local Awareness Campaigns**: Conducting campaigns in public hospitals, private hospitals, laboratories, and among patients to raise awareness about new technological solutions.
   * **Gathering Primary Information**: Collecting feedback from HCPs through meetings and questionnaires to understand how new technologies will impact workflows, identifying benefits and pain points.
   * **Analysis of Bottlenecks**: Analyzing challenges and proposing approaches to overcome identified obstacles.
   * **Educational Iterations**: Implementing a structured educational program to train HCPs on the new technologies and how to work with them effectively.

REPUBLIC OF SRPSKA

While specific details about innovative training programs or workflow adjustments in the Republic of Srpska may not be readily available, it's possible to speculate on potential initiatives based on general trends and best practices in healthcare innovation. Incorporating digital healthcare services into healthcare workflows in the Republic of Srpska will necessitate significant changes to how various tasks are performed. Actual programs and initiatives would require collaboration among healthcare stakeholders, investment in infrastructure and resources, and evaluation to assess their impact on patient care and outcomes.

Overall, integrating digital healthcare services into HCP in the Republic of Srpska will require changes in processes, technology adoption, and provider training. By leveraging digital tools and technologies effectively, healthcare organizations can enhance efficiency, improve patient care, and adapt to the evolving healthcare landscape.

Adjusting workflows for digital health in the Republic of Srpska comes with several challenges, including:

• **Resistance to Change**: Healthcare professionals may resist adopting new digital workflows due to concerns about changes in their roles, increased workload, or unfamiliarity with technology. Overcoming resistance requires effective change management strategies, training programs, and ongoing support to help staff embrace and adapt to digital healthcare practices.

• **Cultural and Organizational Barriers**: Cultural factors and organizational dynamics can also contribute to staff resistance. Healthcare organizations must create a culture that values innovation, encourages collaboration, and empowers staff to embrace digital transformation.

• **Healthcare professionals** require training and skills development to effectively utilize digital tools and technologies in their practice. Addressing the workforce training needs and bridging the skills gap is essential for successful digital health implementation.

**Potential Initiatives:**

• Collaboration among stakeholders is essential for designing and implementing effective programs.

• Investments in infrastructure and resources are necessary to support digital healthcare initiatives.

• Evaluation is vital to measure the impact of programs on patient care and outcomes.

**Overall Impact:**

• Integrating digital healthcare enhances efficiency, improves patient care, and adapts to evolving healthcare needs.

• Overcoming challenges requires leadership commitment, stakeholder engagement, and a focus on change management and organizational culture.

By addressing these challenges and implementing effective strategies, healthcare organizations in the Republic of Srpska can fully leverage the potential of digital health to enhance patient care and outcomes.

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LIST OF ABBREVIATIONS

AI - Artificial Intelligence

AIMD - Active implantable medical devices

CA - Competent Authority

DGA - Data Governance Act

DRG - Diagnosis-Related Groups

EESZT - Hungarian National E-health Infrastructure

EHDS - European Health Data Space

eHDSI - Bulgarian eHealth Digital Services Infrastructure

EHRs - Electronic health records

EHTO - European Health Telematics Observatory (EHTO)

ELGA – Austrian Health Record Information System

FBiH - Federation of Bosnia and Herzegovina

FD - Family doctor

GDPR - General Data Protection Regulation

Gottsegen György National Cardiovascular Institute

GPs - General practitioners

HCPs - Healthcare professionals

HCPs - Healthcare providers

HIF - Health Insurance Fund

HTA - Health Technology Assessment

HTA - Health Technology Assessment

ICM - Integrated Care Model

ICT - Information and communication technologies

IoT - Internet of Things

IVDD - In-vitro Diagnostic Directive

IVDR - In Vitro Diagnostic Regulation

IZIS - Integrated health information system of Republic of Srpska

MDR - Medical Device Regulation

MDR - Medical Device Regulation

MoH – Ministry of Health

NAMMD - National Agency for Medicines & Medical Devices

NB - Notified Body

NCPRPM - Bulgarian National Council on Prices and Reimbursement of Medicinal Products

NEAK - Hungarian National Health Insurance Fund

NHIF - Bulgarian National Health Insurance Fund

NHIS - Bulgarian National Health Information System

NHS - National Health System

NNGYK - Hungarian National Centre for Public Health and Pharmacy

PMG - Guaranteed benefit package

PNRR -Romanian National Recovery and Resilience Plan

PP - Project partners

PPPs - Public-Private Partnerships

PSPs - Patient Support Programs

RPM - Remote patient monitoring

RS - Republic of Srpska

RWD - Real-world data

RWE - Real-world evidence

SIDC - Slovak Institute for Drug Control

SO - Specific Objective

SP - Strategic priorities

VCE - Virtual clinical environment

WHO - World Health Organization

LIST OF DIGI4Care PARTNERS

* + - 1. SOTE\_HU - Semmelweis University Magyarország (Hungary)
      2. GOKVI\_HU - Gottsegen György National Cardiovascular Institute (Hungary)
      3. GÖG\_AT - Austrian National Public Health Institute (Austria)
      4. LBI\_AT - Ludwig Boltzmann Institute Digital Health and Patient Safety (Austria)
      5. UP/FM\_CZ - Prague University of Economics and Business (The Czech Republic)
      6. FML\_SK - NGO Future Medical Leaders (Slovakia)
      7. UO\_RO - University of Oradea (Romania)
      8. HoCons\_RO - Hospital Consulting SRL (Romania)
      9. DHI\_BG - Digital Health and Innovation Cluster (Bulgaria)
      10. KH\_BG - Kelvin Health Inc. (Bulgaria)
      11. IFMC\_UA - International Family Medicine Clinic for Internally Displaced People, INTERFAMILY Clinic (Ukraine)
      12. HRTD\_BA - Research and Technological Development Association in Health - Health RTD Cluster (Bosnia and Herzegovina)