Digital Transformation of Healthcare

Zagreb, October 2023

AmCham

American Chamber of Commerce in Croatia Američka gospodarska komora u Hrvatskoj

Table of Contents

Introduction

Digital health solutions have the potential to make healthcare more equitable.

The COVID-19 pandemic, which has led to the widespread adoption of telemedicine and other digital innovations in healthcare, has changed the game in the healthcare sector. However, the pandemic has also laid bare the issue of healthcare inequities. Equitable access to accessible and competent healthcare has the potential to improve patient outcomes by providing a better quality of life, reducing reliance on emergency and late-stage interventions, and reducing early deaths. Digital technologies have the potential to play a key role in efforts to improve health equity. However, rapidly advancing technology can also exacerbate exclusion, introduce unexpected biases, widen the digital divide, and continue to leave a segment of the population out of reach of care. There is a great opportunity for technology and science companies that address health equity challenges through digital innovation, and the economic, financial, and health benefits to society are also significant.

One of the key digital technologies that has great potential in improving health equity is the **European Health Data Space (EHDS)**. The EHDS is a digital platform for storing, sharing and managing patient health data, such as medical histories, diagnoses and prescriptions. The EHDS also allows for better monitoring of the course of the disease, reduction of diagnosis errors and increased coordination between different healthcare professionals.

The EHDS also has the potential to reduce inequalities in access to healthcare, as it allows patient data to be easily shared between different health institutions and healthcare professionals. This is especially important in cases where patients cannot physically reach the doctor or when they travel abroad. The EHDS can help ensure the continuity of healthcare and avoid unnecessary repeated examinations, diagnostics and therapies. Aside from significant economic savings, better access to health data also represents a great potential for advancing research, development and innovation. It reduces the administrative burden on healthcare professionals while allowing patients and healthcare system users control and easy and quick access to and control of their health data.

ChatGPT and other similar tools are exciting innovations (ChatGPT is an AI chatbot that uses natural language processing to create human-like conversations) and another example of digital technology that can help improve health equity. In healthcare, ChatGPT can provide users with quick and easy access to information about their health, provide advice on ways to stay healthy, and help identify symptoms of illness. ChatGPT can also improve access to healthcare for those who live in rural areas or those who do not have access to traditional sources of healthcare.

However, it is important to keep in mind that digital health solutions should be adapted to the different needs and abilities of patients, not the other way around. Technology should not replace human contact in healthcare but should be a tool to improve the quality of healthcare for all patients, regardless of their socioeconomic conditions or geographic location.

Equalizing the availability and quality of healthcare not only improves individual and overall levels of health but also has beneficial effects on the wider economy: good health and quick and effective treatment allow patients to live active and productive lives. Improvements in global health have contributed to about a third of overall economic growth in advanced economies over the past century. To sustain this growth rate, digital health solutions must be designed to reach previously excluded or underrepresented groups.

Today, there is a huge number of digital health solutions available – from artificial intelligence (AI) and robotics in the operating room to diagnostic algorithms that use large amounts of data – but it is difficult to know which actually have a clear benefit for patients. For this reason, there is a need to demonstrate the value of any digital tool before their widespread adoption by public health.

A good example of the use of AI is the **Croatian lung cancer screening model**, which is already a part of pilot programs in four European countries – France, Great Britain, Poland, and Hungary. In two years of screening, 16,000 people were examined, and most of them did not feel any symptoms of the illness. Patients are sent for screening according to the recommendation of their family doctors. Most of them are citizens between the ages of 50 and 75, mostly smokers or ex-smokers who have stopped smoking in the last 15 years. The findings are read with the help of artificial intelligence, and patients are sent for imaging through a special digital platform. This method allows lung cancer to be detected in the first stage of the illness, when it is curable. The goal is to detect cancer cells between 6 and 15.5 mm in size, not metastatic cancer, as has been the case so far.

It is well-established that digital solutions bring up many questions, both for doctors and patients, such as data privacy, ownership, and protection. Many healthcare professionals are wary of using digital solutions, which is an important obstacle to the widespread use of digital solutions in everyday clinical practice. For this reason, it is necessary to **increase awareness among healthcare professionals and experts about the value of various digital technologies for patients**.

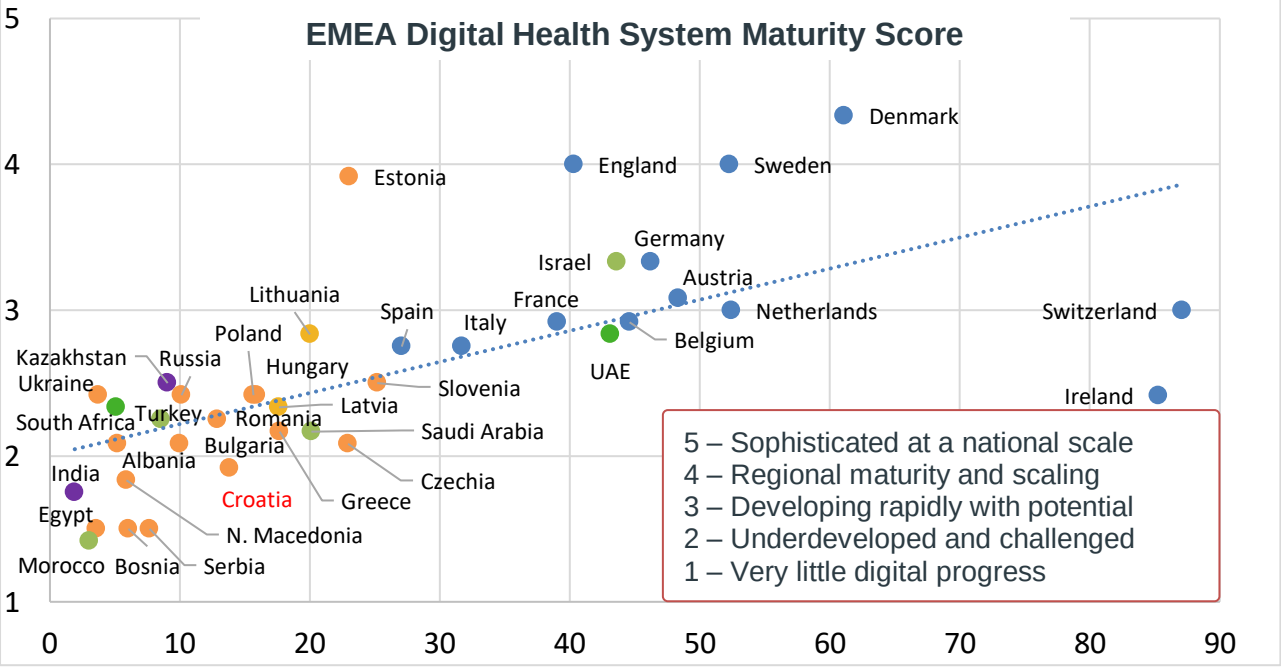
It is also necessary to prove the economic value of public healthcare systems in order for the national health fund to decide to pay for digital medical solutions.

State of play in Croatia

The research conducted by IQVIA at the end of 2021 examined the digital maturity of countries, taking into account 12 elements divided into three areas:

- Initiatives (policies, financing, data management, interconnectedness of institutions);
- Infrastructure (electronic patient records, standardized data, data interoperability, genomics infrastructure);
- Implementation (telemedicine, use of artificial intelligence, use of data in healthcare, virtual clinical research).

Figure 1 Assessment of digital maturity of countries in relation to GDP in the Europe, Middle East, and Asia regions – source: IQVIA "Switching On the Lights – Benchmarking digital health systems across EMEA"



The results show that Croatia achieved a score close to 2, which indicates that Croatia does not have sufficiently developed digital healthcare solutions, which is a significant contributor to numerous challenges within Croatia's healthcare system.

Within the infrastructure in Croatia, there are several segments that are satisfactory. E-prescriptions were introduced very early compared to the rest of Europe, and a large number of general practitioners use IT systems that incorporate good elements of the Electronic Health Record. However, the use of this infrastructure is at an elementary level of transaction monitoring between healthcare institutions and the Croatian Health Insurance Fund. The hospital system also implemented IT systems

that contain elements of the e-health record; however, they are not connected in any way, and they have no prescribed standards or procedures that would enable data interoperability and interconnection of systems and data within the country and internationally.

The introduction of e-records (electronic health record, EHR) into the healthcare system represents a significant step towards the modernization and optimization of healthcare services. The improved legislative framework aims to define the concept and role of the EHR, which will provide healthcare providers easy access to basic patient data and medical history.

Furthermore, the new regulations will define the rights and responsibilities of participants in the implementation of the necessary IT infrastructure, ensuring compliance with relevant laws and ethical standards related to the protection and use of data.

It is worth noting that the improved legislative framework is already in the public consultation phase, which allows for feedback and proposals from the general public and relevant stakeholders. This approach aims to ensure that the legislation meets the current needs and challenges of the healthcare system and, at the same time, ensures the privacy and security of patient data.

In terms of implementation, the biggest challenges are in the current position of Croatia in relation to other countries. Telemedicine has been implemented sporadically, mainly in the private sector. Skills and competencies that would enable the use of health data to improve health outcomes for the patient, with control and rationalization of costs within the primary care system, are not being developed within the healthcare system. When it comes to implementation and use of advanced IT solutions that use complex databases combining multiple data sources, artificial intelligence, modern and properly structured patient registries, more widespread use of genomics, and implementation of virtual clinical research in Croatia, we see very few initiatives, and this is the area where we see Croatia significantly lagging behind the more advanced countries in the EMEA region.

The common elements of countries that have reached the highest level of digital maturity of Estonia, England, Sweden and Denmark are widespread **national genomics programs**, **advances in the decentralization of clinical research, and the use of structured national health data for evidence-based healthcare decisions**. Additional success factors are:

- The digitalization process started much earlier than in other countries – Estonia
- Highly centralized healthcare system – England

- Cultural predisposition of the population toward the realization of complex projects, such as complete genome sequencing in large numbers – Denmark and England

Interoperability of electronic health records is a major challenge for most countries due to a lack of standards, which causes low coverage of data that can be compared. Even though many countries are raising the priority of increasing data compatibility, this is currently the area where it is most difficult for them to make progress. The main barriers to implementing large and complex projects in order to improve infrastructure and standards are insufficient funding and a lack of technological competencies. Spain is an example of a country where data that was not well structured, in the form of free text, is beginning to be structured and used using NLP technology (*Natural Language Processing*). Austria demonstrated good practice with the implementation of the ELGA system, which enables the linking of health data from different institutions in a central location and controlled access to data for healthcare professionals and patients. Estonia was the first in the world to implement the national e-health record in 2008, and today, it covers 100% of patients and uses *blockchain* technology for additional data security.

Genomics is increasingly becoming the focus of countries, but it is generally poorly developed and only a few countries have adopted a comprehensive strategy in this area. Programs usually start within the academic community at universities before expanding to the national program level. England is one of the leaders in this field with the outline of a strategy that includes full genome sequencing of 300,000 patients and a program of *screening* newborns. Denmark has also implemented a national genome sequencing program with plans to reach 60,000 patients by 2024, led by the Danish National Genome Center.

DATA-CAN is an example of a public-private partnership in the United Kingdom with the aim of improving the care and treatment outcomes of oncology patients by providing high-quality health data and making it accessible to specialists and scientists. The system delivers health data through an online portal, collects data constantly in real time, and is used by healthcare providers to promptly identify issues and respond to them. In addition, the system helps identify patients with certain characteristics and direct them to relevant clinical studies using technology along with a simultaneous transparent dialogue with patients and the public that ensures that data is used in a transparent and responsible manner. This system has numerous advantages:

- **Clinical** – Understanding a specific population of patients with certain oncological characteristics in real time, identifying medicines in use and the trend of introducing new therapies, using RWE to help inform patients about possible outcomes, comparing the odds of survival of oncological diseases and other outcomes in order to make better decisions about appropriate treatment options;
- **Operational** – Real-time data analyses improve the overview of the current system load and, together with trends over time, improve planning, enable

monitoring and increasing access to innovative therapies, and understand how therapies are used in practice.

From the beginning of 2022 until today, several major projects on the topic of digitalization in healthcare have been announced for public procurement in Croatia:

1. eLijekovi project – Procurement of services for developing an integrated system for the management of medicines; the value of the selected bid was approximately €650,000;
2. Establishment of the National Cancer Network and the National Cancer Database, the maximum value of the project financed through the EU fund was approximately €8.5 million;
3. Creation of a system for monitoring and preventing medicine shortages in Croatia; the maximum value of approved funds from the EU fund was approximately €1.1 million – a project for which we are still awaiting a public procurement announcement.

The eLijekovi project aims to achieve integrated management of medicines data at the national level in order to enable a simple and safe exchange of information on medicines among various stakeholders in the healthcare system, rationalize resources, improve the safety of administration of medicines, and contribute to the further improvement of the entire healthcare system. It consists of three segments:

1. Creating a single medicines database
2. Implementing a system for checking interactions when prescribing and dispensing medicines
3. Developing the functionality of direct reporting of side effects from CEZIH and the e-Citizens system to the Croatian Agency for Medicinal Products and Medical Devices (HALMED).

The goal of the comprehensive National Cancer Network is to collect all data and exchange medical documentation on all patients during oncology care in accordance with the guidelines and a single/complete database on the quality of oncology care and to connect all public and private healthcare institutions involved in patient care. Within the IT platform of the National Cancer Network, the plan is to incorporate appropriate algorithms of basic diagnostic procedures necessary for starting and monitoring the treatment of the most common diagnoses in order to standardize diagnosing and treatment at all levels in Croatia, from small oncology clinics to clinical hospital centers.

The abovementioned examples show a small shift in the area of initiatives in the Republic of Croatia, but at the same time, the public procurement procedure for the e-Lijekovi project has lasted more than a year, which still significantly affects the slow development of the infrastructure and the (overly) long time required to implement new digital solutions in healthcare.

European Health Data Space

The European Commission has recognized the need for digital transformation and the value of data. In order to ensure European competitiveness and data sovereignty, the Commission launched the European Data Strategy, which aims to create a single data market by enabling easier and safer access to and use of data. Through the strategy, it announced the creation of common European data spaces in strategic economic sectors and domains of public interest, including healthcare.

In May 2022, the European Commission presented a proposal for a Regulation on the Establishment of a European Health Data Space, which will be discussed by the Council and the European Parliament. The European Health Data Space (hereinafter: EHDS) builds on the General Data Protection Regulation (GDPR), the proposed Data Governance Act, the draft Data Act, and the Network and Information Systems Directive. It will be financed by both the member states and the Commission, within the framework of various Union funds and instruments. It is a specially designed healthcare ecosystem consisting of rules, common standards and procedures, infrastructures, and governance frameworks aimed at enabling the sharing of health data, both in healthcare and for secondary purposes in research, innovation, and decision-making. Citizens will have full control over their data and will be able to easily share it with healthcare professionals in their own country and other member states, and thus gain access to better healthcare.

The EHDS will rely on two different pillars: *MyHealth@EU* and *HealthData@EU*. *MyHealth@EU* is focused on the exchange of health data between patients and healthcare professionals across member states. *HealthData@EU* will focus on the secondary use of data. [1]

The work of healthcare professionals will become easier and more effective. Greater interoperability will allow them cross-border access to patients' medical records, which means they will have a greater evidence base for making diagnoses and treatment decisions.

Regulatory bodies and policymakers will be able to more easily access the health data needed for the better functioning of healthcare systems. This will lead to better access to healthcare, lower costs, greater efficiency, more resilient healthcare systems, new research and innovation, and more evidence-based policymaking.

[1] "Primary use of electronic health data" means the processing of personal electronic health data for the provision of health services for the purpose of assessing, maintaining a state of health, or curing the individual to whom the data relates, including prescribing, issuing, and administering medicines and medical products, and for the provision of relevant social security services, administrative services or reimbursement of costs.

"Secondary use of electronic health data" means the processing of electronic health data for the purposes set out in the Regulation itself. The data used may include personal electronic health data originally collected in the context of primary use but also electronic health data collected for secondary use.

In order to gain access to such data, researchers, companies, or institutions will request permission from the authority for access to health data, which will be established by each member state. Access will be granted only for the use of the requested data for special purposes, in a safe and secure environment, without revealing the identity of the individual. Thanks to the greater availability of electronic health data, the health of citizens will improve, and the production of innovative medicines and medical products that enable better and more personalized care will be easier.

Projects arising from the EHDS proposal

One of the tools for the development of the EHDS and access to health data for secondary use is the Joint Action Towards the European Health Data Space (hereinafter: TEHDAS). The project includes 25 European countries and is coordinated by the Finnish innovation fund Sitra. The purpose of TEHDAS is to assist member states and the Commission in developing concepts and guidelines for the management, use, and sharing of health data for secondary purposes. The results will serve as input for the legislative proposal of the European Commission on the EHDS.

The European Commission also launched a pilot project for the EHDS in July 2022 that will bring together national data licensing authorities, public health infrastructures, and health research infrastructures to enable data linking and integration between data sources. This pilot project is a major first step that will enable the practical validation of the concept of accessing health data in Europe. The project leader is the French Center for Health Data ("Health Data Hub").

Croatia is involved as a partner in both mentioned projects through the Croatian Institute for Public Health and the Croatian Health Insurance Fund.

In February 2022, as part of one of the TEHDAS work packages, in which Croatia is also included, the Report on the secondary use of health data using European examples was published. The results showed that European data users face a wide range of barriers to cross-border sharing of health data for secondary use, mostly related to legal and data management issues caused by inconsistencies in interpretation and implementation. Based on the examples of best practices, policy options have been developed to address the identified barriers, and these will be used to develop recommendations for European countries, which will need to be considered when planning national legislation to enable cross-border exchange and secondary use of health data.

An overview of the Croatian legislative framework in healthcare digitalization

The legislative framework that is currently applicable in healthcare digitalization in the Republic of Croatia consists of a large number of regulations (laws, by-laws, and EU regulations and guidelines), of which the following regulations are objectively the most important: Act on Health Data and Information (Official Gazette 14/2019); General Data Protection Regulation (EU 2016/679); Act on the Implementation of the General Regulation on Data Protection (Official Gazette 42/2018).

The key drawback of the described legislative framework within the Republic of Croatia is its incompleteness and mutual inconsistency, as well as only partial harmonization with the existing legislative framework at the EU level, and only in the area of general provisions on data protection, while harmonization in the area of use, collection, and processing of health data is yet to be done.

The by-laws (regulations) whose adoption is prescribed by the Act on Health Data and Information have not yet been adopted (even though the deadline for their adoption was 60 days from the entry into force of the act), which leads to the current situation where we have a basic legal act that is in practice only partially enforceable or completely unenforceable due to the lack of harmonized regulations. Due to such a situation, in addition to the present act, there are by-laws currently in force that were adopted in the period from 2000 to 2010 under the previous Act on Records in the Field of Healthcare from 1978, which are only partially or not at all aligned with the governing law.

These are the following by-laws:

- Ordinance on the method of managing, keeping, collecting and disposing of medical documentation of patients in the Central Health Information System of the Republic of Croatia – Official Gazette No. 82-2344/10 (date of publication: 7/1/2010, valid from: 11/1/2010),
- Ordinance on the method of managing personal health records in electronic form, OG No. 82-2345/10 (date of publication: 7/1/2010, valid from: 11/1/2010),
- Ordinance on the use and protection of data from the patients' medical records in the Central Health Information System of the Republic of Croatia, OG No. 14-348/10 (date of publication: 1/29/2010, valid from: 2/6/2010),
- Ordinance on the implementation of the Act on Records in the Field of Healthcare for geriatric patients, Official Gazette No. 82-1353/02 (date of publication: 7/12/2002, valid from: 7/20/2002),
- Ordinance on the implementation of the Act on Records in the Field of Healthcare for inpatient healthcare and disease and addiction monitoring,

OG No. 44-1018/00 (date of publication: 4/26/2000, valid from 5/4/2000, application from 1/1/2001),

- Ordinance on the implementation of the Act on Records in the Field of Healthcare for primary and specialist-consultative care, OG No. 4-39/95 (date of publication: 1/19/1995, valid from 1/27/1995, application from 1/1/1995)

In short, this means that the specified by-laws that are still in force in the Republic of Croatia are **not harmonized with any regulation passed on the specified matter in the Republic of Croatia and the EU after 2010**.

In addition to the aforementioned regulations, the key regulation that will be the umbrella regulation at the EU level for the legislative regulation of the digitalization of health and the primary and secondary use of health data, and whose adoption is still expected in the EU Parliament in 2024 at the earliest, **is the proposed Regulation on the European Health Data Space**, whose proposed text has been in the legislative procedure of the EU Parliament since May 2022.

The proposed regulation aims to legislatively regulate all important areas of exchange of health data in the EU as a single area, creating prerequisites for all EU citizens, all health authorities of EU countries, as well as all health, scientific, educational, and other EU institutions to be able to properly use health data for prescribed purposes, and with legislative protection of the guaranteed citizens' rights regarding their health data.

The fact is that a single digital space for the exchange and primary and secondary use of health data will be created at the EU level and that the legislative framework for this area will be regulated by a regulation, i.e., a legislative act that is directly applied on the territory of all EU members as their domestic regulation.

In view of such a legislative situation, it would be opportune to start immediately, if this has not already been done, to establish a working group for the preparation of proposals for the harmonization of legal and implementing regulations with the proposed Regulation on the European Health Data Space, and in this way, to be ready from the legislative side and wait for its entry into force without delay.

Digital medication management and automation in healthcare institutions

Changing market demands and business process disruptions caused by new technologies have imposed numerous challenges on organizations around the world.

Research shows that organizations that do not automate and do not innovate are doomed to fall behind.

Healthcare systems face the same challenges today. As issues in the healthcare sector have become a priority for European citizens and the European Union, the creation of the European Health Union demonstrates the need for innovative, resilient healthcare systems with extensive resources. In order to create a strong European Health Union, it is necessary to prioritize investment in the digital infrastructure of hospital core activities. Digital transformation in hospital environments, especially investments in *medication management pathways*, is a great opportunity for both Croatia and the entire European Union since medication management is a key core activity for hospitals.

Medication management pathways in hospitals are complex and include activities such as ordering, receiving, storing, prescribing, preparing, distributing, and issuing/dispensing medicines to patients in hospital wards. Inventory control, management, and monitoring activities along this pathway require different clinical groups to ensure sufficient supplies and safe administration of medicines to patients. However, the tasks on this pathway are defined mainly by manual activities, and digitalization lags behind.

Digitalization of medication management includes complete solutions for tracking medications (*track-and-trace*), otherwise known as *closed-loop medication management systems*, from the pharmacy to the ward and all the way to the bed, i.e., patient with a smart, automated, fully integrated digital approach. Due to the revision of the basic pharmaceutical regulation, in the context of the European Pharmaceutical Strategy, the implementation of the EU4Health program, and the emergence of the European Health Data Space, the issue of digitalization and automation represents an opportunity for implementation in the existing and upcoming policy and legislative framework and programs that will revolutionize medication management pathways in healthcare institutions.

A recent OECD publication, "*The Economics of Medication Safety, improving medication safety through collective, real-time learning,*" emphasizes that digital technologies and automated systems, such as medication administration with a barcode scanner, smart infusion pumps, and automated medicine cabinets, have significant potential to improve medication safety outcomes. With automation, processes become more efficient, resulting in increased protection of patients and healthcare professionals.

Low levels of digitalization of medication management pathways in healthcare institutions have implications for:

1. **Patients** – Errors in medication administration are the biggest cause of side effects in hospitals in terms of morbidity and mortality rates and have significant economic and health consequences (Elliott et al., 2018). They are one of the 10 leading problems in patient injury. Adverse events associated

with the wrong use of medication cause greater mortality than traffic accidents, breast cancer, or the human immunodeficiency virus (HIV); 1 in 5 patients in the OECD region experienced a medication-related adverse effect during hospitalization.

2. **The well-being of healthcare professionals** – Only 5% of doctors avoid close or direct involvement in adverse events during their entire career. Involvement in an adverse event causes psychological and emotional damage to healthcare professionals; 31% of nurses involved in an adverse event require up to 3 months of absence from work due to chronic workplace stress.
3. **Healthcare system** – In OECD countries, the costs associated with adverse effects due to errors in the use of medicines, which can be avoided, amount to more than 54 billion dollars. In Spain and the United Kingdom, errors in medication cost up to 3% of their national health budgets and create approximately 3 million avoidable hospital stays (Elliott et al., 2021).

Examples of digital tools to improve medication management

Digital tool	Description
Pharmacy information systems and robots intended for central hospital pharmacies (versus shelves and manual inventory control)	Pharmacy information systems integrated and linked with logistics robots and departmental automated medication dispensing cabinets to break down supply chain silos in hospitals. The pharmaceutical robot is an automated solution for receiving, storing, and issuing medicines.
Electronic Prescription for Medication (CPOE) (vs. manual prescribing)	The process of medically entering and sending medicine orders and treatment instructions electronically through a computer application instead of paper. Evidence shows the importance of computerized provider order entry systems in reducing errors in medication (it is estimated that at least a quarter of all medication-related adverse effects could be prevented using such systems due to eliminating errors from inaccurate manual entry).
Automated Dispensing Cabinets (ADC) (versus shelving and manual inventory control in wards)	Computerized medication storage devices that allow medication to be stored and dispensed near the point of care while controlling and monitoring medication distribution. Hospital pharmacies traditionally supply wards with medication through a ward inventory system. Designed to replace non-automated inventory storage in wards. They facilitated the transition to alternative delivery models and more decentralized medicine distribution systems. Automated dispensing cabinets, including a link to computerized provider order entry (CPOE), reduce medication error rates and costs and improve healthcare staff efficiency. Clinical studies indicate the importance of optimal implementation of automated dosing systems to ensure the greatest clinical success and economic benefits.

Electronic preparation systems and digitalized medication inventory management	To support medication preparation, including unit dose systems to ensure that prepared/compounded medication doses are correct and ensure traceability through global standards for identification and barcoding, such as the use of GS1 standards. Central pharmacies in hospitals are best equipped in terms of professional resources and technology for the preparation of medicines. Despite this, there is a significant amount of medication prepared outside of central pharmacies, in intensive care units and general wards, so similar resources and skills should be available in any environment. As a result, it is critical to implement electronic systems in preparation areas to support preparation and ensure safety (e.g., preparation of parenteral preparations).
Barcoded Medication Administration (BCMA) and identification systems	Using global standards, e.g., GS1 standards for barcoding, linked to electronic prescription systems and electronic health records in departments. The BCMA reads the barcode of the patient's wristband, the healthcare professional's identification, and the medicine. The system confirms the right medicine, the right patient, and the right time. It also checks that only authorized personnel administer the medication.
Smart pumps with Dosing Error Reduction Systems (DERS)	To prevent programming errors. The new smart pumps include full connectivity and interoperability with electronic systems, including automatic pump programming and auto-documentation functions to prevent errors and increase efficiency.

Source: ECAMET, 2022

The benefits of digitizing medication management and automation in healthcare institutions include:

- **More resilient hospital systems** – Consumption would be optimized, productivity increased, and waste would be reduced throughout the entire medication management pathway by automating manual activities that will reduce and eliminate unreliable manual processes. Hospital managers and pharmacists would have data on expired medication, which would support the ecological sustainability of supply chains.
- **More reliable information on medication availability** – More accurate visibility of hospital medication inventory can provide real-time information on the availability of critical medical products, supporting the European Medicines Agency's expanded role in managing medication shortages through the new European Shortage Monitoring Platform (ESMP). Accurate information on the supply of medicines can reduce inventory and support the redistribution of products within regions and between member states.
- **Availability of real-world data in interoperable systems** – Hospital budgets can save up to 15% by making better use of health information. Interoperable patient-generated health data, including medicine data, can pave the way for personalized healthcare, the implementation of artificial

intelligence (AI), the successful implementation of the EHDS (*European Health Data Space*), the monitoring and evaluation of treatment outcomes, and provide real-world data to support evidence-based decision-making (EHMA, 2022)

- **Better management of antimicrobial drug administration** – Combating antimicrobial resistance (AMR) through judicious use of antibiotics can be improved by modernizing medication management pathways in hospitals. Implementing digital tools and systems can support antimicrobial stewardship programs to reduce antibiotic use and help healthcare professionals ensure the correct dose of the most appropriate antibiotic for patients.
- **Bridging the problem of the lack of professional staff and the well-being of healthcare professionals** – The COVID-19 pandemic has further emphasized the problem of the lack of healthcare staff in Croatia and throughout Europe. Now, more than ever, it is necessary to find ways to reduce staff workload and increase productivity within healthcare systems. A robot in a central hospital pharmacy or, for example, automation in a laboratory can replace work that otherwise would not be possible to do in the same time with the existing staff. Automation will free up the necessary time that professional staff can devote to the patient, analyses, etc. Technology also plays an important role in reducing the burnout syndrome among healthcare professionals. Clinicians today are overloaded and exhausted with the amount of data, alarms, inputs, and information they have to deal with for each patient in a given day. The new generation of devices must be integrated and autonomous in order to minimize everyday tasks and information and automate tedious and repetitive tasks.
- **Reduction of human error and standardization** – Clinical evidence shows that the introduction of drug traceability systems in hospitals is the most effective way to reduce treatment errors, as well as to improve the efficiency and quality of care of medical staff (Romero M. et al., 2019). It is recommended to use technology that promotes standardization in diagnostics and in the use of medication in order to reduce variability, especially in the phase when the medication is prepared in a hospital unit.

Ireland

The Irish National Cancer Information System (NCIS) project is managed by the *Irish Health Service Executive's National Cancer Control Programme*. The NCIS is a computer system that can record information about the oncology patient, diagnosis, and systemic therapy. The digitalization of medication management is a key driver of the NCIS. It was created in response to requests identified by healthcare professionals who provide care services for oncology patients and began operating in 2019. The aim is to eventually introduce the NCIS in all 26 public hospitals in Ireland that provide oncology services.

The NCIS addressed key issues, such as the lack of a system for sharing information between hospitals, difficulty in obtaining patient records, and the absence of a

centralized IT system. The platform ensures that all relevant healthcare providers have access to patient data in an appropriate and timely manner. In addition, the NCIS has several key functions that can be used by a variety of healthcare professionals, including prescribing, electronic medication administration records, support for aseptic medication preparation, multidisciplinary team meetings, and medication management. One implementation provides access to cancer data in a standardized way and overcomes many of the barriers associated with data sharing. This standardization and data collection can also support wider research applications.

The project is making a significant difference to patients receiving systemic therapy in Irish hospitals by enabling digital support for the prescribing and administration of cancer medicines. This successful project demonstrates the importance of digitizing medication management to generate harmonized data for treatment assessment, research, and artificial intelligence.

Germany

In September 2020, the Hospital Future Act (*Krankenhauszukunftsgesetz*, KHZG) was adopted following a series of political and legislative decisions to support the transition of the German healthcare system to digital healthcare systems. The goal of the *Hospital Future Act* is to encourage investments in IT infrastructure and digital solutions in healthcare. The act is a unique opportunity for German hospitals to modernize their medication management systems and create a resilient hospital medication supply chain that can absorb shocks from unexpected events, supporting Germany's path to digital transition. With access to the EUR 4.3 billion "Hospital Future Fund," hospitals can invest in capacities for emergency cases, digital infrastructure, development and strengthening of regional care structures, and IT security. The eleven eligible projects under the legislation include digital medication management systems, digital care and treatment documentation, and the establishment of partially or fully automated clinical decision support systems. The establishment of digital medication management systems in German hospitals is expected to provide information on all medication-related treatments throughout the healthcare process and increase patient safety from medication therapy. Emphasis is also placed on system interoperability, including technical, structural, process, and multidisciplinary communications. Funding may also cover investments in qualified personnel needed to implement and enforce the measures envisaged. The act, described as "Europe's biggest digital healthcare investment opportunity", will also impose penalties on hospitals that receive funding but do not introduce eligible digital services by 2025.

Active involvement of patients in measuring treatment outcomes

Patient-Reported Outcome Measurements allow the provision of highly effective healthcare. Leading healthcare systems use **PROM (*Patient-Reported Outcome Measurement***) to support optimal decision-making regarding the quality of medical services and reduction of treatment costs. PROMs are validated instruments that use the patient's answers to questions to create a measurable value of a health outcome or health status. PROMs allow the physician to understand a patient's specific symptoms—for example, depression, anxiety, or pain level—from the patient's perspective. When a patient's initial PROMs are compared to those of other patients with a similar condition, both the patient and physician can understand whether it is worthwhile to continue with the planned treatment. As an example, we can take the case where PROM results, collected after previous patients' surgeries, help the new patient set realistic expectations regarding pain and functional ability in the weeks and months after surgery. Shared decision-making, a core principle of high-value healthcare, has been shown to reduce the cost of public healthcare. Up to 20% of patients who participate in the joint decision-making process choose less invasive surgical procedures as a form of treatment. Shared decision-making empowers patients to choose treatments based on their values and preferences, but patients often do not have adequate information to make fully informed decisions; for example, how exactly does my current pain level compare to the pain I'm likely to experience during rehabilitation or after full recovery? PROMs help the physician show how an individual patient's response results compare with those of similar patients to facilitate a shared decision-making process. As patients realize that PROMs can assist in making decisions about major surgery, they will likely gravitate to facilities that use such measures. This will allow for value-oriented healthcare systems to prepare for **the introduction of PROM procedures in order to make harmonized decisions of patients and healthcare professionals,** which will ultimately be their competitive advantage in the market. Pioneers in that process discovered that the preparation for the introduction of PROM as an optimal decision-making process takes years. That is why the PROM journey should start with doctors, experts in specialties where PROMs have been confirmed and understood as a valuable criterion in making optimal clinical decisions. Physicians should be able to convince their colleagues that the use of PROM is good for their patients.

Estonia

Philips, Nordic Healthcare Group, and Meditsiinigrupp have developed a "Stroke Patient Pathway" pilot project in Estonia in cooperation with the Estonian Health Insurance Fund (EHIF). In a two-year period, all parties implemented IT solutions for measuring the outcomes and costs of care for patients who experienced an ischemic stroke. The goal of the "Stroke Patient Pathway" pilot project is to improve the quality

of life of patients through the development of a more integrated care pathway from the patient's perspective. The pilot consists of three main parts – different development projects run by four hospitals. For the first time, Estonia is beginning to measure patient-reported outcomes and is testing a new, bundled payment model for the entire care pathway of stroke patients. It is known from the experience of other countries that it is important to have an IT system capable of supporting this type of pilot project. Every year in Estonia, approximately 3,200 people experience an ischemic stroke. Patient mortality within one month after a stroke is approximately 20, while 45 stroke patients who survive will continue their lives with some degree of functional impairment. Due to the high disease burden and its fragmented and complicated care pathway, ischemic stroke was chosen as the focus for the first pilot project. Measuring and benchmarking outcomes, including patient quality of life and costs, is a vital part of the pilot project. The pilot project includes 4 out of 6 hospitals in Estonia providing acute stroke care, so it will be possible to compare hospitals through different perspectives: patient-reported outcome measures, clinical outcome measures, and costs. Benchmarking enables the discovery of best practices and learning from them. If the process is successful, the measurement can be extended in Estonia to other hospitals and diseases. In the pilot project, data on patient health outcomes will be collected and analyzed using Philips patient-reported outcome measurement software via standardized and validated questionnaires. Financial data will be provided by EHIF. NHG, which became ICHOM's (International Consortium for Health Outcomes Measurement) certified implementation partner in Europe in 2019, will combine this information into a visual monitoring platform, creating a correlation between data on real costs and outcomes. Through the monitoring platform, experts can compare results and costs between individual hospitals, including the clinicians' results. Hospitals are also acquiring knowledge to improve the treatment and recovery of stroke patients. Standardizing outcomes in relation to the initial situation of the patients enables comparable indicators, such as the ability of the patients to live a normal life, the successful return to work, and the progress of the care process. In addition to measuring and benchmarking results, Estonia is testing a new payment model, which is a single fixed price for the entire course of treatment for a stroke patient over 365 days. There are seven fixed prices, depending on the treatment group and age, since these characteristics are the main cost drivers. In the payment model, the primary service provider bears the financial risk for the patient's entire care pathway during the first year. This model gives the service provider the motivation to plan care more fully to avoid complications and gives a higher degree of freedom in line with the needs of the patient.

Implementation of a preventive project

In order to advance the digitalization of healthcare, AmCham also proposes the implementation of a pilot project in **preventive medicine**.

In Croatia, more than 3,000 new lung cancer cases are detected annually. Almost 90% of all lung cancer patients are smokers or ex-smokers. The five-year overall survival of advanced lung cancer is 18% in the USA, 8.9% in Europe, and about 6% in the Republic of Croatia. In its early stages, lung cancer is a potentially curable disease with a five-year survival rate of 66–82%.

The goal of the preventive program is to detect lung cancer in the first stage of the disease (National Lung Cancer Prevention Program, 2020). Detection and treatment of patients at an early stage of lung cancer, in addition to reducing mortality by 14% (U.S. Preventive Services, 2021) also has financial benefits. In the USA, the treatment of a patient with a lung tumor in the early stage is $28,000, and in an advanced stage, it is $179,000 (IQVIA, 2022).

The goal of the pilot project is to **upgrade the existing information systems** so as to consolidate all available data on the preventive program in one place, such as health, financial, and outpatient data collected through surveys, etc. Preventive programs have proven to be the most optimal part of the healthcare system for developing an upgraded centralized information system. They include the target patient population, the target specialist profession, and the institutions where they are carried out, and enable the easier establishment of standards for working with data. From the point of view of IT infrastructure, the advantage of preventive medicine is that it does not require the creation of a highly complex system. In prevention, there is no need to develop real-time systems that need to be implemented in curative medicine. Therefore, the financial cost of developing and maintaining an upgraded preventive information system is lower.

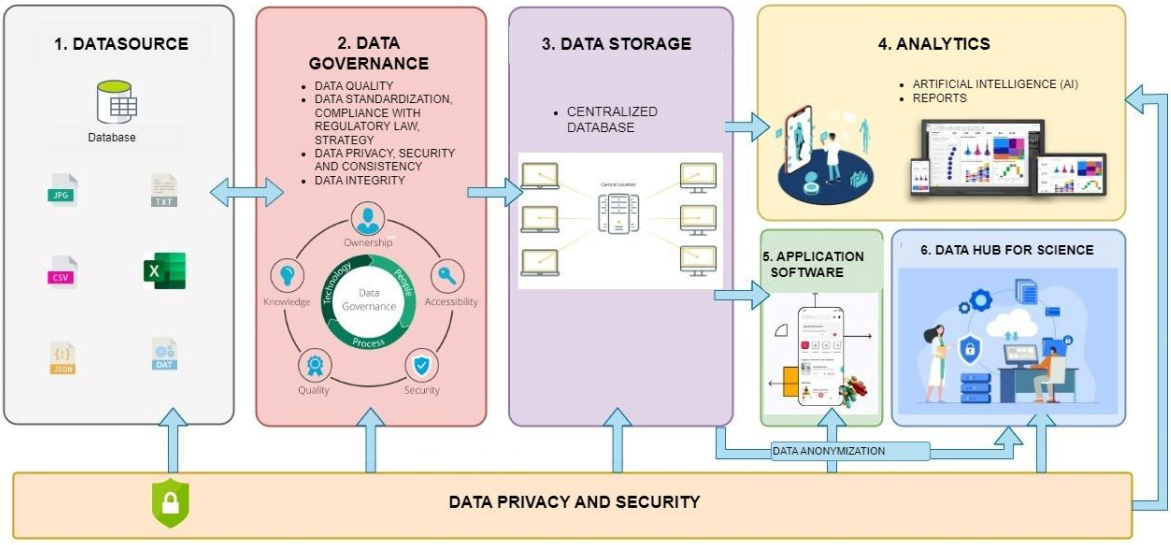


Figure 1 IT architecture proposal for a preventive project

When planning and implementing a preventive project, it is recommended to consider the following steps (Figure 1):

1. The first step when planning a preventive project is to assess the state of available data sources. Structured and unstructured data, such as tabular data (e.g., database, Excel tables), text data, images, signals, etc., are used as data sources. Currently, there are several challenges related to data in healthcare that need to be addressed, such as the partial connection of the health information system between institutions, the non-existence of standards when entering, processing, and applying data, incomplete statutory regulation of health data analysis, etc. The data in the healthcare systems often do not follow the latest trends in the behavior of the population. For example, the only visible data related to smoking in the health records is whether someone is a smoker or not. Currently, no system monitors the use of alternative nicotine products such as electronic cigarettes, heated tobacco products and nicotine pouches. The recommendation is to harmonize such outdated data with the real situation in the field in order to obtain high-quality, new data on the number of smokers and the number of users of electronic cigarettes, heated tobacco products, nicotine pouches, etc.
2. To establish a **comprehensive interconnection of the healthcare system**, it is necessary to include experts in individual areas who will participate in **creating documentation** on health, legal, strategic, and financial standards. **The introduction of standards** will improve interconnection and cooperation between institutions and departments within the healthcare system. The goal of establishing standards is to **reduce financial costs** by eliminating double work, reduce the administrative burden within the profession, and increase the availability,

diversity, and uniformity of information needed by different institutions and departments.

3. To enable better visibility of various data (e.g., radiological images, ECG records, data from the Hospital Information System, etc.), it is recommended that the data be **integrated** and stored in a shared location. Storing data in one location will make it easier to control how the data is used. In addition to consolidating data in a single location, the manner in which the data is interconnected, including data integration, is crucial. Given that the goal is for the data to be viewed and used by different institutions and departments, it is important to involve experts in different fields in the project's conceptual solution.
4. **Analytics** in preventive medicine enables **simpler and more accurate early detection of chronic and malignant diseases**. One example is the early detection of suspicious lung lesions with the help of artificial intelligence. Scientists from the Massachusetts Institute of Technology and the Mass General Cancer Center have developed an artificial intelligence model called Sybil, which has an accuracy of 86–94% in predicting the development of lung tumors. Figure 2 shows four patients and their first LDCT findings (standard read radiological findings declared normal) and later findings where the tumor process is visible. The Sybil model detected suspicious lung lesions already on the first LDCT findings that were declared radiologically normal in patients who later developed lung tumors (Mikhael P.G. et al., 2023).

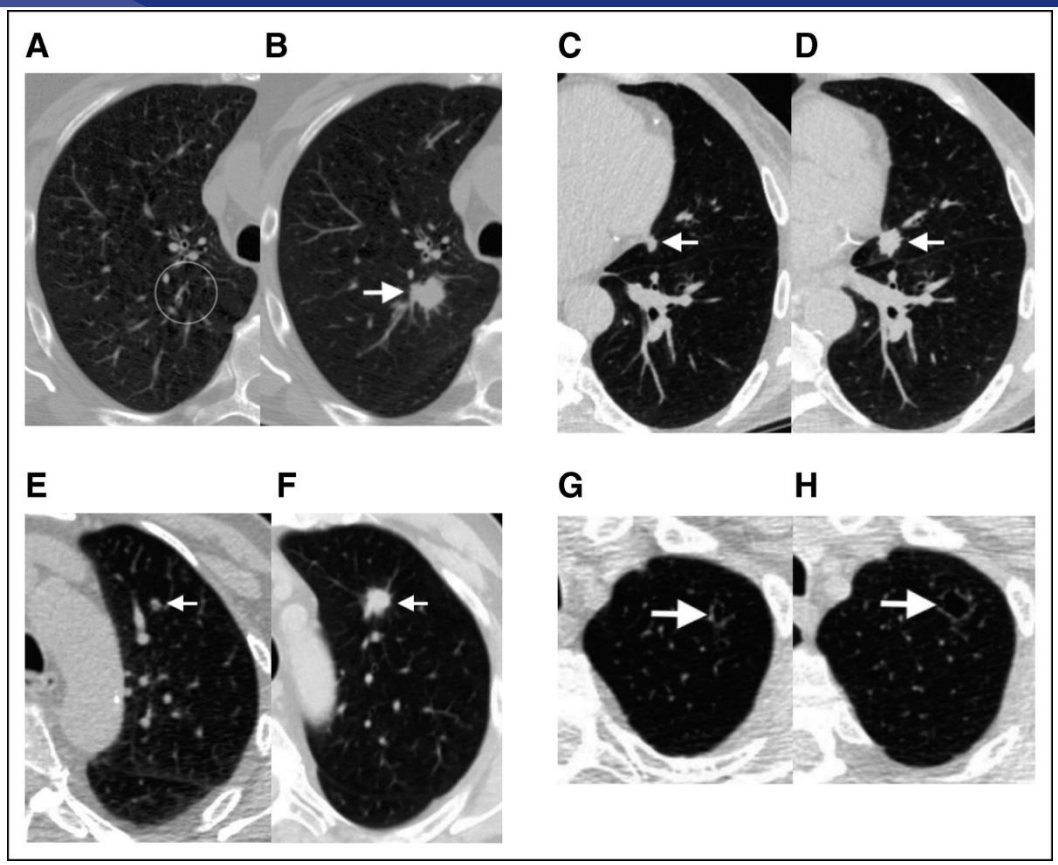


Figure 2 Example of screening LDCT findings from 4 patients (Mikhael P.G. et al., Sybil: A Validated Deep Learning Model to Predict Future Lung Cancer Risk From a Single Low-Dose Chest Computed Tomography, Journal of Clinical Oncology 41, no. 12 (April 20, 2023) 2191–2200.)

One example is the AI model, IQVIA Linguamatics Natural language processing (NLP), which analyzed text data, i.e., 1212 radiological findings read within 14 months. The purpose of the IQVIA NLP model is to alert doctors promptly about the received report in which the suspicion of a malignant disease has been raised. Performing 64 biopsies led to a confirmation of 37 malignant cases in the early stages of the disease.

Analytics can speed up and simplify the **evaluation of the effectiveness** of preventive programs, the **evaluation of the costs** of preventive programs and treatment, the **creation of new guidelines** for preventive programs, the identification of public health problems, and the monitoring of the health status of the population. Analytics can help in s**trategic decision-making** in medicine, etc. Figure 3 shows an example of business intelligence dashboards on the analysis of medicine consumption according to different segments, such as manufacturers, products, sales channels, trends in the last 12 months, geographical distribution, and contribution to growth in relation to product segments.

Figure 3 Business intelligence dashboard – Medicine consumption analysis (IQVIA, 2023)

5. The **application** for people who are candidates for a preventive examination can supplement the current booklets with instructions on preventive examination, appropriate survey questionnaires, and promotional leaflets on harmful factors to health.
6. A separate protected space for data storage, which will be used for **scientific and educational purposes**, could greatly contribute to the development of analytics in medicine at the national level. The goal of such a space is to enable uniform, high-quality data for scientific needs, easy access and use of data by accredited users, and facilitated collaboration between scientists.
7. In order to ensure the confidentiality of data, it is necessary to record technical, organizational, and legal risks of information technologies and continuously implement **security measures** when working with data.

Conclusion

The education of healthcare professionals must be focused on understanding and applying digital technologies in everyday practice. That includes training in the use of electronic medical records, telemedicine, medical analytics, data privacy, data ownership**,** artificial intelligence, and other relevant areas. Access to quality educational programs should be available to all healthcare professionals in order to ensure equal knowledge and skills for all.

Use of EU funds for the digital transformation of healthcare: European funds can provide financial support for the implementation of digital healthcare transformation projects. This includes applying for funds from relevant EU programs and funds, such as Horizon 2020 and subsequent programs, in order to ensure

additional funds for implementing innovative solutions and improving the healthcare system.

Pilot projects are crucial for testing new technologies and innovations before their wider application. It is necessary to select appropriate pilot projects that will cover different segments of the healthcare system and identify potential advantages, challenges, and opportunities. The evaluation of the results of these projects allows for the adjustment of strategies and the optimization of implementation before wider scaling.

Patients should be **active participants** in the process of digital transformation of healthcare. This can be achieved by educating patients about digital tools and the possibilities they provide, such as electronic access to their medical data, telemedicine, mobile health monitoring applications, etc. It is necessary to ensure the accessibility and comprehensibility of digital tools for all patients, taking into account the special needs of different groups.

Drafting specific **legislative regulations** is essential to ensure security, privacy, and interoperability of systems. There is a need to develop clear guidelines and regulations governing the use of digital technologies in the health sector, including the protection of patient privacy, data security, and ethical issues. The use of sanctions, as introduced by the example of Germany, for organizations or individuals that do not comply with the prescribed standards can also encourage compliance and advance the digital transformation of healthcare.

The successful implementation of all proposals requires a **close connection between the Ministry of Health and the Croatian Health Insurance Fund**. The cooperation between these two institutions facilitates the harmonization of strategies, the sharing of resources, and the establishment of efficient communication channels. Regular meetings, joint planning, and progress monitoring will facilitate the optimal use of resources and the achievement of common goals in the digital transformation of the healthcare system.

When it comes to initiatives, above all, a **clear and comprehensive strategy** is needed to ensure the following:

- All the needs and requirements of Healthcare Digitalization have been identified,
- All strategically important stakeholders have been involved,
- Full scope of digitalization with medium and long-term goals has been defined,
- Data sources to be used have been defined, quality standards and procedures for data processing, and required types of analytics have been introduced.

Considering Croatia's membership in the EU and the current availability of funds intended for digitalization, it is necessary to **drastically increase the quality of project planning and the efficiency of the use of funds**.

Adopting and implementing a comprehensive digitalization strategy would bring:

- Data quality and security – the basis for quality analytics;
- Capacity and resource management – better system efficiency;
- Optimizing the quality of healthcare services;
- Population health management through prevention – based on evidence and registries;
- Analytical research solutions.

The measurement of outcomes and the use of data are key to the successful digital transformation of healthcare in Croatia, as they facilitate monitoring the impact of new digital technologies on the healthcare system. Reaching a greater level of digital maturity in healthcare would bring opportunities to collect evidence on treatment outcomes. Many more digitally mature countries have implemented the use of data at the patient level, which brings them opportunities to compare treatment outcomes and optimize treatment methods. The implemented use of information would enable the adoption of effective preventive healthcare strategies. Furthermore, advanced HTA analyses are another area that brings savings and optimization of spending within the healthcare system and provides space for the implementation of innovations, such as systems for the early detection of infectious and chronic diseases that enable early interventions and improved patient outcomes. **The implementation of quality registries** can significantly contribute to the improvement of key parameters of the Croatian healthcare system – primarily quality and costs (through financial consolidation by realized savings). In addition to being a prerequisite for the rational functioning of areas of the healthcare system within their scope, quality registries also represent an exceptional opportunity for the rapid advancement of specific areas of Croatian medicine. Quality registries can relatively quickly show that the best Croatian healthcare professionals / healthcare organizations are not only capable of providing outstanding treatment outcomes to patients in Croatia but based on improved clinical practice and results, they can turn out to be at the level of their European colleagues. It is, therefore, imperative that the healthcare administration implement measures to enable examples of best practice quality registries to start appearing as soon as possible. They will provide very valuable guidelines and momentum for further and wider introduction of registries in the areas of key diseases with all the aforementioned synergy and cumulative effects on the quality of outcomes, the efficiency of the healthcare budget, and, what is equally important, the reputation of Croatian medicine and healthcare professionals / healthcare institutions in the country and at the international level.

It is necessary to adopt measures that **recommend and encourage the digitalization of medication management pathways and automation in healthcare institutions** in order to improve patient safety, the well-being of healthcare professionals, and the resilience of hospital systems, standardize

processes and the collection and exchange of data within interoperable systems, bridge problems of lack of professional staff and achieve greater efficiency and savings in hospitals, and more reliably collect information on availability/shortages of medicines within the hospital system. It is also necessary to support the **development of digital skills of healthcare professionals** to ensure that trained experts support change management for the implementation of the digital transition of hospitals in Croatia.

For this purpose, funds from the Recovery and Resilience Facility are also available to Croatia, and the National Recovery and Resilience Plan provides for investments from the mentioned area in the following items: C5.1. R4-I1 (Central preparation of parenteral preparations in 8 Croatian hospitals), C5.1. R4-I2 (Introduction of a unit therapy distribution system in 40 Croatian hospitals), C5.1. R4-I3 (Digitizing medicine tracking through healthcare institutions at secondary and tertiary levels of healthcare), C5.1. R4-I4 (Development of a medicines shortages monitoring and prevention system in Croatia).

For additional information, please contact:
American Chamber of Commerce in Croatia
Andrea Doko Jelušić,
Executive Director
T: +385 1 4836 777
E: andrea.doko@amcham.hr