January 2023

EUROPEAN DATA SPACE IN HEALTH

Interconnecting Innovation Ecosystems for Common European Data Space in Health

Funded by the European Union

D2.2 CASE STUDY: CZECH REPUBLIC

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History of Versions

Version	Date	Changes	Page (if applicable)
V0	12/12/22	Draft	N/a
V1	21/01/23	Advanced draft, reviewed by Czech Republic Representatives	N/a
V2	31/01/23	Final version	N/a

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Executive Summary

The present Deliverable 2.2 "Case Study Czech Republic" has been developed within the framework of WP2 "Analysis of ecosystems and innovation agendas" of **EDAH**.

EDAH (Interconnecting innovation ecosystems for common European data space in Health) is a 2-year preparatory action funded by Horizon Europe that aims to contribute to the development of the European Health Data Space. The 4-partners-consortium seeks to establish close collaborations with the EU presidencies during the project's lifetime, to help prioritise EHDA in their successive agendas. EDAH also seeks to engage a wide range of quadruple helix stakeholders from diverse innovation ecosystems across Europe in identifying barriers and enablers to EHDS, channelling the different Member States' inputs into EU policy processes. By bridging the current digital health divide in Europe, EDAH contributes to the New European Innovation Agenda with more inclusive, dynamic, diverse and interconnected European innovation ecosystems

EDAH aims to unlock the power of health data for innovative medicines and future healthcare by helping develop the European Health Data Space.

The project's key milestones are:

- Set an open dialogue to facilitate the agreement among Member States, Associated Countries and EU Regions about key aspects related to EHDS.
- Advancing towards common legal, governance, data quality and interoperability framework to facilitate the advancement of EHDS.
- Scaling up good practices and addressing important gaps in the regional and national innovation ecosystems, through a better understanding of the digital health innovation landscape.

The following report is the second of a series of 7 case studies produced in this project (namely, Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria). The studies are connected to the EU presidencies happening during the timespan of this preparatory action (September 2022 to August 2024), corresponding to the end of Czech Republic's, Swedish, Spanish, Belgian and the initial weeks of Hungarian Presidency.

The Czech Republic held the Presidency of the Council of the European Union from 1 July to 31 December 2022. In this period, there have been a number of results in the legislative and non-legislative areas. For the purposes of this report we have followed the results on the Health area, particularly regarding digital health and health data (discussed at the Employment, Social Policy, Health and Consumer Affairs Council). According to official sources[1], a significant part of the Presidency was devoted to continue the discussions regarding the European Health Data Space, conducting to agreements on wording of chapters of the proposal, particularly regarding electronization of healthcare in the EU.

Czechia's decentralised health care is characterised by information systems with limited interconnection, with large amounts of data being collected centrally. Prior to the pandemic, limited data were shared widely, and this was typically done in an aggregated form, often with time delays to allow for collection and validation. Moreover, digitalisation of health care has been slow in Czechia. In 2019, only 9 % of physicians had all their patient records in electronic form (with 20 % keeping them solely on paper) (ČSÚ, 2020). After the pandemic, digitization and digitalisation of the healthcare sector has become a hot topic in the Republic. The

[1] https://czech-presidency.consilium.europa.eu/en/

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Government intended to use around €1.6 billion of the €7.2 billion from the National Recovery Plan to develop e-government, e-commerce and digital transformation,

In the following pages the authors gather information from primary sources about the healthcare innovation agenda of the country, the level of digitalisation, and the main legislation providing legal framework to this field.

This report has been elaborated by the Council of European BioRegions (EDAH consortium partner, WP 2 leader) and Biocat (coordinator). The public sources used are listed as footnotes. An interview was conducted with members of the Permanent Representation of the Czech Republic to the European Union. We thank Mr. Petr Čermák (Health attaché) and Mr Dalibor Vojta, members of the Permanent Representation of the Czech Republic, Ms Renáta Pfefferová, Project Manager at the Czech Republic National Cluster Association and Mr Jakub Havlín, Project manager at DIGI2Health, the digital innovation hub in Olomouc focused on telemedicine.

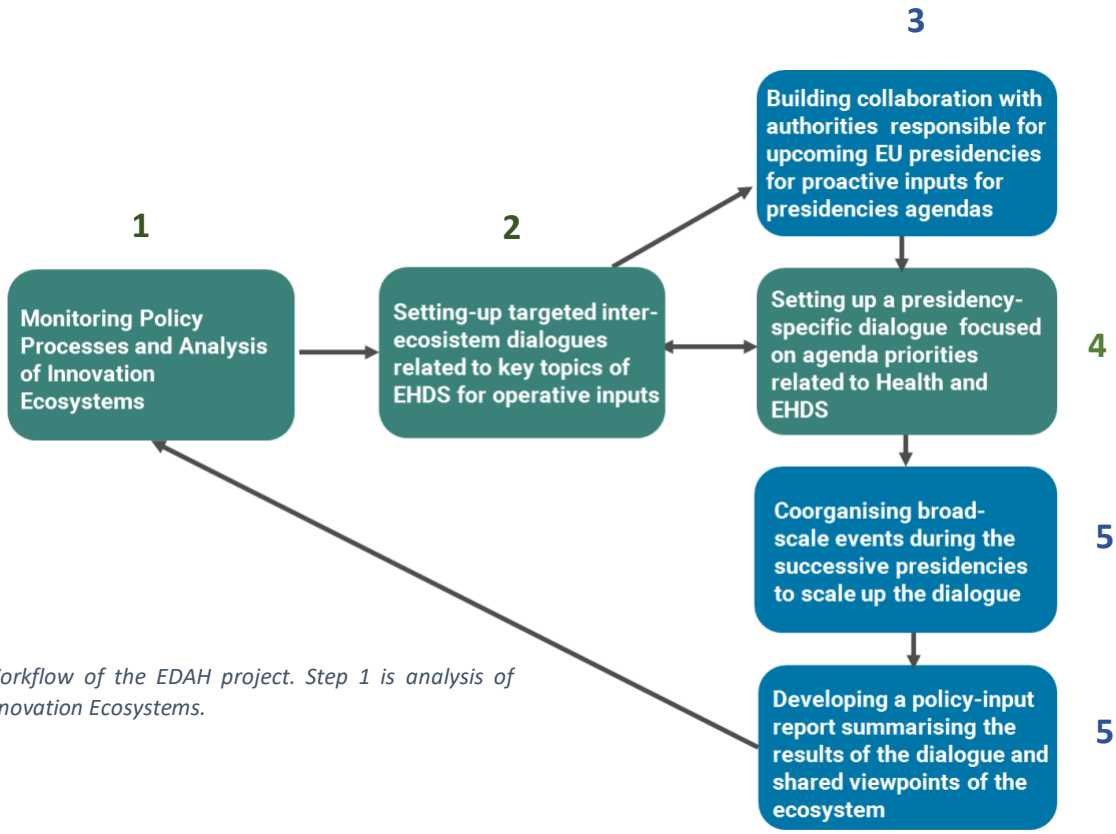
The EDAH consortium presented the project at a large scale event linked to the Czech Presidency in Prague on November 29th, at a panel discussing the role of Digital Health and Health Data for Europe's resilience (see picture below).

Introduction to this report

Specific objectives of EDAH

The partnership implementing EDAH has five specific objectives:

- O1 – Ensuring a coherent overview of the (ongoing) strategic developments related to the European Health Data Space (EU level policy processes, important initiatives and projects) and developing a deeper understanding of seven important EU ecosystems (innovation agendas and ecosystem stakeholders) represented by clusters/networks from Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria.
- O2 – Setting up a coordination mechanism to connect important stakeholders from innovation ecosystems all around Europe and engage them in focused dialogue around key challenges and opportunities related to advancing the EHDS.
- O3 – Scaling up the dialogue at the EU level via developing further collaboration pathways with EU presidencies.
- O4 – All of the above will be used for, step-by-step, developing, validating and finalising the Joint Action Plan (JAP) for synergetic work in the interconnected ecosystems of EU health-related clusters/ networks (facilitated by the dialogue mechanisms and collaboration frameworks developed in this project) to jointly advance the development of the EHDS.



Workflow of the EDAH project. Step 1 is analysis of Innovation Ecosystems.

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List of consortium partners and beneficiary numbers

Beneficiary No.	Name	Acronym	Country code
1	BIOCAT LA FUNDACIO BIOREGIO DE CATALUNYA	Biocat	ES
2	HEALTH CLUSTER PORTUGAL	HCP	PT
3	SCANBALT	ScanBalt	EE
4	COUNCIL OF EUROPEAN BIOREGIONS	CEBR	BE

Work Package 2 – Analysis of ecosystems and innovation agendas

Objectives

- Monitoring and analysing strategic EU-level processes related to the development of the European Health Data Space;
- Getting in-depth understanding of seven key innovation ecosystems, namely in Portugal, Czech Republic, Sweden, Spain, Belgium, Hungary and Bulgaria;
- Based on the above, identifying good practices, potential for synergies and complementarities in innovation agendas and with ongoing initiatives/processes to advance the development of EHDS as a joint effort of EU interconnected innovation ecosystems.

Task 2.1 Scanning strategic developments regarding European Health Data Space

The consortium will continuously track advancements in various important EU-level policy processes, monitor progress related to important initiatives such as TEHDAS and GAIA-X (e.g., key milestones achieved), relevant new studies and analyses, etc. This information will be processed and analysed to identify potential synergies, needs for action and inputs by EDAH to support important developments in line with the idea of more dynamic, inclusive, gender diverse, and connected innovation ecosystems for the joint development of the European Health Data Space, fostering innovation in industry and the public sector.

The work under this task will materialise into **monthly Strategic Progress Updates** (SPUs) prepared for the monthly EDAH Coordination Working Group meetings. The SPUs will cover the key developments as well as suggestions for related response and actions in the context of the EDAH project.

Task 2.2 Carrying out case studies. Task leader: CEBR. Contributors: all partners

Case studies on **seven key EU clusters/networks** will be carried out in order to 1) facilitate learning from various good practices of strong EU clusters/networks in advancing digital health and related innovation in their regions/ countries as well as good practices related to quadruple helix collaboration; 2) reach a better understanding of the ecosystems and innovation agendas of these clusters/networks; 3) five case studies will additionally focus on the possibilities of advancing specific topics related to the EHDS in the context of the upcoming EU presidency in the clusters´/networks´ country of origin. The clusters/networks selected for case studies represent Portugal, Czech Republic, Sweden, Spain, Hungary, Belgium (the five upcoming EU presidency countries), and Bulgaria (as an example of current Modest Innovator region, to get insights about key needs for development in terms of digital health and related ecosystem in such context).

1 – Czech Republic Ecosystem Overview

BASIC DATA

Data for 2022 indicate that Czech Republic has a population of approximately 10.7 million inhabitants[2] and a surface of 78,886 km^2, with a population density of 139 inhabitants per km^2. It has a GDP of 238,238 million euros, which represents an increase of 2.9 % in comparison to the previous year.[3] In 2020, life expectancy at birth in Czechia was 78.3 years, which is 2.3 years below the EU average, although it was among the highest in central and eastern European countries.[4]

The Government of the Czech Republic holds executive power as a unitary parliamentary democratic republic. The President is the head of the state who appoints the Prime Minister (Chairman of the Government), the head of Government.

The Czech constitution provides for a bicameral Parliament that is responsible for final decision-making to approve new legislation. The 200 members of the Chamber of Deputies (Poslanecká sněmovna) are elected for four-year terms, while the 81 members of the Senate (Senát) are elected for six-year terms. As the head of government, the prime minister is the government's chief representative and is responsible, among other duties, for organizing the activities of government and choosing government ministers.

In the moment of publication of this report, a new president of the Republic was elected (second rounds 27 and 28 January), Petr Pavel, and was expected to assume office on 9 March. The President has executive powers to appoint or dismiss the cabinet although no major changes are expected at that point, according to some experts consulted.

HEALTH SYSTEM

The Ministry of Health is the primary regulatory authority responsible for setting health care policy, overseeing the system and managing several health care providers. It supervises and works in close collaboration with its subsidiary bodies: the National Institute of Public Health, the Institute of Health Information and Statistics, the State Institute for Drug Control and the regional public health authorities.

The government proposes new legislation for the health sector to the Parliament, usually through the Minister of Health. Moreover, the public sector is further represented by 14 regions, districts and municipalities, which establish and direct various health-care facilities and have responsibilities in licensing and supervising providers.[5]

Czechia's health expenditure in 2019 was 7.8% of GDP and 2.362€ per capita, both significantly below the EU averages (9.9% and 3.521€).

A comparison between the Czech Republic and countries with similar expenditures and institutional characteristics suggests that health outcomes remain partially inadequate. OECD benchmarking shows that the Czech health condition is still below Slovenia, Korea and Greece, even after taking into account other differences in lifestyle and social factors. This indicates that, at the current level of funding, it is possible to increase efficiency and improve health results in the Czech healthcare system.[6]

2 https://countrymeters.info/es/Czech_Republic
3 https://data.worldbank.org/indicator/NY.GDP.MKTP.KD.ZG?locations=CZ
4 https://read.oecd-ilibrary.org/social-issues-migration-health/czech-republic-country-health-profile-2021_8b341a5e-en#page1
5 https://www.euro.who.int/__data/assets/pdf_file/0005/280706/Czech-HiT.pdf%3Fua%3D1
6 https://www.oecd.org/economy/surveys/Czech-Republic-2018-OECD-economic-survey-overview.pdf

Since the early 1990s, the Czech Republic has had a system of social health insurance (SHI), highly regulated by the Government. Most health expenditure is financed from public sources, predominantly through the SHI contributions (consisting of wage-based contributions for employees from employers, income-related contributions from self-employed people and state contributions for specific groups of economically inactive people), supplemented by funding from state and territorial budgets, EU funds and private expenditure. There are seven public health insurance funds operating as payers and purchasers of care. However, the market is concentrated: the largest health insurance fund (VZP) insures 56 % of the population.[7] Joining the health insurance fund is compulsory, and the health insurance funds must accept all applicants who, according to the constitution, are eligible to join the fund.[8]

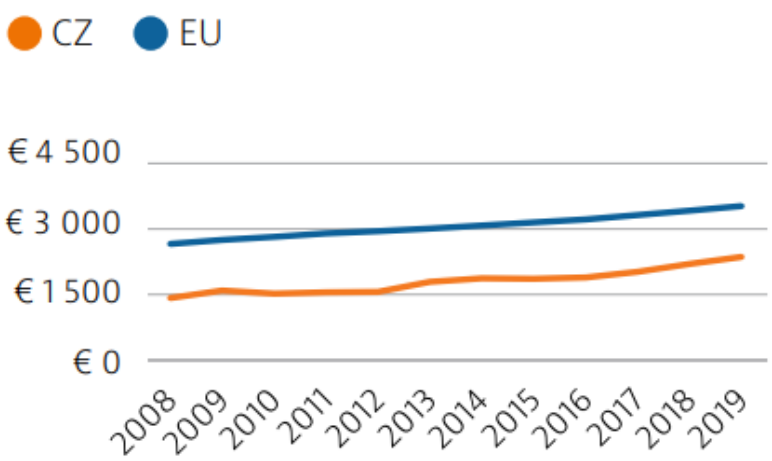

Figure 1: Per capita spending (EUR PPP). Source: Czech Republic: Country Health Profile 2021

Czechia's decentralised health care system is characterised by information systems with limited interconnection, through which large amounts of data are collected centrally. Prior to the pandemic, limited data were shared more widely, and this was typically done in an aggregated form, often with year-long or longer time delays to allow for collection and validation. Moreover, digitalisation of health care has been slow in Czechia. In 2019, only 9 % of physicians had all their patient records in electronic form (with 20 % keeping them solely on paper) (ČSÚ, 2020).[4]

Data from functional registers and annual departmental statistical surveys of the healthcare system can be summarized in the following manner:

HOSPITALS

There were 265 hospitals in Czechia in 2021, a number that has remained stable since 2005, 161 publicly owned hospitals and 104 private hospitals.[9]

[7] https://www.oecd-ilibrary.org/docserver/8b341a5e-en.pdf?expires=1672179439&id=id&accname=guest&checksum=EE94800D11C4C7170BBA590FDE1235E9

[8] https://www.eu-healthcare.fi/health-services-abroad/country-specific-information-about-health-services/czech-republic/

[9] https://www.statista.com/statistics/556792/hospitals-in-czech-republic/

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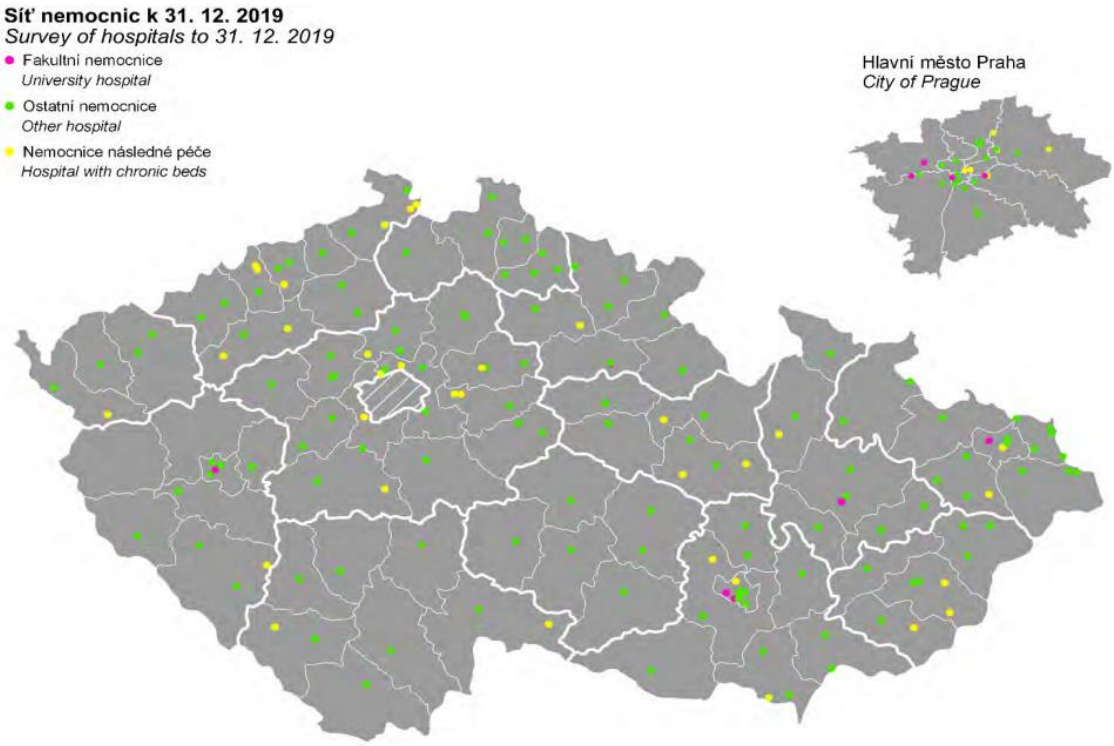

Figure 2: Distribution of hospitals in the Czech Republic. Source: Czech Health Statistics 2019[10]

HEALTH CARE PROFESSIONALS

Overall, the system quantifies the total capacity of physicians as approximately 42,000, followed by dentists (7,540) and pharmacists (6,460). Nurses and midwives report a total of 82,300 full-time active positions in the system. In 2017, the total number of jobs of employed healthcare workers was 214,797.

In the Czech Republic there are a total of about 4.0 physicians' jobs per 1,000 inhabitants, slightly above the average of OECD countries, but lower compared to similar healthcare systems such as Germany or Austria (4.1 - 4.3 jobs per one thousand inhabitants).

An important issue in the Czech Republic is the unequal distribution of physician capacities in the system, they are concentrated in the main cities, especially in Brno and Prague, where the available capacities exceed 6.5 doctors per 1,000 inhabitants. On the other hand, in the Central Bohemia, Ústí nad Labem, Liberec and Zlín Regions, the amount is lower than 3.3 jobs per one thousand inhabitants, which may also be interpreted as lower than the EU average.

In terms of gender equality, a significantly higher proportion of women than men graduate from medical faculties in the last decade (on average 64% to 36%).

[10] https://www.uzis.cz/res/f/008381/zdrroccz2019.pdf

With regard to the number of physicians in hospitals per capita, the Czech Republic does not differ from the average of European countries, with 225 hospital physicians per 100 thousand inhabitants, the same number as Germany. Quantitatively, the number of physicians is increasing slightly (about +250 to +350 full-time physicians join the health service provider system every year), and the number of inhabitants per physician is therefore declining due to a larger number of retirees, new graduates choosing other sectors outside of healthcare or going abroad.

The number of dental practitioners in outpatient care increased slightly between 2010 and 2017 period. This trend is positive, as it leads to the rejuvenation of this group of specialists.

In the Czech Republic, there are a total of approximately 7.8 nurses per one thousand inhabitants, which is moderately below average compared to the OECD countries. In contrast to physicians, the total number of general nurses in hospitals in the Czech Republic (8 per 1000 inhabitants) is lower than the OECD average (9 per 1000 inhabitants). The Czech Republic has one of the lowest numbers of nursing graduates within the OECD – 16 per 100,000 inhabitants – and a downward trend has been observed in recent years.[11]

PATIENT ORGANISATIONS

There are approximately 140 patient organizations in the Czech Republic[12]. The Patients' Council is an advisory body to the Minister of Health, composed of representatives of patient organizations, which provides a consultative service to the Minister.

In contrast, the National Association of Patients' Organizations was set up for advocacy and awareness-raising activities and is authorized to represent patients before state authorities. It also represents Czech patient organizations at international level.[13]

The Patient hub is a project of the Ministry of Health of the Czech Republic financed from European Economic Area and Norway Grants for 2014–2021. The Patient hub supports patient organisations, it is a space for the development, cooperation, and meeting of patients, experts, and the public in the sphere of health. The Patient hub's key activities include: operation of a shared working and community space in the Vršovice neighbourhood in Prague, organisation of a comprehensive educational program, administration of an interactive web portal, and organisation of awareness events for the public.[14]

[11] Strategic Framework for Health 2030

[12] https://pacientskeorganizace.mzcr.cz/res/file/dokumenty/media-poster_aj_final.pdf

[13] https://silapacientu.cz/en/about-us/

[14] https://www.pacientskyhub.cz/en/who-we-are

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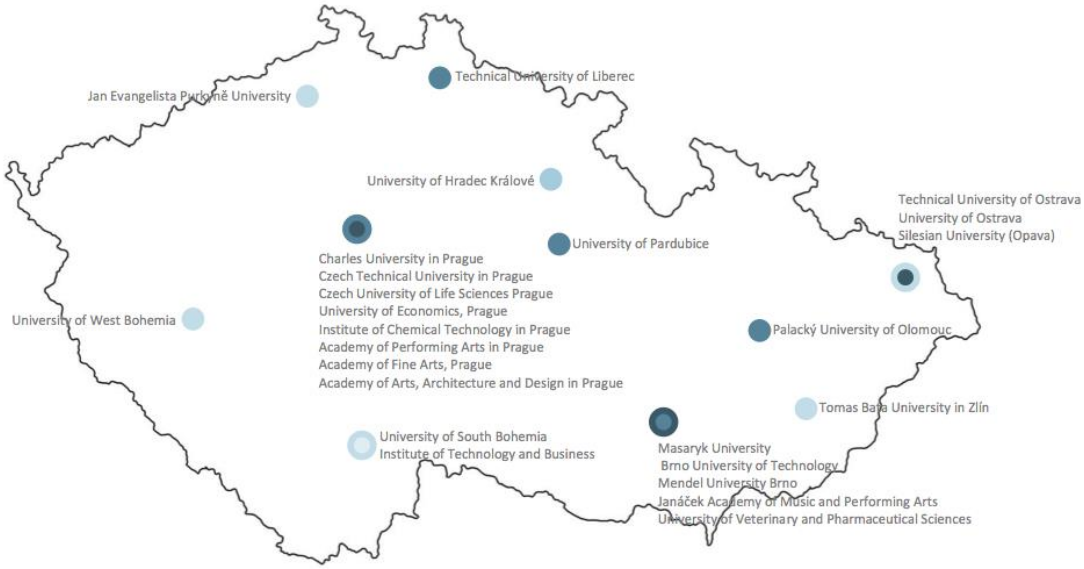
SCIENTIFIC AND RESEARCH CENTRES

There are more than 200 research organizations in the Czech Republic. Many of them are associated with universities and the Academy of Sciences, but there are also private ones among them.

UNIVERSITIES



Source: European campus research: locations of public universities in Czech Republic – the darker blue, the older the universities (George Tzovlas & Alexandra den Heijer 2013 https://managingtheuniversitycampus.nl/2013/04/29/bohemian-universities/

Universities comprise an essential part of the R&D infrastructure in the Czech Republic. Overall, there are 64 universities, 52 public and 12 private universities[15]. The following overview presents a selection of the main educational institutions of STEMM disciplines:[16]

Universities with a STEM focus

- Czech Technical University in Prague – www.cvut.cz
- Brno University of Technology – www.vutbr.cz
- VŠB – Technical University of Ostrava – www.vsb.cz
- Technical University of Liberec – www.tul.cz
- University of Chemistry and Technology Prague – www.vscht.cz
- Czech University of Life Sciences Prague – www.czu.cz

Universities with STEM-oriented faculties

- Charles University in Prague – www.cuni.cz
- Masaryk University, Brno – www.muni.cz
- University of West Bohemia, Pilsen – www.zcu.cz
- Palacký University, Olomouc – www.upol.cz
- Tomáš Baťa University in Zlín – www.utb.cz
- Mendel University in Brno – www.mendelu.cz
- Jan Evangelista Purkyně University in Ústí nad Labem – www.ujep.cz

[15] https://www.czechuniversities.com/catalogue-of-universities

[16] http://www.czech-research.com/rd-environment/universities/

- University of Hradec Králové – www.uhk.cz
- University of Ostrava – www.osu.eu
- University of Pardubice – www.upce.cz
- University of South Bohemia in České Budějovice – www.jcu.cz
- University of Veterinary and Pharmaceutical Sciences Brno – www.vfu.cz
- Silesian University in Opava – www.slu.cz

START-UP ECOSYSTEM

The Czech Republic is a country with a strong industrial sector whose economy has been advancing since 2008. In the recent years, the central government has been making an effort to encourage businesses in new technologies with investment incentives.

There are 44 investors identified and 208 start-up infrastructures in the Czech Republic, including start-up incubators, accelerators, business centres, digital innovation hubs, financial instruments, education, networks, areas of expertise and co-working places (Figure 3). [17]

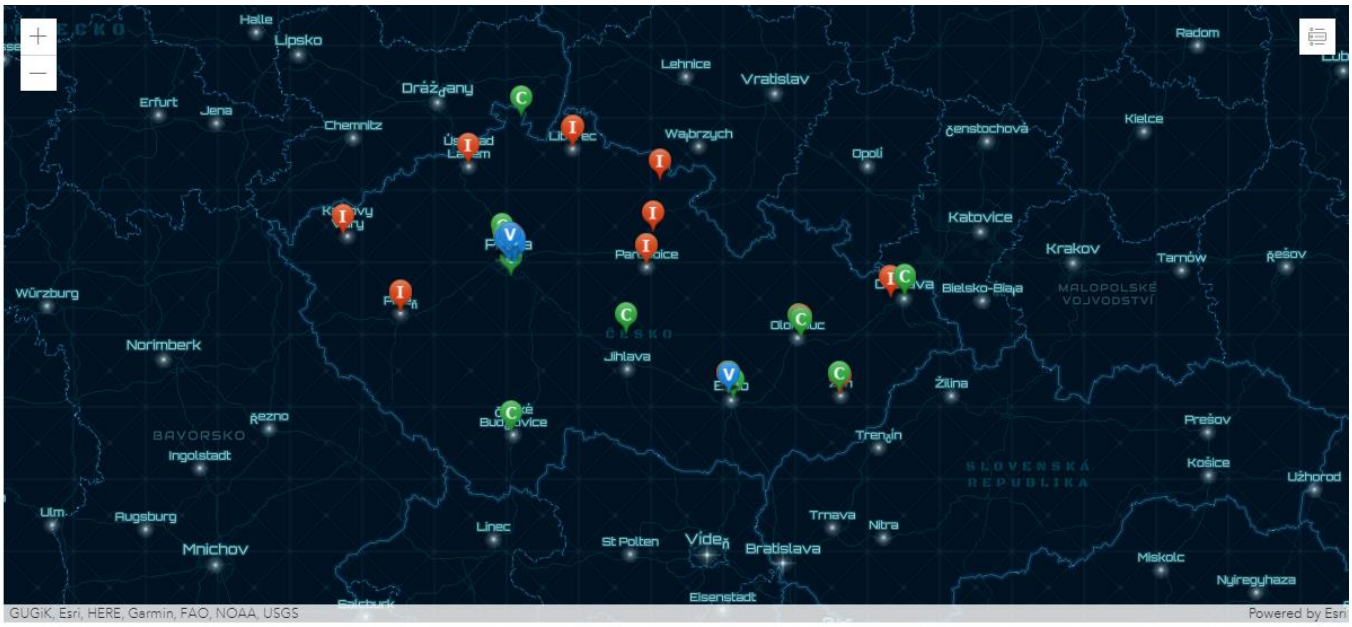


Figure 3: Interactive map of the start-up ecosystem in the Czech Republic. https://www.czechstartups.org/en/startup-ecosystem/

DIGITAL INNOVATION HUBS

European Digital Innovation Hubs (EDIHs) are one-stop shops supporting companies to respond to digital challenges and become more competitive[18]. These DIH[19] give support to start-ups, spin-offs and SMEs in e-

[17] https://www.czechstartups.org/en/startup-ecosystem/

[18] https://digital-strategy.ec.europa.eu/en/activities/edihs

[19] https://s3platform.jrc.ec.europa.eu/digital-innovation-hubs-tool?p_p_id=eu_europa_ec_jrc_dih_web_DihWebPortlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view

health. Four of these hubs are focused on the life sciences and healthcare sectors in the Czech Republic (Figure 5):

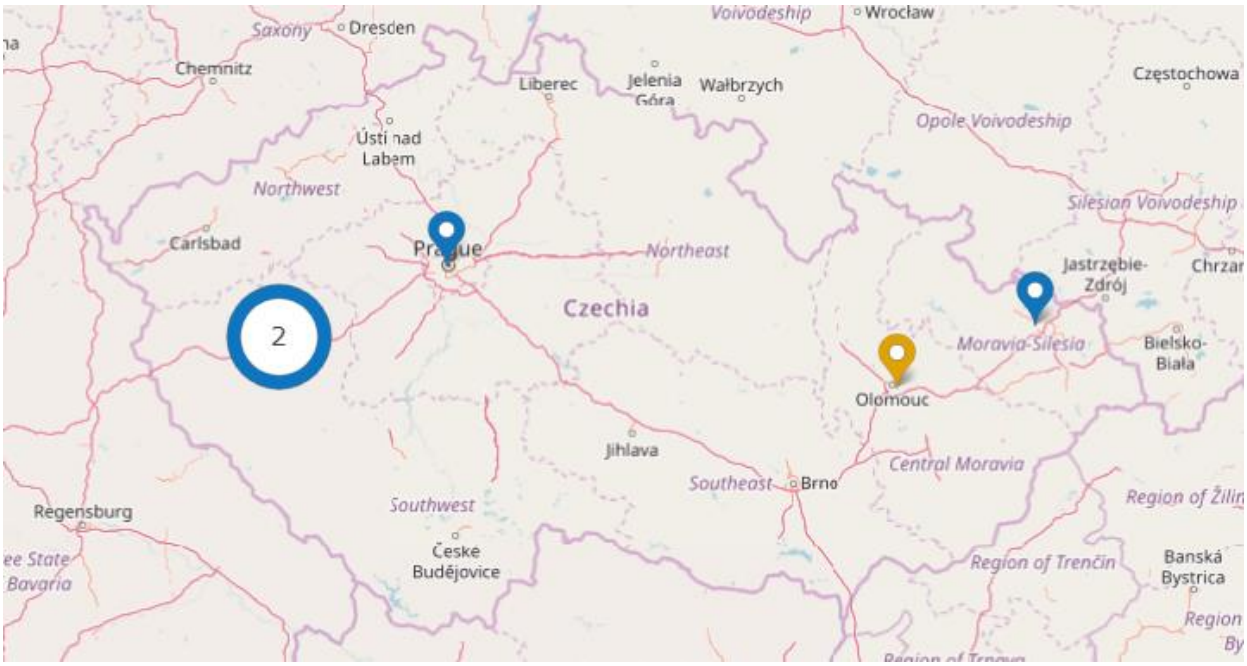


Fig 4: DIH of the Czech Republic related to Life Sciences and Health Sector

- **DIGI2Health**

DIGI2Health was founded by the Olomouc Faculty Hospital and the Innovation Centre of the Olomouc Region. It offers a scientific and commercial sphere to meet in a space created by The Czech National eHealth Centre at the Olomouc University Hospital, Science and Technology Park of Palacký University Olomouc, The Institute of Molecular and Translational Medicine at the Faculty of Medicine and Dentistry of Palacký University Olomouc or Tomas Bata Hospital in Zlín. They seek to foster technology transfer and share the academic work with small and medium companies. The aim of this cooperation is to develop digital technology, increase digital literacy and competitiveness of SMEs.

- **DIH HIVE**

DIH HIVE's goal is to help with the comprehensive implementation of the digitalization of the economy in the Pilsen and Karlovy Vary regions and to have a visible physical presence, working closely and successfully with other actors (universities and RTOs, chambers of commerce, training centres, SMEs and other companies, supply chains, consultants, etc.) as an important partner of a regional ecosystem. University of West Bohemia (UWB), as a founding member, is the main knowledge disseminator in the region.

- **IT4Innovations National Supercomputing Centre**

IT4Innovations National Supercomputing Centre at VSB – Technical University of Ostrava leads research, development, and innovation in the fields of High-Performance Computing (HPC), Data Analysis (HPDA), and Artificial Intelligence (AI) and their application to other scientific fields, industry, and society. IT4Innovations provides their supercomputing systems to research teams from both academia and industry.

- **Research Centre for Informatics**

RCI is the centre of scientific excellence focused on computer science and artificial intelligence. It promotes and integrates internationally competitive research conducted at Czech Technical University. The goal of RCI is to foster collaboration between the different stakeholders in the fields of computer science, fundamental sciences and application-driven research.

Furthermore, there are 212 HealthTech start-ups in Czech Republic. Here is a selection of some of the most innovative:

- **Kardi AI**

Provider of AI-based heart health monitoring device. The company offers a Polar chest belt to monitor the user's heart and the data gets transmitted to the user's phone and subsequently, it is streamed into the Cloud.

- **Photothera Labs**

Photothera has developed devices and patches for phototherapy that provide cold light (a combination of cryo and phototherapy) using electroluminescence used for the treatment of skin diseases, moderate depressive disorders, and diabetics-led vision loss. Some of the partners are PepMed, International Pharmaceutical Chemical Institute and The National Institute of Mental Health in Klecany.

- **Vitadio**

Vitadio is a provider of an online information platform for diabetic patients. It helps patients to manage weight, control glucose levels and improve quality of life. It provides information about weight reduction and treatment for diabetic patients. Furthermore, it offers solutions on how to decrease blood sugar and glycated haemoglobin (HbA1c). The app also supports patients in building new habits. The personal dietitian will be available on chat and video.

- **Futura Genetics**

Futura Genetics is a provider of software to assist clients in life insurance claims. The platform offers line genomic analysis, AI abilities, and tailored preventive care programs to provide life insurance clients genetically based medical recommendations.

- **ULekare.cz**

uLékaře.cz is an online platform that helps users to ask health questions and discuss health conditions with doctors in an open forum or privately. Furthermore, the platform provides health articles on various diseases.[20]

- **S-Case**

The Slovak-Czech telemedicine start-up S-Case, develops a portable diagnostics medical device to improve access to primary healthcare in more remote areas. Their diagnostic solution consists of a mobile, point-of-care medical device combining smart sensors with a digital patient database. Using AI technology, the device allows healthcare providers to communicate, visualize, and monitor their patients' data remotely.[21]

- **VR Medicals**

[20] https://tracxn.com/explore/HealthTech-Startups-in-Czech-Republic
[21] https://therecursive.com/5-czech-health-tech-startups-for-2023/

VR Medical is the only certified medical device using VR in rehabilitation available in the Czech Republic. It is a unique healthcare system helping patients to return to normal life, thanks to virtual reality, makes the physio and neurorehabilitation of patients faster.

- **UPOlife**

UPOlife provides a wearable biosensor for monitoring heart function. It monitors the patient for seven days and the data is evaluated by a team of cardiologists.

CLUSTERS AND ASSOCIATIONS OF THE SECTOR

There are several cluster organisations on life sciences and health field such as:[22]

CzechBio is an association of companies, renowned research institutions and universities operating in the Czech Republic. It offers guidance through the Czech biotech sector and partnership with biotech companies and academic institutions.

CZECHIMPLANT is the first medical cluster in the Czech Republic with a focus on implantology. It aims to provide a functional platform that unites leading manufacturers, universities and physicians in a combined effort to further develop the field of implantology.

The MedChemBio cluster in organisation with the goal of supporting the future development of Medicinal Chemistry and Chemical Biology.

The Science and Technology Park, Palacky University Olomouc helps transform good ideas into companies and provides the ideal environment for entrepreneurship in Olomouc. Its Technology Transfer division administrates UP intellectual property. It connects companies with Palacký University, provides commercial collaboration with firms in the areas of research.

2 – Existing legal framework

The following section provides an overview of the legislative measures for processing health data in the Czech Republic:[23]

2.1. Processing health data for the primary use of providing health and social care

1. Primary use of health data for purposes health and social care

Concerning the processing of health data for the provision of health care, Article 53, paragraph 1 of **Act No. 372/2011 Coll. "Health Services Act"**, regulates the use of medical records by healthcare providers. **Decree No. 98/2012** sets out the detailed content of various parts of medical records, as well as the periods during which medical records must be retained by the health care provider.

Act No. 89/2012 Coll., **The Civil Code** regulates the storage of medical records and the treatment of health data in Articles 2647 to 2650. Furthermore, the Civil Code addresses certain subjects not covered by the Health Services Act, such as the sharing of anonymised patient data for population health statistics (Art. 2650).

Act No. 378/2007 Coll., **Pharmaceuticals Act** sets out the E-Receipt information system, it establishes rules for the development, production, distribution, dispensation, use, control and disposal of pharmaceuticals.

2. Authorisation of health care providers or professionals to share health data with other health care provider or professional for health care provision purposes

[22] https://nca.cz/en/members-and-partners/

[23] https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_annex_en_0.pdf

The **Health Services** Act, Art. 51, paragraph 2, establishes that healthcare providers can share patient information (including health data) with other healthcare providers to ensure continuity of health services, in this case patient consent is not required.

E-prescriptions	The **Pharmaceuticals Act** describes the E-Receipt information system. This public administration information system is administrated by the State Institute for Drug Control and consists of the Central Repository of Electronical Prescriptions and the Patient's Medication Record. Physicians are required to issue all prescriptions electronically since 2018, except in specific cases listed by law. Cross-border e-prescription is expected to be available in 2023. E-prescriptions are stored for a period of 5 years from their creation in the Central Repository of Electronic Prescriptions. Please refer to Chapter 5 – GOOD PRACTICES for a detailed description of the initiative.
Patient's Medication Record	The shared electronic patient's medication record is established by art. 81d of the **Pharmaceuticals Act** and has been established since June 2020. Physicians and pharmacists have access to data stored on the patient's medical record. This access is based on the opt-out principle, and is mainly intended to provide healthcare and ensure patient safety (it helps doctor's prevention of undesirable drug interaction and assess possible duplications).
Patient summary	The patient summary is referred in the Article 56a of the **Health Services Act**. Health care providers can decide whether they want to create and store a patient summary or not (it is voluntary). It contains basic information about the patient's health status and the health services provided. The aim of its creation is cross-border sharing of basic health data between health care providers from different EU Member States for the purpose of providing health care. A patient summary can be shared based upon request by a healthcare provider/professional to the National Contact Point, administered by the Ministry of Health. Data is securely shared through eHDSI.
E-sick leave	From 2020, e-sick leave has been introduced according to **Act No 589/1992**, on Social Security and State Employment Policy Premiums, and **Act No 187/2006**, on sickness insurance. It is an electronic system for processing decisions related to temporary incapacity to work (which also contains health data about why the employee is temporarily unable to work). Communication between the physician, employer and also Social Security Administration is electronical in the information system.
Laboratory results	Since January 2022, according to the **Act on Digitisation of Health Care**, the provider who performed the requested laboratory examinations and reported this health service to the health insurance company, also submits data to the National Register of Paid Health Services.

3. Processing health data for providing digital health services

There is no specific legislation for the treatment of health data in the provision of digital health services. However, there are some partial regulations:

4. Specific legislation on genetic testing

The **Specific Health Services Act** sets out the purposes for which genetic testing may be provided, establishes that genetic testing can be provided after the patient has given written consent, establisher the rules on which genetic counselling is recommended to a patient and his relatives, and under which biological material obtained during the provision of health care can be used for genetic testing.

2.2 Secondary use of health data for planning, management and improvement of the healthcare system

The secondary use of health data concerns the re-use of health data initially collected in the context of providing care, but which may later be re-used for wider public health purposes including planning, management, administration and improvement of health and care systems; prevention or control of communicable diseases; protection against serious threats to health and ensuring high standards of quality and safety of healthcare and of medical products and devices.

1. Treatment of health data for planning, management, administration and improvement health system entities such as health authorities

Health Services Act Article 70, establishes the National Health Information System (NHIS), the unified system administered by the Institute of Health Information and Statistics of the Czech Republic (Statistics Institute, IHIS), an organisational state unit created by the Ministry of Health.

Among other things, it states that NHIS is intended to process data in the health sector in order to obtain information on the scope and quality of the health services, for the management of the health sector, for the creation of health policy, assessing quality and safety indicators of health services etc.

This data is transferred to NHIS without subjects' consent unless stated otherwise in the Health Services Act, by persons such as providers and health insurers.

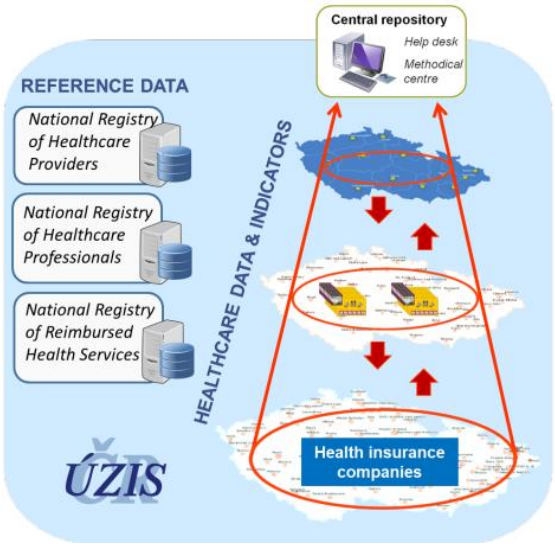


Figure 5: Structure of the National Information System. Source: Czech comprehensive ICT model: description and implementation guide

2. Processing of health data originally collected for providing care to allow it to be used for market approval of medicines and devices

Article 39 paragraph 4 of Public Health insurance Act states that health care providers submitting highly innovative products are required to provide data related to the efficacy assessment and the status of the product in clinical practice to a health insurance company and, in anonymized form, to the marketing authorisation holder of the medicinal product for the purpose of reimbursement setting.

The scope of the data (including health data) transmitted to the health insurance company and to the marketing authorisation holder is set out by **art. 43 of Decree No. 376/2011 Coll.,** that implements selected provisions of the Public Health Insurance Act.

Health Insurance Companies have established the Health Insurance Bureau (HIB), a private association, and empowered HIB (among others) to process data on highly innovative products. Data collected can be used for other procedures – e.g. extension of temporary reimbursement or decision on "permanent" reimbursement by The State Institute for Drug Control.

3. Processing of health data originally collected for providing care to allow to be used for monitoring of medical device safety and/or pharmacovigilance

Pharmacovigilance

Art. 90 of **Pharmaceuticals Act** sets rules for the pharmacovigilance system of Czech Republic which is in compliance with EU legislation – Directive 2010/84/EU (amending of Directive 2001/83/EC). The pharmacovigilance system is managed by the State Institute for Drug Control and is intended to:

a) gather information on the risks to patient or public health of human medicinal products
b) evaluate this information and consider options for minimisation and prevention
c) adopt measures consisting, where appropriate, the marketing authorisation holder is obliged to ensure the functioning of the pharmacovigilance system.

Art. 93a paragraph 2, establishes the obligation to report to the European EudraVigilance database in case of suspected serious and non-serious adverse reactions.

Art 93b of the Pharmaceuticals Act regulates the reporting by health care professionals to the Institute when they notice a suspected serious or unexpected adverse reaction and other facts that might affect the health of the treated patients related to the use of a medicinal product. Only pseudonymised data as defined by GDPR are reported to the Institute.

Medical devices

Medical devices can also be prescribed electronically. They are regulated by the directly applicable **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Vigilance is regulated in Article 87 et seq. of the Regulation. Related provisions are laid down in Act No 375/2022 Coll., on medical devices and in vitro diagnostic medical devices, in Article 48 et seq.

4. Processing of health data originally collected for providing care to allow it to be used for protecting against serious cross-border threats to health

The **Public Health Protection Act** regulates the epidemiological monitoring of certain infectious diseases. Art. 75a establishes a national system of epidemiological surveillance which is fixed for infectious diseases (such as measles or influenza).

Art. 75a paragraph 4, clarifies that healthcare providers are obliged to collect and communicate data on selected infectious diseases according to a defined structure and report them to the regional hygiene station (public health authority) through the Information System of Infectious Diseases administrated by the Statistics Institute. Hygiene stations are obliged to collect data on reported infectious diseases and provide the data to the Ministry of Health. Eventually, the Ministry of Health is responsible for transferring data on reported infectious diseases to The European Surveillance System (TESSy).

For infectious diseases not included in the surveillance system the general rule in the Public Health Protection Act applies – the health care provider is required to report findings on infectious diseases or suspicion on infectious diseases to the regional hygiene station and to act in accordance with the regional hygiene station's orders.

Treatment of personal data by public health authorities and providers are regulated in Public Health Protection Act which:

• Enables public health authorities to use data from state information systems such as the population register

• Declares that health care providers are obliged to report to public health authority personal data of a person who is carrier of an infectious disease named in art. 53 (such as HIV/AIDS, typhoid fever etc.).

• States that public health authorities are obliged to process these personal data in order to fulfil its obligations with regard to protection and promotion of public health.

• Public health authorities are also entitled to process personal data of employees carrying out risky work.

5. Specific legislation enacted to address the creation of disease registries

Art. 70 paragraph 1 of the **Health Services Act** states that National Health Registers (e.g. disease registries) are part of NHIS. There are 12 National Health Registers which form a mutually interconnected system within the NHIS, where aggregate data can be gathered for the purposes specified in Health Services Act. All Health Registers are private and accessible only to persons specified in the legislation, with the exception of the National Register of Providers which is publicly available.

The Statistics Institute can also provide data (only in anonymous form) from the National Health Registers for statistical and scientific purposes. Art. 78 of the Health Services Act and **Decree No. 373/2016 Coll**., on Transmission of Data to the National Health Information System stipulate details on the provision of data to Health Registers, such as entities that transfer data to health registries and the procedure for transferring data.

Public Health Protection Act regulates the Information System of Infectious Diseases created according to art. 79 paragraph 2 and 3 of the Act, states that data from this registries can be used in anonymous form by public health authorities or National Institute of Public Health for purposes of developing health policy, evaluation of state of support and protection of public health and for monitoring trends of infectious disease occurrence.

2.3 Secondary use of health data for scientific or historical research by public and private sector organisations

It concerns the re-use of health data initially collected in the context of providing care, but which may later be re-used for scientific or historical research by both public and private sector organisations (third parties, not being the original data controller), including the pharmaceutical and medical technology industries and insurance providers.

The Czech Republic does not have specific legislation regulating the treatment of data for scientific research. However, the following are relevant laws.

1. Legal or regulatory mechanisms which address the use of health data for research purposes

There is no specific regulation on access to health data for research. However, the following list of forms to access to health data for research are used in the Czech Republic, not excluding other forms that may exist at regional level.

The Health Services Act does not allow anyone to access medical records for research purposes without patient´s consent. Patients can consent with the storage of biological material and data gained during provision of health services in biobanks for the purpose of research.

On September of 2020 the Additional Protocol to the Convention on human rights and biomedicine, concerning biomedical research, entered into force in the Czech Republic. The Additional Protocol states that every research project involving intervention on humans shall be submitted to an ethics committee for review. In practice, a description of the processing of health data is part of a research project protocol.

Regarding interventional research projects, the access to health data for research will be often reviewed by an independent REC established by the university or hospital carrying out research. Regarding non-interventional projects (such as retrospective analysis of data) the REC will not be obligatory however, in projects carried out by public institutions (universities, public hospitals) there will also be an independent REC, scientific board or similar independent body. Also patient´s consent to participation in a research project is required by the Convention and its Additional Protocol (if it is not a retrospective analysis of data of deceased person). The appropriate legal basis for processing health data for research purposes must also be found by the researcher before accessing the data.

Art. 73 of the **Health Services Act**, states that data collected in National Health Registers can be provided by the Statistics Institute for scientific and statistical purposes based on request, only in an anonymized form. Art. 16, specifies safeguards referred to in art. 89 of GDPR that are necessary when processing personal data (including health data) for scientific or historical research or statistical purposes. The Statistics Institute is entitled to request payment covering the costs related to the provision of data. Reimbursement for extremely extensive data searches can also be requested.

Moreover, **the Methodical document on implementation of GDPR on science data** mentions multiple legal bases as possible, e.g. explicit consent, broad consent, public interest in the field of public health and research purposes. Therefore, the legal basis used by researchers may differ depending on key characteristics of the research; such as the nature of the research institution (public or private), research purpose (e.g. public or private interest), etc.

There are several systems for sharing data for secondary use, administered by separate ICT vendors or service providers. There is no centralized data access infrastructure in the Czech Republic. However, in this context a national node of BBMRI-ERIC (European Research Infrastructure Consortium) – BBMRI-CZ is established. Networks of individual biobanks operate within this consortium (there is no centralised system). Data can be searched and requested with the use of BBMRI-ERIC's Sample/data locator and negotiator.

2. Patients' rights

2.4. Electronic Health Records and technical standards

Electronic Health Records (EHRs) are a core building block of electronic data collection, processing and sharing.

ICT system through which patients can access their HER data

In the E-Receipt information system, patients have access to all electronic prescriptions and from June 2020, patients also have access to the electronical patient's medication record which is also part of the system.

Data of apps and devices to track and record issues can be included into EHRs through the following mechanisms:

Article 15 'right to access data concerning him or her'

- Patients can request directly to health care providers access to their data kept in medical records by reference directly to art. 65, paragraph 1, of the Health Services Act.

Article 16 'right to rectify any inaccurate data concerning him or her'

- The right to rectification is restricted based on sectoral legislation adopted in accordance with Article 23. According to art. 54, paragraph 4, the corrections of entries in the medical records are made by a new entry, indicating the date of the correction an signature of the health care professional and the patient.

Article 17 'right to be forgotten'

- Medical records must not be deleted before periods which must be stored by health care providers.

Article 20 'right to data portability'

- Patients can obtain a portable copy of medical records according to art. 65, paragraph 1, of the Health Services Act.

Healthcare providers can incorporate patient generated data into healthcare professional/ provider held EHRs, but in practice hardly ever do so. No legislation explicitly forbids healthcare professionals to incorporate patient generated data into EHR so it should be considered as legal.

However, according to art. 54 paragraph 2 of the Health Services Act, a health care provider is obliged to keep medical records in a conclusive, true, legible and continuous manner. The health care professional bears the responsibility that data in medical records are correct and it is his responsibility to decide whether and how to use patient generated data for purposes of providing healthcare.

Participation in the European infrastructure eHDSI (eHealth Digital Service Infrastructure)

The Czech Republic participates in eHDSI through sharing patient summary records.

Interoperability policies

In the Czech Republic, technical standards for interoperability are not defined by legislation. According to the proposal of the Act on Digitisation of Health Care, the Ministry of Health shall issue standards after consultation with Statistics Institute.

Technical standards used in Czech Republic are for example:

• Standard NCP used in NIX-ZD is the project for developing cross-border exchange of health data – for example sharing of patient summary.

• National standard DASTA in version 4 (DS4) issued by the Ministry of Health which is used for communication with IHIS – providing data to National Health Registers.

• International standard HL7 (Health Level 7) is used for exchange of heath data between software applications of healthcare providers.

Health data security policies

There are no specific data security policies, partial rules are:

Art. 55 of the Health Services Act outlines several rules on electronic medical records which must be fulfilled when a healthcare provider desires to keep medical records only in electronic form. Art 54. Paragraph 3 of Health Services stipulates conditions under which entries to electronic medical record are made.

Data quality policies

There are no specific health data quality policies, partial rules are:

Section 54 paragraph 2 of the Health Services Act stipulates that medical records must be led in true, legible and conclusive way. This rule applies both for paper and electronic medical records.

Art. 54 of the Act states that any entry into medical records kept in electronic form, shall be provided with the entry identifier and shall contain the unchangeable, undisputable and verifiable data. Furthermore, the corrections of entries in the medical records shall be made by a new entry, with the date of the correction and the original entry must remain legible.

According to Act on Digitisation of Health Care, the standards shall be issued by Ministry of Health.

Primary use of health data. **c**ategories of information digitalised in the Czech Republic

patient summaries	PARTIALLY
electronic prescriptions	YES
Electronic dispensations	YES
laboratory results	YES
discharge reports	YES

Healthcare providers may decide whether they want to create and store patient summary or not (it is voluntary).

Secondary use of health data. Are the following categories of electronic data available for secondary use in your region / ecosystem?

Yes, Statistics Institute can provide anonymous data collected in National Health Registers for scientific and statistical purposes based on request. The Statistics Institute is entitled to request payment covering the costs related to the acquisition of excerpts, copies, the provision of technical data carriers and the sending of data.

Therefore the legal basis used by researchers may differ depending on key characteristics of the research; such as the nature of the research institution (public or private), research purpose (e.g. public or private interest) etc.

Researchers can access to health data through patient's consent

2.5 Cybersecurity

The Ministry of Health in the Czech Republic presented and approved a cyber-security strategy for the years 2021-2025 on August 3, 2021. The strategy[24], which is a top document, focuses on increasing cyber security across the healthcare sector and is being implemented by the Ministry of Health and other organizations such as the National Office for Cyber and Information Security and the Institute of Health Information and Statistics. It builds upon a similar strategy from 2015-2020 and has a broader scope and strategic focus. An action plan and communication strategy will also be developed to detail goals and inform those affected by the strategy of its progress and impact on their daily functioning.

In addition, the government has recently taken steps to support healthcare providers in cybersecurity through initiatives[25] such as publishing a Minimum Security Standard for organizations not regulated by the Cybersecurity Act, which was a joint effort by experts from the National Agency for Information Technologies and the Ministry of Interior in 2020. Additionally, in February 2022, the National Agency for Information Technologies and the Ministry of Health created a recommendation for healthcare providers to help reduce two specific cyber threats based on the current situation.

3 – Innovation agenda in the field

In Czech Republic the strategic plans related to digitalization in healthcare are part of a more general and comprehensive framework related to the development of health, called "*Strategic Framework for Developing Healthcare in Czechia to 2030*[26]" (Health 2030), a document firstly approved in 2019 and then revised in 2020 because of COVID-19.

The main vision of the Health 2030 Strategic Framework – the main source of information for this chapter - is to ensure affordable healthcare for all citizens of the Czech Republic, regardless of their social and geographical environment, while at the same time ensuring that citizens are more concerned about their health condition.

The document builds on and includes previous strategies, with relevant action plans, the National e-health Strategy, Primary Care Reform and Psychiatric Care Reform and its implementation is under the responsibility of the Ministry of Health and its subsidiary bodies, up to 2030, when most of the goals are planned to be achieved.

Health 2030 identifies three main strategic goals and each of them is broken down into specific objectives. Strategic goal number two is entitled "Optimising the health system", where Objective 2.3 is "Digitalisation".

[24] https://ncez.mzcr.cz/cs/kyberneticka-bezpecnost/strategie-kyberneticke-bezpecnosti

[25] https://joinup.ec.europa.eu/sites/default/files/inline-files/DPA_Factsheets_2022_Czech_Republic_vFinal.pdf

[26] zdravi-2030-strategicky-ramec.pdf

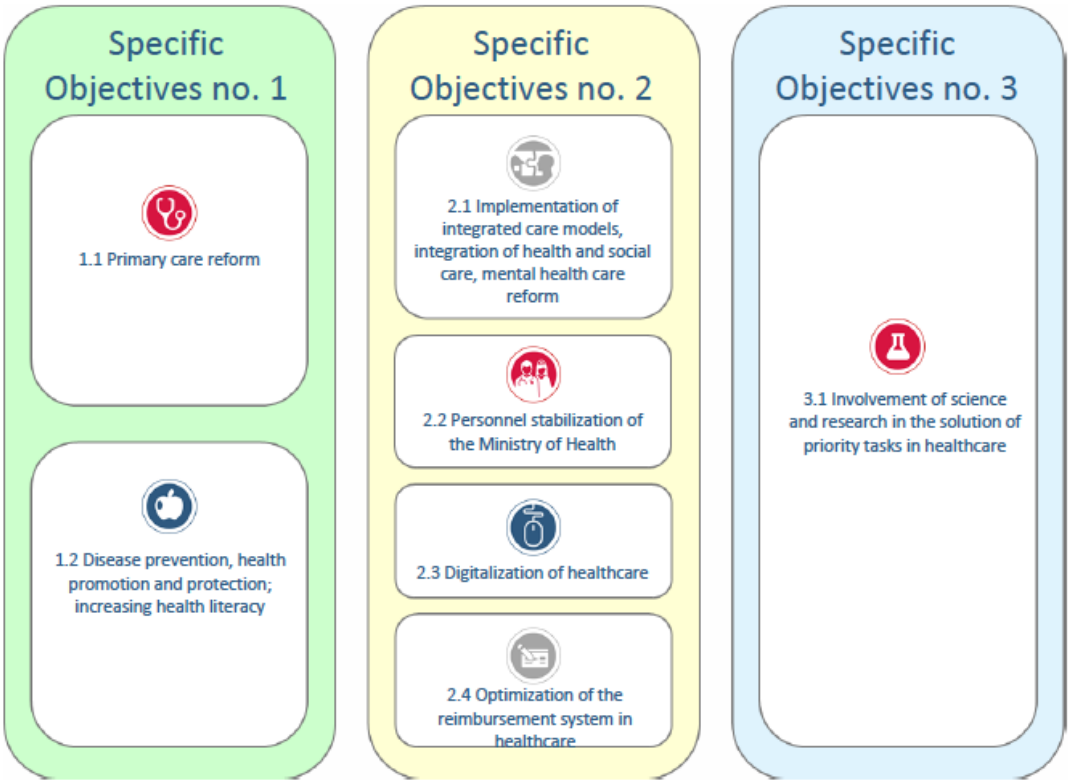


Figure 5: The Three pillars of the Health 2030 strategic document

Digitalisation is recognized to bear a high potential in terms of impact on the improvement of health of Czech population, as well as to cope with current trends in socio economic development, such as ageing population, emerging threats like epidemics or infectious diseases with pandemic potential, the need to reduce inequalities and the impact of social determinants on health etc. It could also have a preventive function, able to support quality of life and the keeping of healthy conditions during the entire lifespan of the citizens, following a much more integrated, individual-centred care approach, facilitating the transition from treatment to prevention. Digitalization is also considered able to pave the road to more efficient and effective ways of organizing and delivering health and social services both at national and cross-border level, facilitating the transition from a hospital-based system to more community-based and more integrated care structures. Finally, through digitalization, the use of health data for research and innovation purposes could be strongly enhanced, promoting better and personalized healthcare.

The document acknowledges that this kind of paradigm shift needs to be supported by a very robust IT infrastructure, with the highest possible standards of information security, privacy and protection of human rights and ethical principles. A specific legislative action is envisaged and recommended, mainly as a pre-condition for the capability to manage possible future health-related crises, as well as for the development of the IT healthcare solutions market. With this regard, m-health and telemedicine are explicitly mentioned as area of interest and future development, in particular because of the effects of Covid-19 pandemic.

Funded by the European Union

Digital Health definition

In the Czech documents the term “digital health” is used to refer to "an area of knowledge and practice associated with any aspect of adopting digital technologies to improve health, from creation to operation". This definition is in line with WHO EB142/20 of 2017 and includes eHealth. The term “digital healthcare” is then used as a broad umbrella term encompassing eHealth as well as emerging areas, such as the use of advanced computational sciences (“Big Data”, genomics and artificial intelligence).

Objective 2.3 “Digitalisation” of the Health 2030 Strategic Framework, identifies a “target status” i.e. a desired condition to be achieved by 2030. It is clearly stated that the post-2020 period will be characterized by the emergence of new digital technologies and practices in the field of personalized medicine, clinical applications of artificial intelligence, practical applications of shared health record models (including Blockchain, Big Data and related concepts), mobile health technologies (mHealth) and telemedicine. Digitalization is also expected to play a key role in developing the health literacy of the population so both health professionals and citizens would need to be targeted by measures.

In general digitalization in healthcare is expected to:

- increase support of the reform of and access to healthcare services,
- strengthen the ability of individuals to care for their own health,
- support the overall efficiency of the healthcare system,
- support the transition to integrated, individual-centrered care models and facilitate the transition from treatment to prevention,
- facilitate the achievement of strategic public health objectives.

Legislative support and material support for standardization in the field of health record keeping and sharing, and in mobile eHealth and telemedicine, including the certification of information systems and digital health services, will make a significant contribution to the development of the IT healthcare solutions market.

In order to move towards this desired scenario, Objective 2.3 “Digitalisation”is split into 15 sub-goals. Each of them is described into the “Health 2030 implementation plan[27]”, which also sets out associated budgets, a series of quantitative indicators, a timeframe for periodic checks on progress made, a section on risk analysis and possible mitigation measures, as well as a (quite general) timeframe for the completion. In the majority of the cases the implementation period is set “between 2021 and 2030”, while in only three cases some sub-sub-objectives are planned to be achieved before 2022 or 2023. They are:

- Act on electronic healthcare, which was in fact issued in 2021
- National Health Information Portal (NZIP) functioning (by 2023)
- Development of a teaching and learning system for healthcare workers (by 2023)

Here we introduce a summary of the 15 sub-goals with related budgets.

[27] https://www.databaze-strategie.cz/cz/mzd/strategie/implementacni-plan-c.2.3-digitalizace-zdravotnictvi

2.3.1 Development and implementation of the concept of digitization of healthcare, institutionalization of electronic healthcare

The need to create legal support in the planned and implemented measures according to the National Electronic Health Strategy and its Action Plan, as well as the solution of serious yet unsolved problems in the health sector leading to a reduction in the availability and quality of health services and an increasing risk of unsustainability of financing health services in the required quality (Electronics Act healthcare)

Timeframe: 2020-2030 (legal framework to be ready by 2022)

Budget: no specific budget required

2.3.2 Development of a central infrastructure for sharing medical documentation, guaranteed and secure communication and information exchange in the healthcare sector

Unified access to electronic healthcare services and the construction of the Integrated Data Interface of the Ministry of Health as an infrastructure ensuring the safe sharing of data and medical documentation and conducting authorized communication between entities involved in electronic healthcare and further development of electronic healthcare infrastructure.

Timeframe: 2020-2030

Budget: 1.096 million CZE → ≈ 45 Meuro

2.3.3 Development of the authoritative data service provision system, departmental authoritative registers and guaranteed data model

Timeframe: 2020-2030 (Act on Electronic Healthcare by 2022)

By 2030: Development of integrated data interface functionalities and services, including strengthening hardware and software infrastructure as well as security hardware and software

Budget: 300 million CZE → ≈ 12.5 Meuro

2.3.4 Development of the National Health Information System (NZIS in Czech)

This is composed by 4 sub-goals, namely expansion of the NZIS with new functionalities, expansion and strengthening of its HW and SW infrastructure, periodic publication of analytical outputs, regular revision of registers and methodological materials

Timeframe: 2020-2030

Budget: 760 million CZE → ≈ 31.3 Meuro

2.3.5 Development of the National Health Information Portal (NZIP in Czech)

Completion of the working version of the NZIP system, to be regularly updated and than to be implemented with new functionalities.

Timeframe: 2020-2030, but first version by 2021 (constant updates and new functionalities will follow)

Budget: 50 million CZE → ≈ 2.06 Meuro

2.3.6 Management of the system with the development of the catalog of healthcare electronic services

Preparation of management acts, methodologies, decrees for the centralized management of the system catalog of services and their continuous updating, with related approved compatibility standards.

Timeframe: 2020-2030

Budget: 100 million CZE → ≈ 4.12 Meuro

2.3.7 Support for the use and standardization of electronic healthcare tools (tools for standardizing the digital healthcare environment, interoperable environment for users of common shared electronic services in healthcare)

Tools for MOH standardization of the environment, creation of an interoperable environment for users, with a set of common shared and standardized services in healthcare.

Timeframe: 2020-2030 (pre-condition is the Act on Electronic Healthcare to be issued by 2022)

Budget: 400 million CZE → ≈ 16.5 Meuro

2.3.8 Support for the use of new digital technologies and procedures in the field of personalized medicine, home care, and integrated care

Timeframe: 2020-2030.

By 2026: Development of sub-strategies for the use of digital technologies to support personalized medicine, home care, integrated care. After that, creation, development and adoption of a methodological framework in the field of digital support for integrated care and personalized medicine.

Budget: 380 million CZE → ≈ 15.7 Meuro

2.3.9 Support for the use of artificial intelligence in healthcare and the implementation of services based on it

Timeframe: 2020-2030

By 2026: development of a strategy for the use of artificial intelligence (AI) in healthcare. Creation of a framework for the quality and life cycle of datasets for training AI systems and for the performance of AI applications intended for use in healthcare Drafting legislative amendments for AI in healthcare.

Budget: 500 million CZE → ≈ 20.6 Meuro

2.3.10 Development of the scientific research and innovation base for the digitization of healthcare and the development of the knowledge base of digital healthcare

Creation and development of a scientific research or innovation program or center

Timeframe: 2020-2030 (it implies the possibility of creating a dedicated reseach centre)

Budget: 240 million CZE → ≈ 9.9 Meuro

2.3.11 Practical applications of models of safe sharing of health records, application of Blockchain technology and related concepts, use of concepts from the field of Big Data

Timeframe: 2020-2030

Promotion of new technologies and good practice in their application. With this regard, the involvement of the Czech Republic in international cooperation in the above areas is explicitly mentioned and encouraged.

Budget: 230 million CZE → ≈ 9.5 Meuro

In addition, it is important to note that the topic of Big Data is also mentioned in the present National Strategy for Research Development and Innovation.

2.3.12 Support of mobile healthcare technologies (mHealth) and telemedicine at all levels of healthcare provision, especially for end users (hospitals, ambulances, patients)

Timeframe: 2020-2030

Creation of mHealth telemedicine service/application, verification, updating and implementation, Telemedicine implementation plan, launch of pilot projects.

Budget: 130 million CZE → ≈ 5.36 Meuro

2.3.13 Development of platforms for communication and coordination of public administration, industry and academia for the purpose of developing digital services in health and healthcare

Creation and development of tools to support the coordinated development of platforms in the field of healthcare digitization

Timeframe: 2020-2030

Budget: 60 million CZE → ≈ 2.47 Meuro

2.3.14 Programs for the development of general and specific digital literacy for healthcare workers

Timeframe: 2020-2030

By 2023: Development and set up of a teaching and learning system for healthcare workers

Budget: 300 million CZE → ≈ 12.37 Meuro

2.3.15 Programs strengthening building trust in digital healthcare services among citizens and healthcare professionals

Timeframe: 2020-2030

Booting up programs of education and general awareness of citizens and especially patients and health professionals, especially to support the adoption of new digital services

Budget: 90 million CZE. → ≈ 3.71 Meuro

Grand total budget: 4.636 million CZE → ≈ 191.2 Meuro

The budget comes from a mix of sources, which include State budget, EU funds, government Digitalization of the Czech Republic 2018+ programme, EC financial mechanisms – Digital Europe Programme (DEP), ERDF/EU funds, Connecting Europe Facility (CEF) programme, The Invest EU Programme (InvestEU), Structural Reform Support Programme, Horizon Europe (HE), eHealth Network (Joint Action).

By the time this report was completed, it has not been possible to find public information about the state of the art of the work progress towards the envisaged goals.

the eHealth Act

In September 2021, the Czech Government adopted Act No. 325/2021 Coll., on the digitalisation of health care to ensure the interoperability of different eHealth solutions at national level, as well as to safeguard the quality of eHealth services provided by the State. The Ministry of Health is responsible for the interoperability of eHealth solutions, publishing standards for the data sets formats, and ensuring cybersecurity of medical information.
Before that digitalization of healthcare was largely uncoordinated in the Czech Republic and based on ad hoc solutions. So the Act is expected to deliver the following benefits:

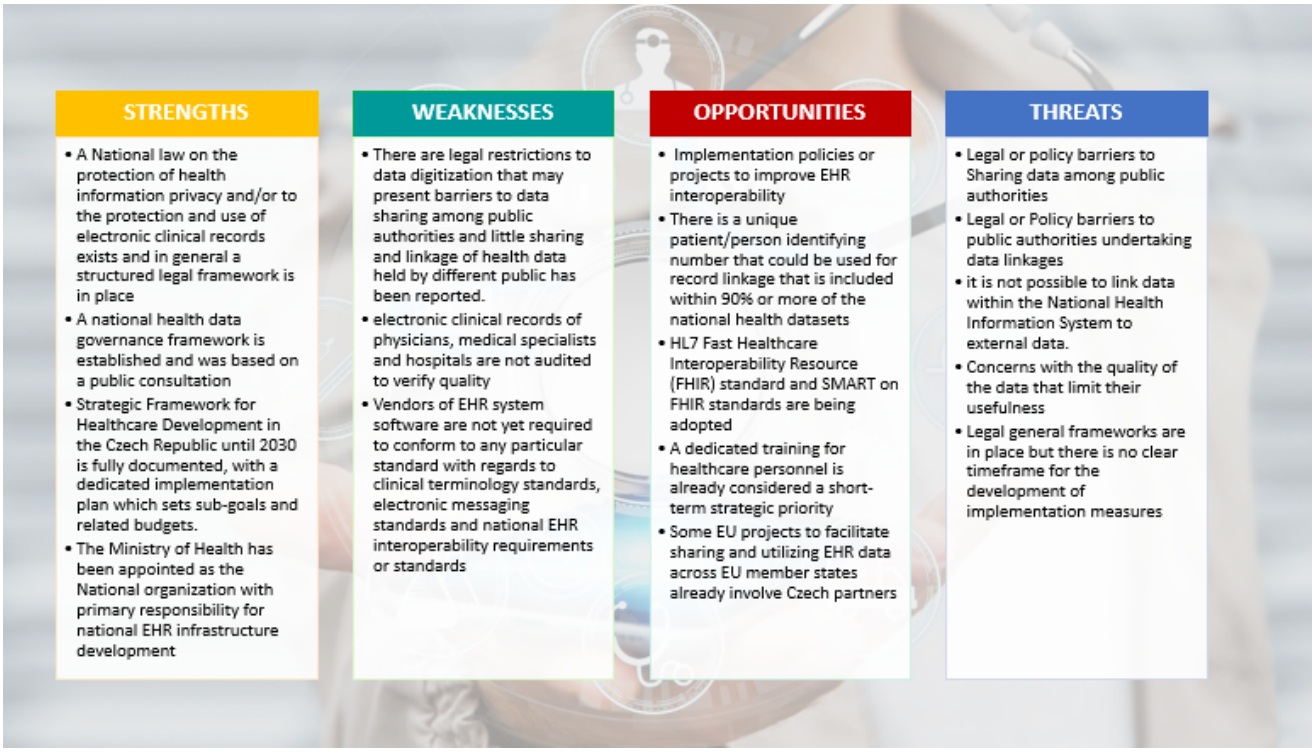
- Automate the processes related to the acquisition of master data and the transfer of medical documentation
- Increase legal certainty for healthcare professionals and providers when working with master data
- Regulate patients' rights and obligations when they use health and e-health services
- Support the increase in the quality and efficiency of health services
- Automate the processes related to the acquisition of master data and the transfer of medical documentation
- Increase legal certainty for healthcare professionals and providers when working with master data
- Regulate patients' rights and obligations when they use health and e-health services
- Support the increase in the quality and efficiency of health services

It is important to note that the Act on E-health does not introduce electronic health records, while it sets conditions for safe sharing of documents among providers or between providers and Health Insurance Funds.

Funded by the European Union

4 – SWOT Analysis on digital health innovation

On the basis of the "Report on the implementation of the OECD recommendation on health data governance[28]" of February 4th, 2022, which relies a set of surveys completed in 2021 and of the data collected for the preparation of this report, it is possible to highlight the following elements:



5 – Transferable good practices

As it has been stated in the body of this document, Czech Republic is still working on the development of a dedicated health data strategy, so existing good practices which was possible to identify are mainly related with digital / ehealth services, rather than on specific highly innovative initiatives state of the art technologies or novel approaches in the use of Health Data. Nevertheless they are pretty relevant and effective at national level and could be transferred to other countries.

5.1 - Good practice epreskipce (ePrescription)

Since January 1st, 2018, the Czech Republic has required doctors to issue prescriptions in electronic format only, exceptions are contempled in art. 81f of Act No. 378/2007 Coll., on Medicinal Products: they are called ePrescriptions or eRecipe and are centrally stored in the so-called Central Repository of Electronic Prescriptions – CREP, or "CÚER" in Czech.

[28] https://one.oecd.org/document/C(2022)25/en/pdf

The doctor can transfer the identifier of the ePrescription (or eReceipt) to the patient in many forms such as email, SMS, via a dedicated mobile phone app etc. It can also be printed and directly handed over to the patient, if necessary.

Once the patient visits the pharmacy, he receives the medicine if the prescription can be found in the CREP, there are still statutory exceptions that a paper prescription can be issued. Information on how and when to take the drug is also registered in the CREP.

The full (mandatory) implementation of the ePrescription tool was part of the National Electronic Healthcare Strategy 2016-2020 and the eGovernment Development Strategic Framework 2014+. The ePrescription system was included in the critical infrastructure of the State, and hence has been subject to the tightest security measures as referred to under the Act on Cybersecurity and related legal regulations.

Even though printed prescription is still used, the popularity of the full ePrescription (fully electronically managed, completely paperless) increased rapidly through the years by moving from less than 6% of all the prescription issued at national level in 2018, to the 15% in 2019 and up to more than 90% currently. [29]

It is pretty much likely that it has now reached 50% and has all the potential to keep growing, also because the system is still being continuously upgraded and modernised, considering suggestions received both from professionals and from the general public. For example, in 2019 the barcode identifier was replaced with a QR code, more tamper resistant and easier to read by different tools and applications. Furthermore, in mid-2019, a fully dedicated backup system was implemented, with the aim of guarantee a smooth dispensing of electronic prescriptions within the territory of the Czech Republic also in case of a sudden outage of the primary ePrescription system. The back-up section is totally independent from the primary one and it is operated in a completely separate location.

Through the years the system has been able to bring clear advantages to a series of different categories:

- insurance companies routinely download batches of ePrescriptions of their insureds, which gives them a complete overview of expenses and an effortless record of them. ePrescriptions cannot be faked.
- doctors can prescribe an eRecipe outside their office through their mobile application, there is no risk of incomplete filling and more space for additional information, when necessary
- pharmacists benefit from a dedicated application which can retrieve information about the prescribed medicines also in the case standard communication with the ePrescription system fails.
- the patient application allows patients to display the list of all the ePrescriptions issued by from their doctors and keep track of their history with no effort. In case of chronic illnesses there is no need to physically see the doctor for repeated prescriptions, if there is no change of patient's status. No risk of lost prescriptions.

The electronic prescription has proven much useful particularly at the time of the COVID-19 epidemics in the Czech Republic. In that difficult period, the electronic prescription supported the required social distancing in a highly effective manner, significantly reducing the necessity for patients to visit their doctors in the offices, remarkably contributing to the protection of the health of all Czech citizens.

The **ePrescription system** has also demonstrated to have a high potential for development and wide adaptation: for example, from May 2021 the electronic prescription system was extended to medical devices (eVouchers), entering into force as an optional mode in May 2022. The e-vaccination system was transferred to the Institute of Health Information and Statistics of the Czech Republic. Secondly, from October 2021 the

[29] https://en.vzp.cz/

central repository of vaccination records became part of the system. Registration of vaccination records in the system is mandatory and it concerns all types of vaccination, i.e. regular, special, extraordinary, voluntary, reimbursed and non-reimbursed.

In addition, it is worth to mention that a project on the "Deployment of Cross Border Services in the Czech Republic (ePrescription/eDispensation)", is under development, with the primary objective of extending electronic dispensation beyond the borders of the Czech Republic to other EU countries. The expected date of the Czech Republic's involvement among other countries participating in cross-border data exchange is 2023.

ePrescription has a fully dedicated website (in Czech): https://www.epreskripce.cz/

5.2 - Good practice eNeschopenka (eSicknote)

As it is described in the Second Voluntary National Review of the 2030 Agenda in the Czech Republic, the so called “eSicknote” (eNeschopenka in Czech) is a system of fully electronic notifications and records of temporary sick leave, which was launched in 2020. In case of sickness and consequent absence from work, employees would have to inform their employer of the specific situation (e.g. by e-mail, SMS, telephone etc.) but, unlike it used to happen in the past, they do not fill in paper forms and physically hand them over to their employer. Nowadays, a paper form can only be used in the event of a technical failure. In addition, information can automatically be received by employers from physicians, through their data boxes. This is extremely useful since the employer, especially large companies, can monitor almost in real time the situation of its employees and see who and up to when has been declared “temporarily unable to work” by his/her physician. The notifications are sent in the form of a PDF file or XML file, for possible automated processing and integration into the payroll or HR management software.

Following a similar procedure, compensation of wages and sickness benefits are now automatically sent to employees. The eSicknote tool has already existed for several years, but the Covid-19 pandemic contributed to its large-scale diffusion and demonstrated not only its usefulness but also its necessity in some cases.

The practice has a high transferability potential since it could be applied, for example, to a series of other benefits from health insurance, i.e. cash assistance in maternity, paternity, nursing, long-term care and compensatory allowance during pregnancy and maternity, procedures for ordering quarantine etc.

For the moment the fully electronic approach is still limited to the temporary inability to work. It must be noted that it became so popular and widely used simply because, due to COVID-19 restrictions, it became mandatory by law and no more optional, as a possible alternative to the traditional paper-based approach. This meant that the all the physicians and general practitioners were forced to adopt the necessary software and all the workers to follow the fully electronic procedure.

eNeschopenka has a fully dedicated website (in Czech): https://www.cssz.cz/web/eneschopenka

5.3 – Possible future good practices

Here following are three ongoing projects which have the potential to become good practices in the future.

- **OP TAC - The Operational Program Technologies and Application for Competitiveness (OP TAC) 2021 – 2027**[30]

[30] https://www.agentura-api.org/en/op-tak/

OP TAC is a flagship programme for supporting Czech entrepreneurs in the **2021–2027 programming period**. Applicants can use the ERDF funds to co-finance business projects **on digitization and digital infrastructure**. The managing authority of OP TAC is the Ministry of Industry and Trade of the Czech Republic (MIT). The target group is primarily small and medium-sized enterprises (SMEs)

- **The eMeDOcS (exchange Medical Documents System) project**
  The project builds and maintains the communication infrastructure for the safe and reliable exchange of medical documentation between medical facilities within the Czech Republic's healthcare system. The organizer and guarantor of the project is the Vysočina Region.

- **"Záchranka"**
  The Czech Emergency Medical Service released in 2016 a free mobile app intended to help ambulances hone in on a patient's location while speeding up response time and offering first aid assistance in the interim.
  The application connects users with the 155 emergency hot-line via a large red-cross button; an SMS with exact GPS location is dispatched to the patient's region's emergency responders.

6 - Good practices related to gender diversity and inclusiveness

Several initiatives have emerged in recent years to address gender inequality in the Czech Republic in certain areas, such as the low representation of women in science (27% of researchers in 2021)[31]. Some of these initiatives include:

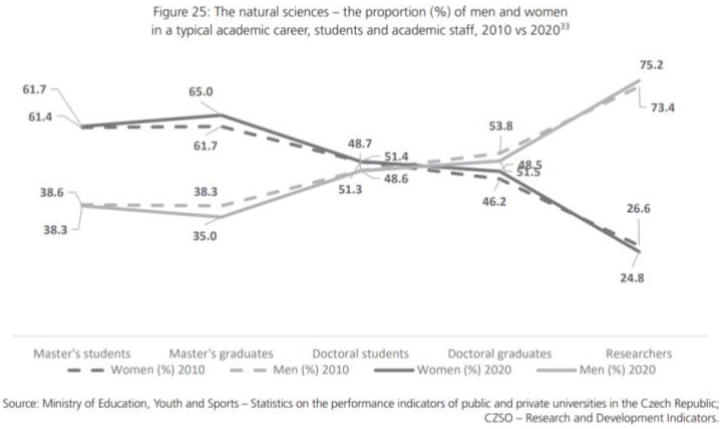


Figure 7: The proportion (%) of men and women in a typical academic career, students and academic staff in natural sciences, 2010 vs 2020.

1. **The Technology Agency of the Czech Republic**
   It promotes gender equality through a positive evaluation of projects with a diverse composition of the research team, introducing a criterion for evaluating the gender dimension in research content in order to ensure equal benefits of applied research, including a balanced representation of women and men in the evaluation bodies, analysing fender-relevant statistical data and participating in the GEECCO project (Horizon 2020) mapping possible tools of providers to support gender equality in research and the practical implementation of selected measures.[32]

2. **The Centre for Gender and Science (NKC) of the Czech Republic**
   The NKC is a specialized centre that focuses on promoting gender equality in research and academic institutions. One of their objectives is to improve the policy-making process in the Czech Republic with regard to the integration of gender equality into national policies for research, development and

[31] https://genderaveda.cz/wp-content/uploads/2022/12/Monitorovaci-zprava-o-postaveni-zen-ve-vede-za-rok-2020_EN_web.pdf
[32] https://www.tacr.cz/en/gender-equality-in-research-and-innovation/

innovation. They act as experts in expert groups and advisory boards of the government to design and implement gender equality policies. The NKC helps Czech Research and higher education institutions formulating and implementing Gender Equality Plans and develop the report "The Position of Women in Czech Science" with several indicators of researchers related to gender in Czechia as well.[33]

3. **The first Centre for Midwifery Assistance (CPA)**
   An example of a good practice in health is the first Centre for Midwifery Assistance (CPA) established within the Bulovka Hospital, a pilot project which was founded in cooperation with the Ministry of Health in February 2019. Moreover, the Ministry of Health has established a working group assigned to draft a method on the exchange of good practice and to increase the number of centres for midwifery. [34]
4. **L'Oréal-UNESCO For Women in Science, Czech Republic**
   Created in 2006, the L'Oréal-UNESCO For Women in the Science, Czech Republic is a talent program that aims to promote young women's participation in science. The program identifies and rewards talented young female researchers in the life and environmental sciences, formal sciences, physical sciences or engineering and technological sciences.

5. **Milada Paulová Award**
   In 2009 the Ministry of Education, Youth and Sports initiated the Milada Paulová Award for lifelong achievement for women researchers. The Milada Paulová Award aims to publicly and financially recognise the achievements of prominent Czech women researchers, shine a light on women role models, and inspire women researchers and students at the beginning of their research careers.[35]

7 - Potential synergies with other EU regions

7.1 - Cross border transfer of patient summaries (MyHealth@EU)

While in many European countries the patient summary, or its analogues in the form of summary emergent data about the patient, is a relatively well-known part of the patient's summary medical documentation (often maintained centrally), in the Czech Republic this service or document is currently only being introduced, namely decentralized.

At present, efforts are being made in order to provide a sound methodology for the technical implementation of the patient summary into the information system and to tackle some organizational and technical issues. Issues which could hamper the mutual compatibility and interoperability when transferring the patient summary between the providers' information systems and when connecting the information system to the National Contact Point for Electronic Health (NCPeH), which in turn is going to be the entity in charge of transferring patient summaries between health service providers nationally and cross-border within the EU. The methodology is part of the instructions of the Czech Ministry of Health related to the standardization of interoperability in the field of electronic health care (Act 325/2021).

[33] https://genderaveda.cz/en/what-we-do/
[34] https://www.ohchr.org/sites/default/files/Documents/Issues/Women/SR/ReproductiveHealthCare/Department_of_Gender_Equality_Czech_Republic.pdf
[35] https://genderaveda.cz/en/about-milada-paulova-award/

The present Czech infrastructure is already able to allow the health data of its citizens to be consulted by doctors from a certain number of countries, namely Luxembourg, Croatia, Portugal, France and the Netherlands. A the same time doctors from Czech Republic can consult the health data of citizens from Croatia, Malta and Portugal: there is a clear need to increase this opportunity by adopting a more internationally open and recognized system. As of the very beginning of 2023, ePrescriptions issued in Czech Republic are not useable in other countries.

7.2 – Existing cross-border cooperation agreements in the field of healthcare and patient management

Previous cross-border cooperation activities in the field of healthcare were activated in the past on ad hoc basis, for example with Slovak Republic for the payment of healthcare services and in the neighboring areas between Czech Republic and Austria and Czech Republic and Germany, with specific regard to the mountain rescue and emergency situations.

Worth to be mentioned are the traditionally friendly relations between Czech Republic and Switzerland, the latter being the seventh biggest investor in the country. The willingness to continue to cooperate has been reaffirmed in May 2022 during a dedicate bilateral meeting where innovation, science digitalization and cybersecurity were identified as the most promising areas of collaboration.

7.3 - Selected European Projects in the field of Health data with partners from Czech Republic

Following a dedicate analysis on CORDIS project repository, it has been possible to identify a set of projects related to the topic of "Health Data" where one or more partners from Czech Republic are involved. We limited the research to the ongoing projects and for each of them we report a short summary, the total budget and the names of the Czech Partners involved. Data are extracted from CORDIS database.

1. **X-eHealth: eXchanging electronic Health Records in a common framework**

   The EU-funded X-eHealth project will lay the groundwork for a practical, interoperable, secure and cross-border Electronic Health Record exchange format, working towards the improvement of the eHealth sector. With the support of over 40 entities, it aims to move towards a uniform interoperable data-sharing format structure. X-eHealth builds on the already existing Patient Summary service and lay the foundations for a common structure for medical imaging, discharge letters, laboratory results and rare diseases.

   Total Budget: 3Meuro

   Czech Partners involved: Czech Ministry of Health

2. **European Health Data and Evidence Network - Health data analysis for better medical treatment**
   The EU generates vast quantities of patient-related information contained in the Electronic Health Record (EHR) systems and other types of health databases. The project will exploit this rich amount of data to enhance future clinical practice and individual patient results by increasing our

understanding of disease and treatment methods. EHDEN will also create a platform to make methods and data sets findable, accessible, interoperable and reusable.

Total Budget: 30.2 Meuro

Czech Partners involved: Odysseus Data Services SRO (private company)

3. **Intelligent Ecosystem to improve the governance, the sharing and the re-use of health Data for Rare Cancers - European data ecosystem for rare cancers**

The IDEA4RC project aims to establish an AI-assisted data ecosystem for rare cancers (RC) to enable access and the possibility to re-use existing health-related data from different sources. The project will be executed within the framework of the European reference network for rare adult solid cancers (ERN EURACAN).

Total Budget: 8.2 Meuro

Czech Partners involved: MOTOL Faculty Hospital and MASARYK INSTITUTE OF ONCOLOGY

4. **A European Health Data Toolbox for Enhancing Cardiology Data Interoperability, Reusability and Privacy**

Cardiovascular disease (CVD) remains the main cause of mortality worldwide, accounting for about a third of annual deaths. Re-use of both structured and unstructured data has the potential for major health benefits for the population suffering from CVD. DataTools4Heart aims to develop a comprehensive, federated, privacy-preserving cardiology data toolbox, including an integrated platform, a common data model, multilingual natural language processing, federated machine learning and 7 language models adapted to the cardiology domain.

Total Budget: 7.7 Meuro

Czech Partners involved: FACULTY HOSPITAL AT ST. ANNY IN BRNO

5. **Beyond COVID**

Beyond-COVID aims to provide comprehensive open data on SARS-CoV-2, and other infectious diseases across scientific, medical, public health and policy domains. It will accelerate access to and linking of data and metadata on SARS-CoV-2 and COVID-19, enable federated data analysis conform with data protection regulations, and harmonisation and management of meta-data and sample-identifiers, as well as long-term cataloguing to ensure interoperability of national and global efforts.

Total Budget: 12 Meuro

Czech Partners involved: PALACKY UNIVERSITY IN OLOMOUC (as a Third party)

6. **HEalth data LInkage for ClinicAL benefit - Training researchers in large data analysis**

European researchers have significantly contributed to the large genomic, transcriptomic and clinical data sets assembled from patients with chronic diseases. Advances in information science provide opportunities for increased use of these data sets. HELICAL project will develop an interdisciplinary training programme for PhD students

Total Budget: 4 Meuro

Czech Partners involved: KARLOVA University

7. **FrAmework for ClInicaL trIal participants daTA reutilization for a fully Transparent and Ethical ecosystem**

Finding ways to access, use and reuse patient data: has the EU General Data Protection Regulation (GDPR) limited Europe's capabilities in innovative drug development? FACILITATE project will explore the issue. Specifically, it will look for ways to allow patients' data to be accessed, used and reused.

Total Budget: 6.9 Meuro

Czech Partners involved: ODYSSEUS DATA SERVICES SRO (private company)

8. **Pancreatic cancer AI for genomics and personalized Medicine**

Pancreatic cancer is expected to become the second leading cause of cancer-related death by 2030. However, our understanding of its biology is improving rapidly and giving rise to innovative treatment strategies. PANCAIM project will apply existing genomic and clinical data to improve personalised medicine of pancreatic cancer. The project integrates the entire range of genomics with radiomics and pathomics, which are the three pillars of future personalised medicine, in addition PANCAIM applies a data-efficient two-staged AI method relying on four central concepts of AI in healthcare: data providers, clinical expertise, AI developers, and MedTech companies to connect to data and introduce AI into healthcare.

Total Budget: 8.2 Meuro

Czech Partners involved: AMIRES SRO (private company)

8 - References and Sources

This report has been elaborated with inputs from available public sources published on the Internet.

The content has been submitted for feedback to representatives of the Czech Ministry of Health via the Permanent Representation of the Czech Republic to the EU in Brussels.

The content has also been submitted for revision to the Czech National Clusters Association to gather a broad perspective of the innovation ecosystem, the gaps and challenges, and good practices related to the use of Health Data.

All the sources used for information or assessment are listed as foot notes or as links to the text.

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