EDAH
EUROPEAN DATA SPACE IN HEALTH

Interconnecting Innovation Ecosystems for Common European Data Space in Health

Funded by the European Union

D2.4 CASE STUDY: BULGARIA

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Executive Summary

The present Deliverable 2.4 "Case Study Bulgaria" 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 (European Health Data Space)[1], 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:

1. Set an open dialogue to facilitate the agreement among Member States, Associated Countries and EU Regions about key aspects related to EHDS.

2. Advancing towards common legal, governance, data quality and interoperability framework to facilitate the advancement of EHDS.

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

> **BULGARIA**, differently to other country case studies delivered in the framework of EDAH, will not hold the EU presidency during the lifespan of the project or in close periods before or after the 2 years of EDAH. Bulgaria held its (first) presidency of the European Council between 1st January and 30th June 2018, with an initial reference[2] to eHealth and the need to advance towards a secure access to electronic health records, the possibility to share these records across borders, and the facilitation of feedback and interaction between patients and healthcare providers. The EDAH Consortium considered that including the Bulgarian health ecosystem would provide a better understanding of the regional context from a country labelled in the European Innovation Scoreboard as 'Emerging Innovator' ("Modest" in editions previous to 2021)[3], that could provide inputs on main challenges, facilitators, needs and barriers that EHDS would face in its deployment.

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[1] https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_2712

[2] https://www.beuc.eu/sites/default/files/publications/beuc-x-2017-145-beuc-memorandum_bulgaria.pdf

[3] For comparison, refer to the Methodological Reports (ec_rtd_eis-2020-methodology-report.pdf; ec_rtd_eis-2021-methodology-report.pdf and ec_rtd_eis-2022-methodology-report.pdf), where the definitions of Modest and Emerging innovators are available.

In 1998, Bulgaria introduced a centralized Social Health Insurance (SHI) system, with the Ministry of Health being responsible for overall organization and policy formulation. This decision ran in parallel with the country's transformation from a centrally planned economy to a market economy[4],[5]. The sole purchaser of healthcare services is the National Health Insurance Fund (NHIF)[6] and is segmented into 28 regional branches known as the regional health insurance fund (RHIF). Although life expectancy at birth is on the rise, Bulgaria's population is experiencing a gradual decline, and the country is ranked among those with the highest population decrease. Voluntary (private) health insurance plays a role though minor.

Bulgaria has had plans to establish an integrated information system since 2006 to improve e-Health. However, as of 2018, the Health Information System in Bulgaria remained fragmented with limited interoperability. The National Health Information System (NHIS) was announced in 2017, funded by the EU and endorsed by the NHS 2020 and Bulgaria's e-government strategy (2014-2020). Despite lacking a quality management system based on reliable indicators and monitoring mechanisms, Bulgaria introduced an e-referral and e-prescription system in 2021.

This report reviews some key aspects of the life sciences ecosystem and the health system in general, focussing on digital health enablers and barriers and the legislative framework on the use of health data, providing examples of good practices that can facilitate or act as references for the European Health Data Space implementation.

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 CEBR – The Council of European Bio Regions (EDAH consortium partner, WP2 leader), ScanBalt (EDAH consortium partner) and Biocat (EDAH coordinator), with the support of the Health & Life Sciences Cluster Bulgaria (a member of the CEBR). The public sources used are listed as footnotes. This report has been submitted for revision to local players with relevant roles in the Bulgarian digital health ecosystem. We thank them for their inputs, critical revision and useful comments.

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[4] https://health.ec.europa.eu/system/files/2017-12/chp_bulgaria_english_0.pdf
[5] https://eurohealthobservatory.who.int/publications/i/bulgaria-health-system-summary
[6] https://www.nhif.bg/en

Introduction to this report

Specific objectives of EDAH

The partnership implementing EDAH has five specific objectives:

o 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.

o 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.

o O3 – Scaling up the dialogue at the EU level via developing further collaboration pathways with EU presidencies.

o 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.
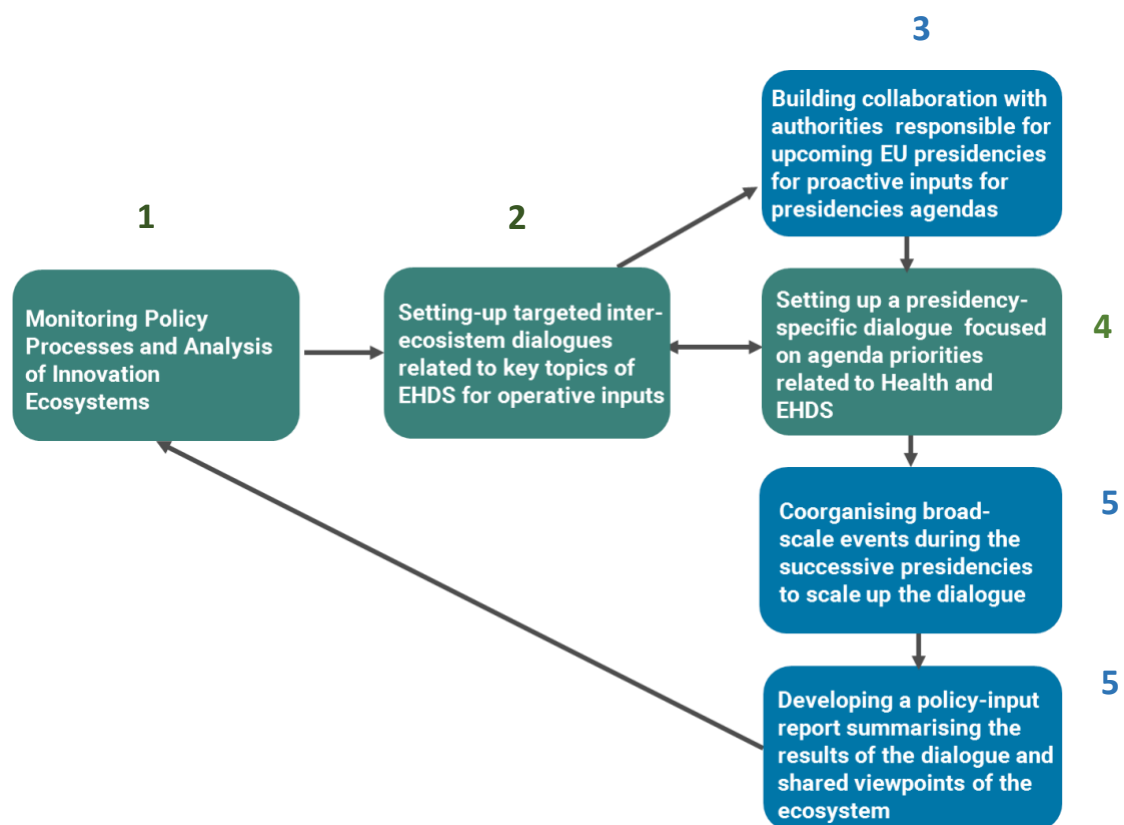

Figure 1 - Workflow of the EDAH project: step 1 is the analysis of Innovation Ecosystems

List of consortium partners and beneficiary numbers

Beneficiary #	Name	Acronym	Country
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 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

Case studies on seven key EU clusters/networks/ecosystems 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 Emerging Innovator country[7]) to get insights about key needs for development in terms of digital health and related ecosystem in such context).

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[7] with one region, Yugozapaden, with its capital city, also national capital city Sofia, ranked as "Emerging+" thanks to an innovation index performance increase of 11.4% between 2014 and 2021 (see

1 – Bulgarian Ecosystem Overview

1.1 - Country overview

Situated in Southeast Europe, Bulgaria shares borders with Romania to the north, Serbia and North Macedonia to the west, Greece and Turkey to the south, and the Black Sea to the east. It has an area of 110,994 square kilometers, making it the 16th largest country in Europe, with a population of 6.9 million inhabitants (World Bank, 2021). Despite the increasing life expectancy at birth, Bulgaria's population is slowly declining. It is estimated that the total population of Bulgaria has decreased by half a million inhabitants over the past decade. Bulgaria is ranked high among the nations with the highest population decline.

Bulgaria is a unitary state with a current administrative structure established in 1999 that includes 27 provinces and a metropolitan capital province (Sofia-Grad) and the provinces are further divided into 265 municipalities. Bulgaria is a highly centralized state where the Council of Ministers directly appoints regional governors, and both provinces and municipalities rely heavily on it for funding. Sofia is the capital and largest city, alongside other major cities such as Plovdiv, Varna, and Burgas.[8]

Bulgaria operates as a parliamentary democracy with the Prime Minister at the highest executive position. The political system has three branches - legislative, executive, and judicial- and grants universal suffrage to citizens of at least 18 years of age. The (directly elected) President serves as Head of State and commander-in-chief of the armed forces. The parliament holds the authority to create laws, approve the budget, select and dismiss the Prime Minister and other ministers and ratify international treaties and agreements.

In 2007 Bulgaria became a full member of the European Union, after signing the European Union Treaty of Accession in 2005. Bulgaria's location offer access to several big and well-developed markets such as Austria, Hungary, Croatia, Romania, Greece, Turkey, Ukraine and the Middle East.

Bulgaria is a European economy with an open, upper-middle-income market that has undergone significant changes over the years. The private sector contributes to more than 70% of the country's Gross Domestic Product (GDP). The economy has experienced ups and downs since 1990, but it is currently relatively stable. The country offers the most competitive tax regime in Europe, the corporate income tax is 10%. However, the average monthly salary in Bulgaria remains the lowest in the EU with an average annual salary of 8.800€.

Bulgaria showed strong economic performance in the early 2000s, which led to a reduction in Government's debt. In 2021, the country's government debt was slightly above 20%, making it the second lowest in the EU. The labor force in Bulgaria is made up of 3.36 million people, with 6.8% employed in agriculture, 26.6% in industry, and 66.6% in the services sector.

Bulgaria's major industrial activities include the extraction of metals and minerals, the production of chemicals, machine building, steel, biotechnology, tobacco, food processing, and petroleum refining. The most developed region in Bulgaria is the Yugozapaden planning area, which includes the capital city and the surrounding Sofia Province. Despite having only 22% of the population, this region alone generates 42% of the national GDP.

Bulgaria R&D intensity (R&D expenditure as of % of GDP) was 0.9 in 2020 (below EU's average of 2.3%)[9], with most of the public funding providing to the Bulgarian Academy of Sciences (BAS). Despite funding is not at

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https://ec.europa.eu/research-and-innovation/en/statistics/performance-indicators/european-innovation-scoreboard/eis)

[8] https://portal.cor.europa.eu/divisionpowers/Pages/Bulgaria-Introduction.aspx

[9] https://ec.europa.eu/eurostat/documents/4187653/11581532/R%26D_intensity_2020.jpg/fa264c5f-b4b4-67b6-698b-e7f9b66bfd13?t=1638176726555

the expected level, research in chemistry, materials science, and physics remains robust in Bulgaria. The country is also a regional leader in high-performance computing and operates supercomputer Avitohol[10], the most powerful supercomputer in Southeast Europe, and the Discoverer, the Bulgarian European High Performance Computing Joint Undertaking (EuroHPC JU) world-class supercomputer inaugurated in 2021. With both infrastructures, Bulgaria is placed to become a major Digital Innovation Hub in Southeastern Europe. The country ranks 35th of 132 economies in the Global Innovation Index 2022, quite an improvement from the 40th place it occupied in 2019[11].

1.2 - Health system

Bulgaria's health system is largely centralized and is primarily overseen by the National Assembly, the Council of Ministers, and the Ministry of Health. The National Health Insurance Fund (NHIF) and professional associations of physicians and dentists are also key players in the system. The Ministry of Health has the responsibility of managing and directing the health system, which includes developing health legislation, overseeing subordinate bodies, regulating healthcare providers, and financing certain types of healthcare services.[12] The National Assembly has the authority to approve budgets and the National Health Strategy, which outlines health policies, and also elects the director of the NHIF. The Council of Ministers (CoM) has the role of overseeing national health policy, whereas the Ministry of Health (MoH) is responsible for the operation and administration of the health system, including ensuring adequate human resources, developing medical science, and managing data related to population health. The regional health inspectorates (RHIs), local entities of the MoH, and municipal health commissions are responsible for implementing district health policies. Additionally, municipalities own a significant proportion of healthcare providers. There are four national professional organizations that advocate for the rights and interests of their members.
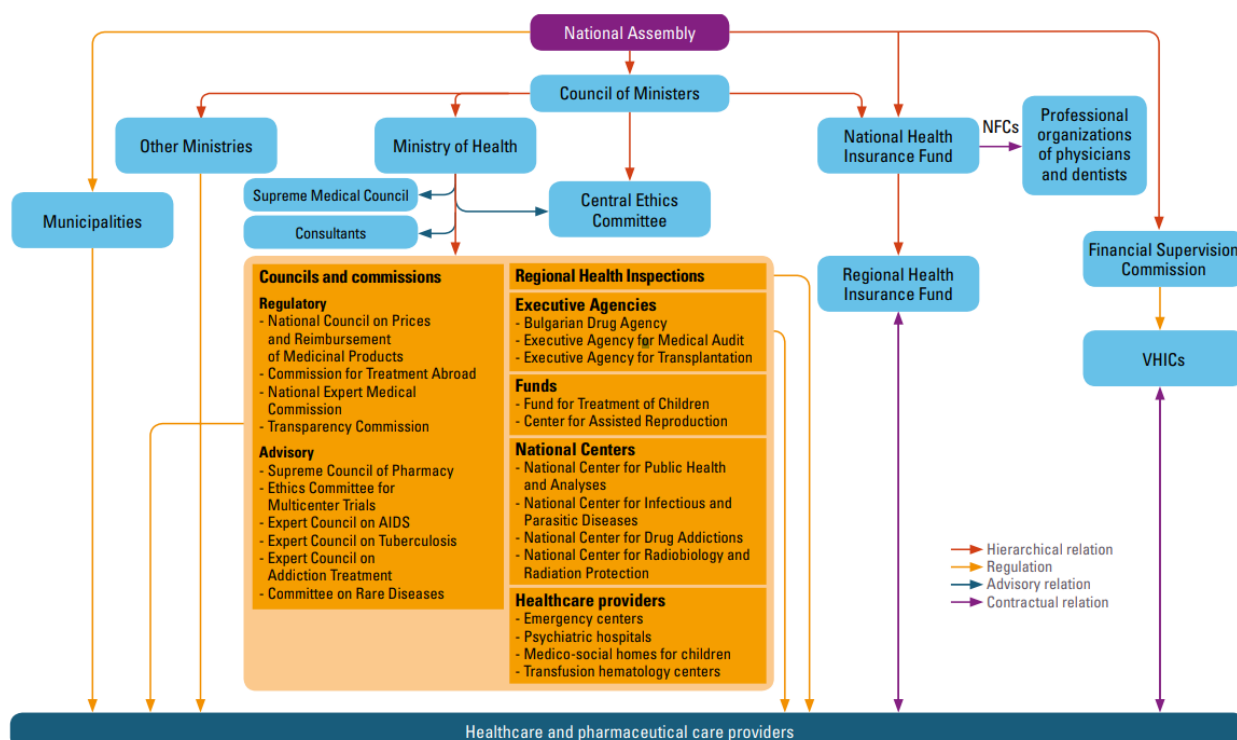

Figure 1 – Organisation of the health System in Bulgaria. Source: Rohova, Maria. "Bulgaria Health System Review." Health Systems in Transition 20, no. 4 (2018): 1–256 (https://www.academia.edu/37503642/Bulgaria_Health_system_review)

The 1998 Health Insurance Act established a health insurance system that includes both compulsory and voluntary health insurance. Social health insurance (SHI) is managed by a single payer, the NHIF, which funds medical and dental services listed in the benefit package and medications listed in the Positive Drug List (PDL). Each year, the NHIF negotiates the benefit package and prices of services with professional associations of physicians and dentists. For-profit joint-stock insurance companies offer voluntary health insurance (VHI) for general and life insurance, and they directly contract with both insured individuals and healthcare providers. While both SHI and VHI cover diagnostic, treatment, and rehabilitation services, as well as medications for the insured individuals, the Ministry of Health is responsible for providing and financing public health services, emergency care, transplantations, transfusion hematology, tuberculosis treatment, and inpatient mental health care. Additionally, the Ministry of Health is responsible for planning and ensuring adequate human resources for the health system, promoting medical science development, and collecting and managing data related to the health status of the population, health system activities, and physical and human resources. In August 2022, the CoM approved a National Health Strategy 2030, which is currently under review by the newly elected government.

The MoH manages capital investment allocations to state health care providers and the system generally. Municipalities (and private proprietors) can invest in their health care establishments, and subsidies are provided for the acquisition of long-term tangible assets, renovations, and information technologies and systems in state and municipal health care establishments. Despite intentions to reform the health system, no significant changes have been implemented since the mid-2000s.

Bulgaria's health spending has increased as a proportion of gross domestic product (GDP) since 2000. However, in 2019, health expenditure in Bulgaria accounted for 5.9% of GDP (Fig. 2), which was 2.1% lower than the EU average. Except for Slovenia, Hungary, and Czechia, Bulgaria spent more on healthcare as a percentage of GDP than other new EU Member States. Despite the persistent growth, per capita spending on healthcare in Bulgaria was the lowest in the European Union in 2019. Public sources accounted for 60.6% of current health expenditure (CHE) at the time, significantly lower than the EU regional average of 79.7%. Conversely, private health expenditure almost doubled the EU average, at 39.4% compared to 20.3% of CHE, largely driven by out-of-pocket spending. As previously mentioned, voluntary health insurance (VHI) makes up a small proportion of health financing in Bulgaria. [13]
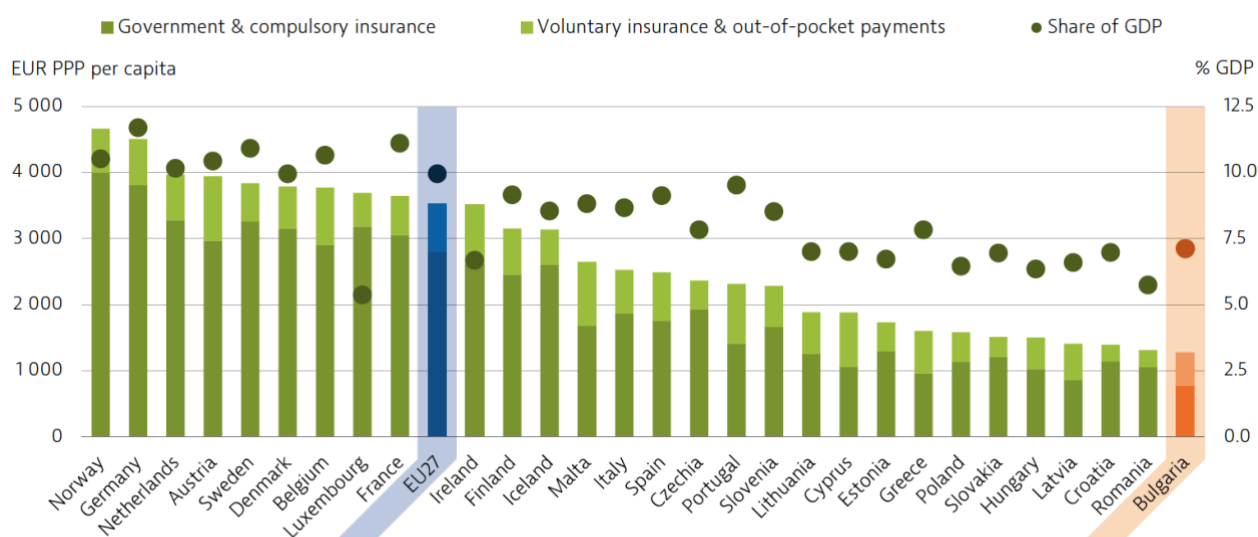
Note: The EU average is weighted.
Source: OECD Health Statistics 2021 (data refer to 2019, except for Malta 2018).

Figure 2 – Health expenditure across EU. Source: EC/OECD – Bulgaria Country Health profile 2021

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[13] OECD Bulgaria Health Profile 2021

The COVID-19 pandemic highlighted the need for additional investment in the health sector, including better preparedness for future health system shocks. Bulgaria was hit hard by the second wave of the pandemic. **In December 2020, an electronic referral system for PCR tests by GPs and other medical diagnostic tests was launched**.
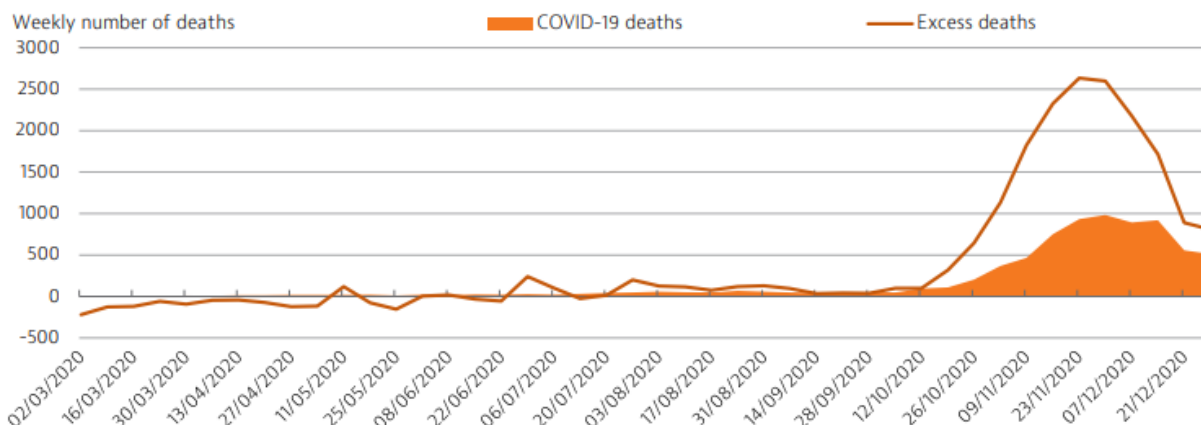
Figure 3 – COVID-19 and excess deaths peaked in autumn 2020 in Bulgaria. Source: State of Health in the EU- Bulgaria Country Health Profile 2021[14], with calculation of excess deaths based on the average with the previous five years (2015-19). Sources: ECDC (for COVID-19 deaths); OECD based on Eurostat data (for excess deaths).

For Bulgaria, the challenge includes investing to create a uniform health information system to speed up the use of e-Health, and to support working conditions for the health workforce. Hospitalization rates in Bulgaria are high, partly due to the underdevelopment and underfunding of both preventive health services and primary care.
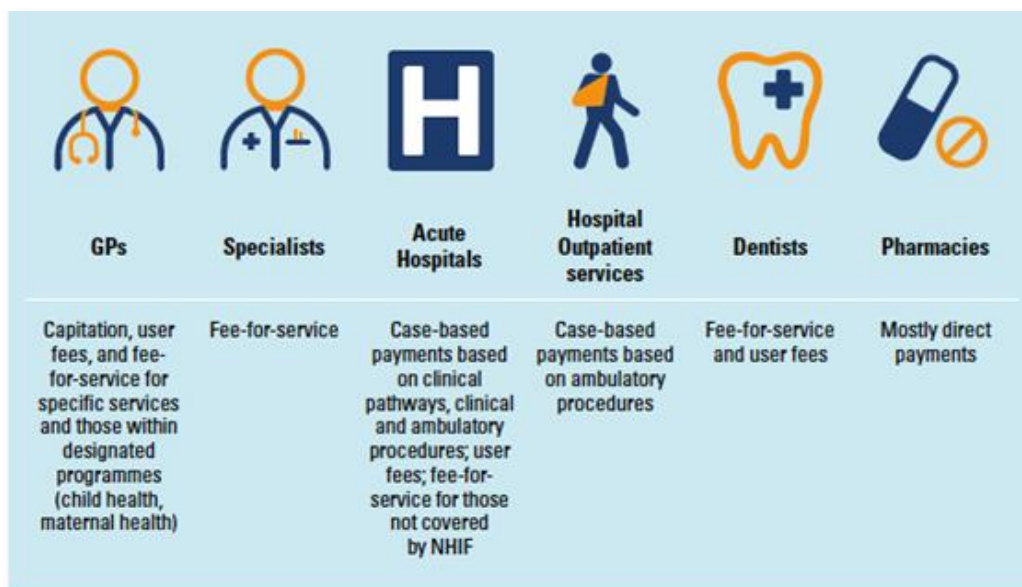
Figure 4 - Provider paying mechanisms in Bulgaria

According to the Republic of Bulgaria's National Statistical Office, in 2021, the country had a total of 319 hospitals, out of which 115 were privately owned, showing an increase from 88 in 2010. Additionally, there were 2133 outpatient health facilities, which is an increase from 2029 in 2016.

In 2019, Bulgaria's hospital system had the highest number of acute hospital beds per 100,000 population in the European Union, with 641 beds compared to the EU average of 387 beds.

With about 29,604 physicians in Bulgaria, there are about 3.99 doctors per 1000 inhabitants. In 1990, the number of nurses was close to 54,000, in 2021 they will shrink to less than 29,000 due to low pay, overwork and bad working conditions. The allocation of healthcare professionals is imbalanced and noticeable in the clustering of physicians in urbanized regions with higher economic activity and medical schools. Encouraging new graduates to replace the aging workforce in areas with fewer physicians is a significant challenge, already tackled by the National Recovery and Resilience Plan.
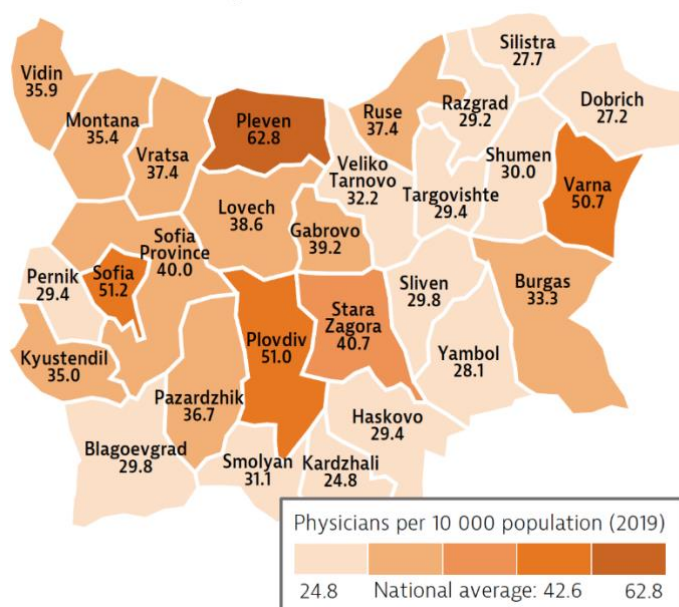
Figure 5- Distribution of physicians across Bulgaria. Source: EC/OECD – Bulgaria Country Health profile 2021

Since 2006, e-Health has been on Bulgaria's policy agenda with plans to establish an integrated information system. However, as recent as 2018, the Health Information System in Bulgaria remained fragmented, with limited interoperability. Providers utilized separate information technologies and databases, exchanging data with the National Health Insurance Fund and National Center of Public Health and Analyses, which then consolidated information at the national level. In 2017, a National Health Information System (NHIS) was announced, which was funded by the EU and endorsed by the NHS 2020 and Bulgaria's e-government strategy (2014-2020). Despite previous attempts to introduce quality and patient safety indicators, Bulgaria currently lacks a quality management system based on reliable indicators and monitoring mechanisms. Additionally, there is no medical error reporting system in place. Analysis of healthcare quality is based solely on vaccination rates, rates of preventable and amenable mortality, and select hospital admissions. However, as of 2021, an e-referral and e-prescription system has been introduced.

1.3 - Life sciences ecosystem

The health and life science industry in Bulgaria is a vital contributor to the country's economy. Health and life sciences is one of the **fifth priority industries** next to National RIS3 Priorities. Accounting for 15% of the GDP, the industry has experienced a growth rate of 7.7%, reflecting the continuous

development of the sector. With over 20,000 companies and organizations operating within the industry, it provides a significant number of employment opportunities in the country. In terms of turnover, the industry generates €13.5 Bn. The pharmaceutical sector, which is a significant player in the industry, contributes €2 Bn in terms of the market value of products manufactured in Bulgaria. These figures demonstrate the importance of the health and life science industry in the country's economy and its potential for further growth and development in the coming years.[15]
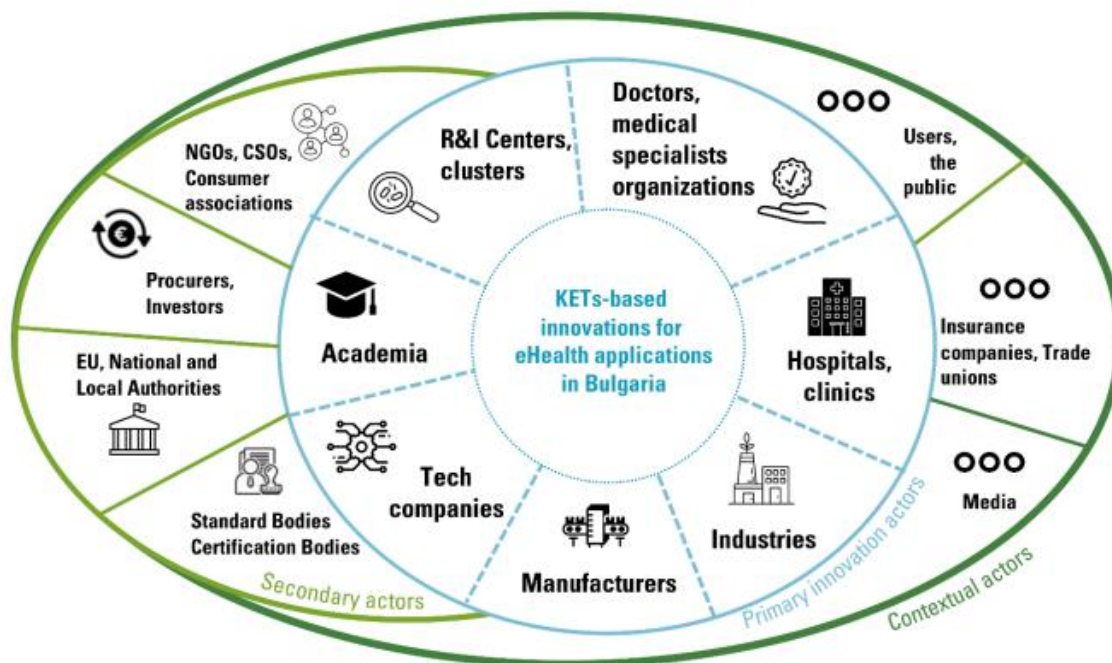
Figure 6 - The innovation ecosystem of e-Health applications in Bulgaria. Source: https://sockets-cocreation.eu/wp-content/uploads/2021/07/SocKETs_D11_eHealth_Bulgaria.pdf

Pharmaceuticals

- The Bulgarian pharmaceutical market is comprised of 90 companies which produce pharmaceutical products.
- The industry generates 2.3% GDP. The market value of pharmaceutical products places in the Bulgarian pharmacies amounts to 2 billion EUR.
- In 2021 although all measures and mechanisms introduced by the Ministry of Health aiming at curbing the spending for pharmaceuticals in combination with the global COVID-19 crisis the Bulgarian pharmaceutical market grew with 8.5 percent reaching EUR 2.5 billion, according to data provided by IQVIA.
- New therapies adoption – 956 days in Bulgaria (18th place ranking in the EU)

Medical Devices

Bulgaria represents one of the smallest medical device markets in the EU, which will register a mid-single-digit local currency compound annual growth rate (CAGR) over the 2018-2024 period. The market is largely reliant upon imports which are primarily sourced from other EU member states.

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[15] https://investbg.government.bg/health-life-science-industry/

Market growth will be dependent upon increasing healthcare funding and the success of efforts to develop the private sector.

Universities

Bulgaria has several universities that offer programs related to life sciences. Health and medicine are the most popular fields of study with 30,000 students enrolled in these programs. In addition, there are 1.400 students studying biotechnology and biology sciences, and 1,600 studying chemistry and physics. The overall number of students studying in STEM fields is 43,000. Among these students, over 4.000 are specifically enrolled in life science studies. The health sector is also a popular field of study, with over 21,500 enrolled students in the 2021/2022 academic year. Interestingly, one-third of the students enrolled in healthcare studies are foreigners, highlighting the international appeal of life science-related programs in Bulgaria.

There are 9 universities with medical and healthcare specialties, with Sofia, Plovdiv, Pleven and Varna being the most important ones.

Sofia Medical University is a public higher education institution located in Sofia, the capital city of Bulgaria. It was founded in 1917 and is the oldest and most prestigious medical school in the country. The university offers undergraduate and graduate degree programs in medicine, dental medicine, pharmacy, public health, and health management. It is known for its high-quality education and research facilities, with a focus on innovative medical technologies and practices. The university has a diverse student body, with over 8,000 students enrolled, including both domestic and international students. It has a strong reputation in the region and is recognized as one of the leading medical universities in Southeast Europe.

Medical University in Plodviv: established in 1945, the Medical University in Plovdiv, is a comprehensive institution offering education in medicine, dental medicine, pharmacy, and public health. It also includes a department of languages and specialized training, a medical college, and a hospital with 2000 beds. The university has laboratories, clinics, and units for diagnostics and treatment, research activities, and training for medical and dental students. Its 4 faculties offer various degrees and specializations, with programs ranging from six years to PhD levels.

The Medical University of Pleven is a state-run institution that was founded in 1974 and established on the foundation of a former regional hospital founded in 1865. The university has a modern preclinical base, specialized clinics, and research sections. It consists of three faculties and a college: the Faculty of Medicine, Faculty of Pharmacy, Faculty of Public Health, and Medical College. The university introduced an English language medicine program in 1997 for international students, making it the first of its kind in Bulgaria. The university has approximately 750 new students every year.

The Medical University of Varna (MU-Varna) is a state-run institution in Bulgaria that provides higher education in medicine and healthcare, and grants graduates with degrees including Master's, Bachelor's, and Professional Bachelor's. The university holds a legal entity status, which allows it to conduct various activities such as training and professional qualification, postgraduate education for medical and non-medical staff, scientific research and applied sciences, providing medical services at university hospitals, and more. The university also has academic autonomy. In 2008, MU-

Varna became the first Bulgarian university to adopt the EFQM® model for Business Excellence by the European Foundation for Quality Management, and its diplomas are recognized across all European Union countries.

Health and Life Sciences Cluster Bulgaria

The Health and Life Sciences Cluster Bulgaria is a non-profit organization aimed at building a sustainable regional innovation ecosystem in the field of health and life sciences. The cluster has established collaborations in major regions across Bulgaria, including Sofia, Stara Zagora, Varna, Plovdiv, and Gabrovo. Its strategic directions include supporting entrepreneurship, creating innovative and customized strategies for target regions, and the creation of spin-off high-tech companies. The cluster has partnered with various institutions and organizations, including the Ministry of Economic and Ministry of Education, Medical University of Varna and Plovdiv, and Bulgarian Investment Agency. The cluster is composed of 26 member organizations, including 20 SMEs, two larger companies, and research organizations, universities, and technology centers. The Health and Life Sciences Cluster Bulgaria also serves as a platform for joint development within the region, promoting networking, and generating value-added for the region.[16]

Patient organisations:

The National Patients' Organization - Bulgaria was founded in 2010 and is currently the largest patients' umbrella organisation in the country with 79 member organisations from across the country. With a decision of the Minister of Health of Bulgaria from 2010 (reconfirmed in 2011), the National Patients' Organization is recognised as a national representative organisation for defense of patients' rights in Bulgaria. The National Patients' Organization is a full member of the European Patients' Forum and the International Alliance of Patients' Organizations (IAPO). The National Patients' Organization is a modern structure which aspires to the European values rooted in understanding, democracy and high morals. In this respect, the National Patients' Organization pursues with dedication the core values of the EU health policy, namely, to ensure citizens' empowerment, to reduce inequalities in health and to promote scientific-based policy.[17] Expert figures acting as Patient Advocates at the Bulgarian Society for Personalised Medicine have been active in promoting discussions and advocating on e-Health (see Sockets project, page 38).

DHI Bulgaria

The Digital Health and Innovations Cluster Bulgaria[18] is a non-profit association founded in 2018 that focuses on supporting digital solutions and innovations in healthcare. The organization aims to create a sustainable and effective healthcare environment for patients, healthcare professionals, society, and institutions. Its mission is to promote data-driven healthcare to increase sustainability and efficiency in the system. The vision of the organization is to establish an ecosystem in healthcare that is open to private entrepreneurs and organizations that can provide innovative tools and resources to create a valuable impact. The DHI cluster holds more than 20 events with over 3000 visitors, including leading professionals, opinion leaders, entrepreneurs, innovators, and experts

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[16] https://www.biocluster.bg/

[17] https://www.eu-patient.eu/Members/The-EPF-Members/Full-Membership/National-Patients-Organisation-of-Bulgaria---NPO/

[18] https://dhicluster.bg/?lang=en

from various fields. They also maintain a database of over 1500 stakeholders, including startups, entrepreneurs, institutions, medical professionals, and students. Overall, the DHI cluster plays a significant role in driving digital health innovation in Bulgaria by bringing together diverse stakeholders and promoting collaboration and knowledge sharing.[19]

European Digital Innovation Hub (EDIH) Zagore - Synergy for Green Regional Digital Transformation of South-east Region of Bulgaria: SynGReDiT

The primary goal of EDIH Zagore is to develop essential digital skills in the South-east Region to bolster the area's industrial ecosystems as they undergo a shift towards green and digital transformation. This will involve concentrating on vital areas such as high-speed computing, upgrading digital skills training, cyber security, data infrastructures, and data management and processing. A comprehensive range of services will be provided over the next three years to achieve this goal.[20]

Bulgarian Sockets Lab
The Bulgarian Lab dealt with Electronic health applications thorough three focused on sharing new technologies applications, ideas to provoke social engagement with KETs, citizen needs, concerns and visions for better healthcare based on digital transformation of medical services.

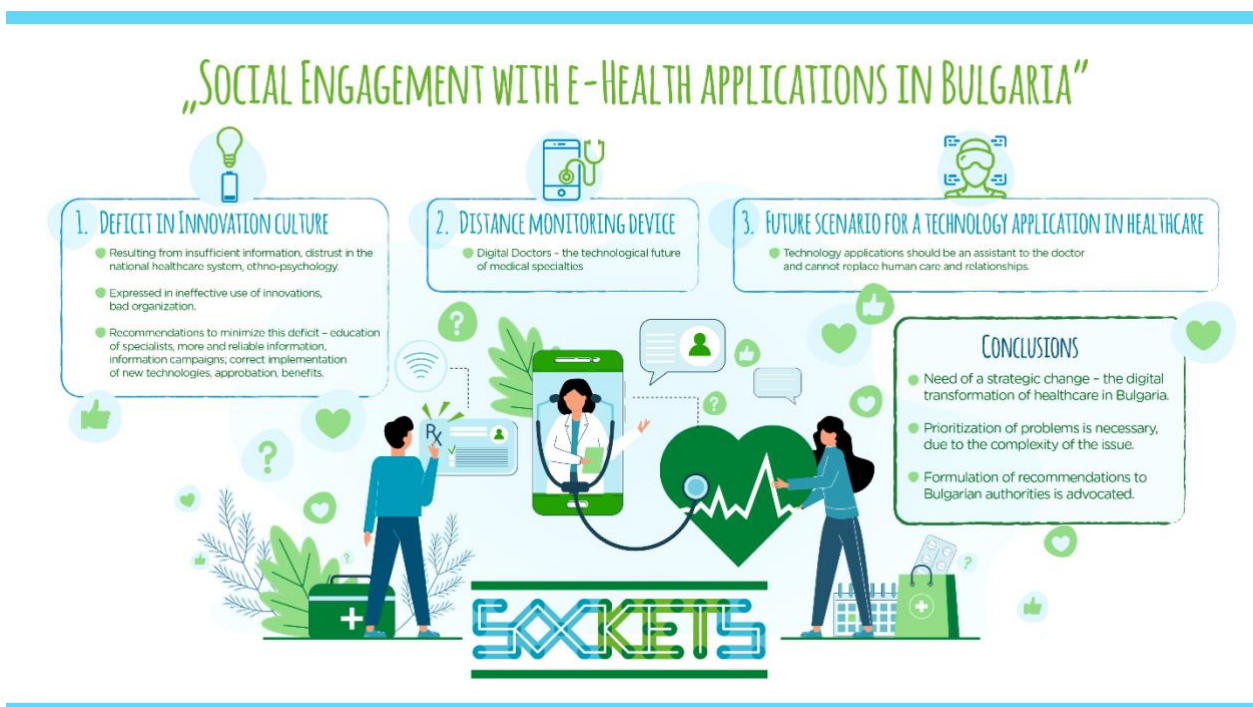*Figure 7: Needs identified in Sockets project to engage citizens in e-health*
Source: https://sockets-cocreation.eu/actions-to-be-taken-to-enhance-the-development-of-ehealth-technology-in-bulgaria/

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[19] https://dhicluster.bg/
[20] https://www.developmentaid.org/organizations/awards/view/404373/european-digital-innovation-hub-zagore-synergy-for-green-regional-digital-transformation-of-south-ea

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the European Union

2 – Existing legal framework

In Bulgaria, health policy priorities and national programs are determined by the Council of Ministers and executed through implementation of National Health Strategy. At district level all health policies are implemented by the Regional Health Inspectorates. The main actors are the National Assembly and its Parliamentary Healthcare Committee representing the legislative power; the Council of Ministers and the Ministry of Health representing the executive power; and the National Health Insurance Fund and the professional organizations representing the public and non-government sector. The Bulgarian Drug Agency (BDA) is a specialized state regulatory authority reporting to the Minister of Health exercising supervision over the quality, safety and efficacy of drugs (incl. biological) and of medical devices. The BDA is responsible for authorizing and registering drugs and medical devices to be launched in the market.[21]

The highly centralized governance of the Bulgarian health system provides limited options for priority setting, planning, organization of service provision, and performance assessment at the regional and local levels. Despite intentions, no significant health reforms have been implemented since the mid-2000s. On the one hand, reform initiatives, coinciding with a fragile political situation, have been resisted by stakeholders. On the other, promising legislation, addressing the most pressing problems of the health system, have been struck down in courts before some of them could enter into force.

Bulgaria does not have a quality management system built on reliable indicators and monitoring mechanisms. Previous attempts to introduce quality and patient safety indicators have not been successful. Additionally, there is no medical error reporting system. Analysis of health care quality is based solely on vaccination rates, rates of preventable and amenable mortality and select hospital admissions.

In general, the legislative situation in the field of eHealth in Bulgaria is characterised by the fact that no specific law regulating this area has been implemented so far. Various laws have been prepared, but due to the difficult political situation, the lack of dialogue between politicians and relevant stakeholders, and the lack of a clear legal framework, they have not yet been implemented. However, some laws and regulations address certain aspects of digital health and health data.

The main strategic documents and legislation that define the functions of the Ministry of Health and the eHealth system in the country offering guidelines, development, and coordination activities for the implementation of state policy in the field of eHealth are:

- Health Act requires healthcare providers to collect and maintain accurate and up-to-date medical records for each patient. These records may include information such as the patient's name, address, date of birth, medical history, diagnosis, and treatment plan. Healthcare providers must also ensure the confidentiality and security of patients' health data, and may only disclose it to authorized individuals or organizations by law. Patients have the right to access their health data, as well as the right to request that any inaccuracies or incomplete information be corrected. In July 2022, a proposal for an amendment to the Bulgarian Health Act was submitted to the Bulgarian parliament, which aimed, among other

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[21] https://www.trade.gov/country-commercial-guides/bulgaria-healthcare-and-life-sciences

things, to regulate the use of telecommunication technologies in the healthcare sector. However, due to ongoing political instability the proposal has yet to be approved.

- Health Insurance Act stipulates that patients have the right to access their medical records, as well as to request that their records be amended or corrected if necessary. Healthcare providers are also required to maintain patient confidentiality and protect patient data in accordance with national privacy laws.

LEGISLATIVE ACT	PATIENT RIGHTS	PATIENT OBLIGATIONS
Health Act	• high-quality and accessible health care services regardless of race, gender, age, ethnicity, religion, education, cultural beliefs, political belonging, sexual orientation and social status • more than one physician's opinion regarding diagnosis and treatment • protection of personal data • information about patient rights, health status and treatment options • health promotion and rehabilitation • visits by GP during the hospital stay • admission or refusal of visitors, etc.	• take care of own health • assisting health care providers in carrying out health services (such as adherence to prescription drugs) • observance of the order in the health care establishments, etc.
Health Insurance Act	• health services included in the NHIF basic benefit package • choice of health care providers • receive emergency care • receive information from the RHIF about contractual partners • participation in the governance of the NHIF • complaints to the director of the RHIF • cross-border health care services by the provisions of the law, etc.	• payment of health insurance contributions and cost-sharing fees • compliance with the prescriptions of health care providers and requirements for disease prevention, etc

Table 1 - Patient rights and obligations. Source: Health Systems in Transition - Bulgaria Health system review 2018
https://www.academia.edu/37503642/Bulgaria_Health_system_review

- Personal Data Protection Act implements the GDPR and provides additional guidance on the processing of personal data, including health data. The Act requires that personal data, including health data, is processed lawfully, fairly, and transparently. It also sets out the rights of individuals in relation to their personal data, including the right to access, rectify, and erase their data. Health information falls, altogether, under the scope of the Personal Data Protection Act. The general data protection regime is therefore applicable to health information together with the specific rules of the Health Act, which further develop and complement it.

Other legislation that applies in terms of data privacy and security in Bulgaria
Medical Establishments Act
Healthy and Safe Working Conditions Act
Medical Products in Human Medicine Act
Medical Devices Act
Recognition of Professional Qualifications Act

Table 2 – other legislation to consider in the development of EHDS in Bulgaria. Source: https://sockets-cocreation.eu/wp-content/uploads/2021/07/SocKETs_D11_eHealth_Bulgaria.pdf

In 2019, a National research program eHealth was initiated. The program was funded by the Ministry of Education and Science in the amount of BGN 2 million. The aim was to provide analyses and results that will help the Ministry of Healthcare to set the vision and elaborate the methodology for further eHealth implementation in the country. The program was focused on collecting and processing large volumes of clinical information, and designed to address some of the existing barriers to eHealth in the country, such as: lack of interoperability between the various software products and systems used by physicians and medical units; lack of evidence for the ICT implementation effects; not well regulated personal data protection; limited connections between the medical establishments; lack of incentives to participate in the exchange of clinical information. [22]

The Framework of the National Strategy for the development of AI, developed by the Bulgarian Academy of Sciences, states "Against the background of the rapid development of eHealth in other European countries, Bulgaria has not yet built an adequate health information system to provide the necessary information for the needs of the management and users of health services, incl. to fulfil the country's commitments in connection with the cross-border exchange of health data. The available information systems and databases are not systematically integrated and do not give a real idea of the general state of the health care system, which complicates the process of health policy planning." [23]

2.1 - The primary use (for the provision of health and social care by health and care providers to the patient)

The National Health Insurance Fund (NHIF) and health practitioners in Bulgaria fall under the legal definition of 'administrator of personal data' (Administrator) and as such are subject to the Personal Data Protection Law's requirements. Administrators cannot begin collecting, hosting, and processing personal data before being officially registered by the Commission for Personal Data Protection. The Commission controls` Administrators' compliance with personal data protection requirements and can impose mandatory instructions on them. ´

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[22] https://sockets-cocreation.eu/wp-content/uploads/2021/07/SocKETs_D11_eHealth_Bulgaria.pdf
[23] https://sockets-cocreation.eu/wp-content/uploads/2021/07/SocKETs_D11_eHealth_Bulgaria.pdf

2.2 - The secondary use for planning, management health systems improvement

There is no legal framework regulating the secondary use of data. However, The Bulgarian Association for Personalised Medicine (BAPEMED) recently released a report which outlines plans to improve public participation and use of secondary data according to global best practices.

2.3 - Secondary use (for scientific or historical research by both public and private sector organisations

Bulgaria has no specific legislation in place for third-party research.

2.4 - Legal or regulatory mechanism which addresses the use of health data for research purposes

The National Centre of Public Health and Analyses (NCPHA) provides statistical information following the Health Act (HA) and the Personal Data Protection Act. The provision of access to public information by the NCPHA is carried out based on a written application or an oral inquiry in accordance with the Internal Rules for Ensuring Access to Public Information in the NCPHA and the Access to Public Information Act (APIA).

2.5 - Patients' rights

The Bulgarian Health Act, states that a patient has the right to access medical records related to his health condition. This includes records of medical examinations, diagnoses, treatments, and any other information related to their health status. The health care provider or medical institution must provide access to the patient's medical records within a reasonable timeframe after the patient's request.

2.6 - Electronic Health Record

A platform for electronic Health Patient Records, supported by the National Health Insurance Fund (NHIF), currently exists. The Health Patient Record contains information on the health status of mandatorily health-insured citizens (immunizations, hospitalizations, medical and laboratory examinations, etc.) as well as information on the general medical practitioner chosen by them. It is accessible through the website of NHIF with an electronic signature or a personal code issued by the NHIF. Yet, Electronic Health Data Act is still in draft and has not been implemented. [24]

3 – Innovation agenda in the field

Over the past two decades, there has been a consistent and systematic statement of political will for the implementation and development of eGovernment in Bulgaria, including e-health. These initiatives have been declared as priorities for the state government but, even if a strong dynamic in the law-making and strategic planning concerning electronic governance in Bulgaria has been observed, the implementation has not been able to keep up. As a result, tangible changes and major and durable improvements at all levels of the public machine, including health are still to come.

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

In response to the COVID-19 pandemic, a National Recovery and Resilience Plan has been launched across the different European countries, providing additional resources for countries to spend on long-term projects. The modernization of the healthcare sector is a key aspect of the Bulgarian NRRP, coupled with the new National Health Strategy 2030, which was introduced in 2022.

The most updated strategic innovation agenda for eHealth can be found in this document, and references to the topic can be found in other strategic documents such as the *Updated Strategy for the Development of Electronic Government in the Republic of Bulgaria 2019-2025*, the *National map of long-term needs for health services*, the national development program *Bulgaria 2030*, the *Updated national strategy for the development of scientific research in the Republic of Bulgaria 2017-2030*, the National Program *Digital Bulgaria 2025*, the national strategic document *Digital transformation of Bulgaria for the period 2020-2030*, the *Updated national roadmap for scientific infrastructures 2020-2027*, as well as the *National strategy for the development of scientific research 2017-2030*.

Trying to follow the flow of strategic documents at national level in Bulgaria, it is natural to start from the highest-level strategic framework document in the hierarchy of national program documents, the one entitled "**BULGARIA 2030**"[25], which identifies "Health and Sport" as national priority n.12.

The priority is composed by several sub-priorities, of which the most relevant for our purposes are n.12.1 "Health promotion and disease prevention", 12.2 "Health network and optimization" but, more important, 12.3: "eHealth", whose objective is to bring about a digital transformation in the healthcare industry by focusing on the advancement of three key technological components:
- cloud technology
- the expansion of wireless communication networks such as 4G/5G
- the widespread deployment of high-speed optical data networks

The priority also states that to provide centralized eHealth services for citizens, an integrated electronic portal and application will be created. These services will include a health information system, a health profile, a health record, and condition monitoring, telemedicine, prescription, and administrative services.

There are three areas of impact identified:

A - Establishment of a National Health Information System (NHIS), using advanced technological solutions that prioritize chronic and non-infectious disease risk prevention. By implementing the NHIS and other eHealth systems, transparency in financial expenditure management, as well as organizational control, planning, and forecasting activities within the healthcare system, will be enhanced. Moreover, it will enable an evaluation of the quality and safety of medical care.
For this action a budget of BGN 23,000,000 (around 11.8 million EUR) has been assigned.

B – Remote healthcare services, including the creation and execution of telemedicine services (including online consultations), primarily intended for patients living in remote areas and those with special requirements, but in general aimed at enhancing the access to high-quality healthcare services for the general population.

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[25] https://www.minfin.bg/en/1394

For this action a budget of BGN 14,000,000 (around 7.16 million EUR) has been assigned.

C – eHealth information systems, aimed at guaranteeing interoperability when exchanging medical data, data protection and a proper integration with other information systems such as the one related to drug supply.
For this action a budget of BGN 100,000,000 (around 51.1 million EUR) has been assigned.

D - Security of information and personal data, including various measures such as the creation of regulations, procedures and actions to guarantee the cybersecurity of NHIS and other eHealth systems. Compliance with personal data protection regulations, including the handling of anonymized and pseudonymized health data will also be emphasized. A platform for monitoring, analysis, and control of logs, network traffic, system files, and incident management will be developed.
For this action a budget of BGN 13,000,000 (around 6.65 million EUR) has been assigned.

E – Large health databases: implementation of measures such as the creation of capabilities to analyze the activities and results of public health policies using extensive health databases. This will provide an opportunity to leverage health data for research and innovation to support personalized healthcare, improve health interventions, and enhance the effectiveness of the health and social care system.
For this action a budget of BGN 14,000,000 (around 7.16 million EUR) has been assigned.

F - Capacity to implement eHealth systems: efforts in this area involve enhancing the competencies of healthcare providers in gathering, assessing, and safeguarding health data, which includes establishing standards for digital health education and offering continuing education programs focused on particular digital skill sets. Additionally, measures will be taken to ensure resource, organizational, and staffing stability in maintaining the optimal performance of NHIS.
For this action a budget of BGN 18,000,000 (around 9.20 million EUR) has been assigned.

The same concepts, with a bit more of detail are included in the most important and most recent health related national strategic document: the one entitled "**National Health Strategy 2030**", published in September 2022 (an action plan for its implementation should follow).

The document identifies three priorities:
1. Prevention and promotion of healthy behavior and an environment that supports health for all throughout life
2. People-oriented health system transformation
3. Focused strategies for impact on specific public health problems

eHealth falls under Priority 2, where under *Policy 2.5* we can find "Development of electronic healthcare and digitization of the healthcare system".
Despite the fact that in the document e-health and in general the digitalization of the healthcare system is considered to be at the basis of the implementation of the strategic goals and priorities of the National Health Strategy 2030, the topic is not tackled with the necessary detail.
All the positive aspects, advantages and opportunities of implementing such a revolution are mentioned, including prevention, personalized medicine, the central role of the patient, efficiency, transparency, telemedicine, the use of data, the cross-border exchange of health information of EU citizens, cybersecurity, AI etc.

Unfortunately, due to its complexity and profound impact, the description of how this revolution is going to take place in the country is held over to a different, fully dedicated strategic document, still under development and not yet published. The document is mentioned in the National Recovery and Resilience Plan (Reform 1 C12.R1 of component 12 "Healthcare" entitled Upgrading the strategic framework of the healthcare sector") and was due for Q4 2022, envisaging the following goals:

- To help implement advanced e-Health services transforming the sector to support patients and health professionals, and increase the quality and efficiency of health services
- To support the utilization of resources provided by digitalization processes and e-Health to facilitate good health for people;
- To help create a digitally-integrated healthcare system in Bulgaria, providing affordable, effective, efficient and high-quality patient care.

As per the end of April 2023, the document has not been published yet.
After the implementation of that another reform, specifically dedicated to eHealth, was envisaged. Reform 2 (C12.R2) aims at increasing the efficiency and coverage of e-Health services through the adoption of the National Strategy for e-Health and Digitalisation of the Health System 2021-2030.
The envisaged reform includes updating the legal framework in the country with regard to e-Health, including telemedicine, prescribing and dispensing of medicinal products, establishment and maintenance of electronic health records, and working processes of the National Health Information System (NHIS). The reform also aims to finalize the upgrade implementation of the NHIS, which will establish a single digital environment for the collection and exchange of medical information, expand its functionalities and a number of administrative services and operational registers, as well as additional modules covering:

- electronic medical records of citizens;
- e-prescriptions and e-referrals modules;
- a system for the collection of data from hospitals.

The deadline for completing the implementation of the reform is 30 June 2023.

As mentioned above, the National Health Strategy 2030, as part of the NRRP, is supposed to be accompanied by an action plan for its implementation but that plan has not been published yet (RRP code 318).

4 – SWOT Analysis on digital health innovation
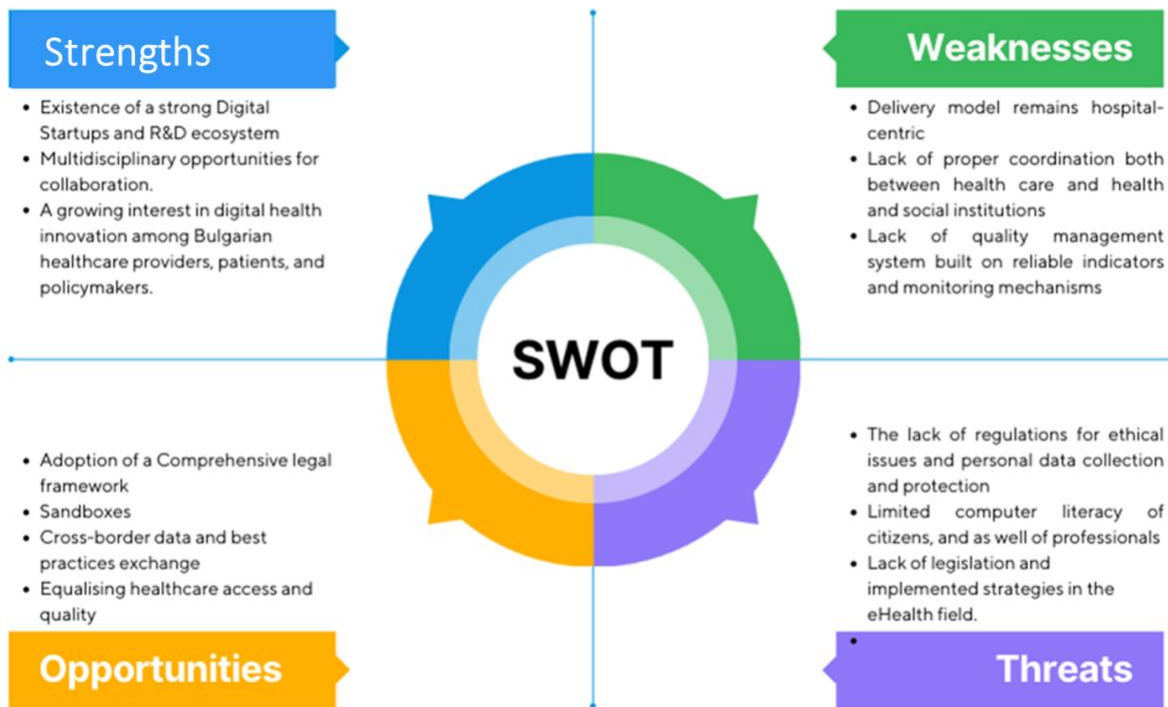
4.1 -

Figure 8: SWOT Analysis on digital health innovation, resulting from the analysis and consultations included in this report. Source: Authors' own compilation.

Strengths

- **Existence of strong Digital startups and R&D ecosystem and multidisciplinary opportunities for collaboration between the sectors.** Bulgaria has a strong tradition in STEM and a developed IT sector. Primary level access to paediatricians and gynaecologists for children and pregnant women, and a wide scope of primary care services and medicines offered by the statutory benefits package, including prophylactic and chronic disease monitoring paid on an FFS basis. 53% of the employees in the field of Health & Life Sciences in Bulgaria are female. The country has a strong academic education. Bulgaria plays a prominent role in high-performance computing in Europe with its pet-scale supercomputer.

- **A growing interest in digital health innovation among Bulgarian healthcare providers, patients, and policymakers.** With more interest in digital health, it's likely that more funding will become available for eHealth projects in Bulgaria which could help improve the quality and availability of eHealth services, as well as spur the development of new technologies. Also, there may be more opportunities for collaboration between healthcare providers, patients, policymakers, and technology companies. This could lead to more innovative solutions and greater progress in the field of digital health.

4.2- Weaknesses

- **The delivery model remains very hospital centric.** The Bulgarian health system is overly focused on hospital care, while primary and secondary outpatient care is inadequate. Primary care is under-developed and under-funded, characterised by a limited operational profile, lack of incentives for teamwork, limited recognition, weak links with secondary care and inadequate funding. In addition, the quarterly referral quotas imposed on family physicians hamper access to outpatient specialist care and undermine their ability to play a real gatekeeping and coordination role. Access to primary care is also a problem. There is a shortage of general practitioners and nurses throughout Bulgaria, with inadequate working conditions and salaries, and poor infrastructure and geographical distances meaning that peripheral rural areas are particularly affected. Recent efforts to strengthen primary care include price increases for GP services and higher fees for GPs providing prophylaxis. However, there is a lack of official, publicly available data on the quality of primary care to systematise improvements.

- **There is a lack of proper coordination both between health care levels and between health and social services.** Despite efforts, there is a lack of proper coordination in health care structures and processes in Bulgaria, both between health care levels and between health care and social services, including in the areas of health promotion, disease prevention, health care management and rehabilitation (the Republic of Bulgaria, 2015). Progress was made in 2015 when integrated care was mentioned in legislation for the first time. Subsequent amendments to the Law on Health Care Institutions have so far led to the establishment of 10 new centres for the provision of integrated services for children with disabilities and chronic diseases, and thus to the creation of new integrated health and social services.

- **Lack of a quality management system based on reliable indicators and monitoring mechanisms.** Bulgarian eHealth lacks a quality management system based on reliable indicators and monitoring mechanisms. Previous attempts to introduce quality and patient safety indicators have not been successful. In addition, there is no system for reporting medical errors. Analysis of the quality of health care is based only on vaccination rates, preventable and avoidable mortality rates, and selected hospitalisation rates.

4.3 - Opportunities

- **Adoption of Comprehensive legal framework** setting up - rules on how to operate with personal data, biodata, how to protect personal medical data, and how to process it so as not to violate privacy. New regulations are necessary that should go in the direction of introducing appropriate innovation practices and eHealth and disease prevention systems. New regulations should offer new pathways for new technologies. This would require:
  - Defining and sharing responsibilities.
  - Not allowing technologies to take advantage and rule out human relations.
  - Involving more competent and knowledgeable people.

- Creating trust between patients and doctors, which is now lacking. Therefore, encouraging dialogue is important to return trust. Strict rules should be observed as to who can pronounce himself in the media on specific specialized topics.
- Promoting new technologies and educating people on their rights and potential benefits.

- **Creating so-called sandboxes** to test new products, services, and business models in a safe space, to confirm their compliance with existing regulations before implementing them within the wider sector. Sandboxes have the potential to be beneficial in driving forward the improvement of health and social care services. In this context, the regulatory sandbox aims to not only improve healthcare experience and outcomes, but also to improve the experiences of healthcare providers, commissioners, and regulators. The sandbox participants collaborate to determine 'what good looks like, and to design and drive innovation without the associated risks.

- **Cross-border data and best practices exchange between pan-European network**s - Community partnerships can help introduce a product or service to a population, provide community-level data that can be used to identify and track gaps in care, and support the users of new digital solutions.

- **Equalising healthcare access and quality** not only improves individual and population-level outcomes but also has salutary effects on the larger economy: good health and prompt, effective treatment allow patients to live active and productive lives. Indeed, improvements in global health have contributed to about a third of all economic growth in advanced economies over the past century. To sustain this growth rate, digital health solutions must be designed to reach previously excluded or underrepresented groups.

4.4 - Threats

- **Lack of regulations and implemented strategies in the eHealth field**. The absence of clear regulations, there may be inconsistent standards for digital health technologies and services in Bulgaria. This could lead to a fragmented eHealth landscape and make it difficult for patients to access the care they need. The lack of clear regulations and strategies for eHealth makes it difficult for investors to justify investing in digital health technologies and services in Bulgaria. This slows the development of new technologies and limit the availability of eHealth services for patients. Without a clear framework for eHealth, Bulgaria may miss out on opportunities to improve healthcare outcomes and reduce healthcare costs through digital health technologies. This could put the country at a disadvantage compared to other countries that have already embraced eHealth. In a number of areas, the role of secondary use of health data in personalised medicine (and for other healthcare and scientific research use-cases) has not been documented. Where processes do exist, strategies to enable secondary use of health data are unclear, for example, while there are national social health insurance datasets, the number of data requests made for secondary use of data is not recorded.

- **The lack of regulations for ethical issues and personal data collection and protection** – who has access to personal information, who can collect and what kind of data can be collected. The systems should be protected so as not to allow data leaks. Data should not be accessible for business purposes, for insurers, employers etc.

- Another major treat is the **limited computer literacy of citizen, and as well of professionals** (e.g. medical staff). The National Health Insurance Fund has already introduced practices for the General practitioners to work online, but these rules cannot cover the needs and vision and strategy of eHealth. For example, in medical institutions the personnel have no practice and habit to working with an e-signature.

5 – Transferable Good practices

5.1 - Good practice example no. 1: National programme '2025 Digital Bulgaria'

In 2021, 16% more SMEs participated in joint R&D projects and technology transfers to either public or private R&D institutions, according to the reporting figures for the implementation of the **National Programme '2025 Digital Bulgaria'**. Other strategic measures to increase digitalisation in enterprises include the establishment of training innovation centres for green and digital transitions, as well as the creation of European Digital Innovation Hubs. These Hubs are one of the most highly visible national measures. Four European Digital Innovation Hub proposals received a successful evaluation result8 and another eight proposals got a Seal of Excellence.

5.2 - Good practice example no. 2: Peta scale supercomputer Bulgaria

Bulgaria plays a prominent role in high-performance computing in Europe with its petascale supercomputer. Petascale Supercomputer Bulgaria, as a founding member of the European High-Performance Computing Joint Undertaking (EuroHPC JU), has supported the establishment of a petascale supercomputer located in Sofia Tech Park. The supercomputer cost EUR 11.5 million and was inaugurated in October 2021. It will be subsidised by EU and national funding. The supercomputer, together with other high-performance systems and the Distributed Computing Grid Clusters, is openly accessible to the research community and other private and public users.

Bulgaria is also a member of the EuroQCI initiative to upgrade its national cybersecurity infrastructure with quantum-level cryptographic keys. A project called QUASAR for the establishment of a competence centre in quantum communication and intelligent security is ongoing.

5.3 - Good practice example no 3: 'Cybersecurity Bulgaria 2030' National Security Strategy

In the last quarter of 2021, Bulgaria presented a draft proposal for the implementation of the 'Cybersecurity Bulgaria 2030' National Security Strategy. In 2021, the National Computer Security Incident Response Team updated its roadmap for amending the national Cybersecurity Regulation in accordance with EU directives to secure the funding of the projects included in the strategy. As of 2022, the new Bulgarian government is expected to have finalised the adoption of the Cybersecurity Law and to have set out the cybersecurity measures for administrative authorities and institutions.

5.4 - Good practice example no 4: "Spinoff Bulgaria"

In 2022 was established the "Spinoff Bulgaria" (www.spinoff.bg) initiative that aims to create and implement a sustainable spin-off ecosystem and culture, which by 2030 will create 100 new technological start-ups in Bulgaria, originating from the Academy, the entrepreneurial ecosystem, or existing corporations. The initiative was created by Biotechnology and Health Cluster Bulgaria, Cluster Artificial Intelligence and Venrize and supported by BASMEA and EC in partnership with many Bulgarian and European organizations. In 2023, "Spinoff Bulgaria" will be held on June 22-23 in Sofia, and the program will include several thematic areas, including Artificial Intelligence, Cybersecurity (in partnership with CyberCLUB), The Future of Medicine (in collaboration with the British Embassy in Bulgaria and BBBA), Drones and autonomous transport, Microelectronics and nanotechnologies (together with the working group on microelectronics at the Ministry of Innovation and Growth and TU-Sofia). The Spinoff Bulgaria initiative conducts and creates a series of events, training, podcasts, and projects related to the development of the culture for creating companies with high-added value (deep-tech, science-based start-ups).

5.5 - Good practice example no 5: International initiative "Together We Make DIGITAL HEALTH Accessible"

Digital Health Innovation Cluster Bulgaria is part of the international initiative "Together We Make DIGITAL HEALTH Accessible" inspired by the need for further collaboration in the healthcare sector. It aims to encourage the connection among innovative healthcare ecosystems worldwide, stimulate knowledge exchange and open new business opportunities. The aim is to work together for more effective and sustainable healthcare systems based on data and technology, and accessible digital health solutions. At the heart of this initiative are good practices in the domain of digital health and use of secondary data, related innovative solutions and methods of co-creation, co-planning and co-investments (e.g. innovative public-private partnerships), definitions of Standards for data interoperability, use of AI for advancing EHDS, cross-border health data exchanges etc.

6 – Good practices related to gender diversity and inclusiveness

6.1 – Gender equality in Bulgaria

Since 2000, the Ministry of Labour and Social Policy (MLSP) has been responsible for the coordination and implementation of the Republic of Bulgaria's state policy on gender equality at a national level. A specialized unit, known as the "Equal Opportunities, Antidiscrimination and Social Assistance Benefits" Department (EOASAB), was established within the MLSP in 2004.

Currently, the department is incorporated into the PPDEOSAB Directorate (Policy for Persons with Disabilities, Equal Opportunities, and Social Assistance Benefits), which oversees policies aligned with The European Pillar of Social Rights[26]. Moreover, the department also serves as the Secretariat of the National Gender Equality Council in collaboration with the Council of Ministers.[27]

By the end of 2020, Bulgaria had not implemented any particular legislation or rules aimed at advancing gender equality in the field of research and innovation. Nevertheless, in April 2016, the Bulgarian Parliament adopted the **Equality between Women and Men Act (EWMA)**. The EWMA

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[26] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/economy-works-people/jobs-growth-and-investment/european-pillar-social-rights/european-pillar-social-rights-20-principles_en
[27] https://www.mlsp.government.bg/eng/equality-policy

imposes obligations on the Minister of Labour and Social Policy to oversee the establishment and maintenance of a system for monitoring gender equality and producing a report on gender equality in Bulgaria. The Act also defines the responsibilities of the relevant institutions in developing and operating the monitoring system. However, the EWMA does not include any explicit provisions regarding gender equality in research and innovation.

The Council of Ministers in Bulgaria adopted the **National Strategy for Research Development in May 2017**, which recognizes that women constitute 53% of the total number of researchers in the country, including those in the higher education sector, and men make up 47%. This relative gender balance is among the best in the EU. Therefore, the strategy does not propose any specific measures to increase the number of women researchers. However, it emphasizes the need for monitoring to ensure equal representation in the selection and promotion of staff to academic and management positions in research organizations (p. 18).[28]

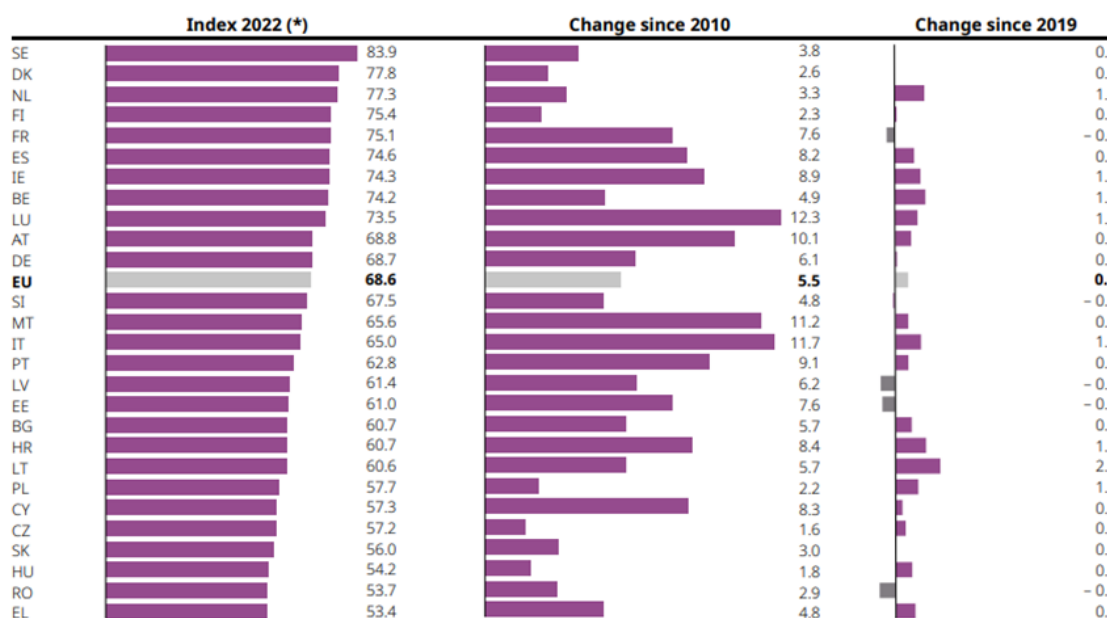|	Index 2022 (*)	Change since 2010	Change since 2019
SE	83.9	3.8	0.0
DK	77.8	2.6	0.0
NL	77.3	3.3	1.4
FI	75.4	2.3	0.1
FR	75.1	7.6	− 0.4
ES	74.6	8.2	0.9
IE	74.3	8.9	1.2
BE	74.2	4.9	1.5
LU	73.5	12.3	1.1
AT	68.8	10.1	0.8
DE	68.7	6.1	0.1
EU	**68.6**	**5.5**	**0.6**
SI	67.5	4.8	− 0.1
MT	65.6	11.2	0.6
IT	65.0	11.7	1.2
PT	62.8	9.1	0.6
LV	61.4	6.2	− 0.7
EE	61.0	7.6	− 0.6
BG	60.7	5.7	0.8
HR	60.7	8.4	1.5
LT	60.6	5.7	2.2
PL	57.7	2.2	1.1
CY	57.3	8.3	0.3
CZ	57.2	1.6	0.5
SK	56.0	3.0	0.0
HU	54.2	1.8	0.8
RO	53.7	2.9	− 0.8
EL	53.4	4.8	0.9

Figure 9: European Gender Equality Index 2022 (data from European Institute for Gender Equality). Source: https://eige.europa.eu/publications/gender-equality-index-2022-covid-19-pandemic-and-care

According to the European Gender Equality Index 2022, Bulgaria has been placed in the 18th position among the member countries of the European Union, with a score 7.9 points below the EU's. Bulgaria's its ranking has stayed the same between 2019 and 2022, with Gender inequalities still highly pronounced in domains like "money" (access to financial resources and economic situation), "knowledge" (educational attainment, participation in education and training over the life course and gender segregation) or "time" (allocation of time spent doing care and domestic work and social activities) the most pronounced gap between men and women in Bulgaria.

The distribution of childcare responsibilities remains highly unequal between women and men. In 2021, 41% of women and 16% of men reported being solely or mainly responsible for taking care of children aged 0-11. Additionally, women still bear the primary responsibility for household chores,

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[28] https://eige.europa.eu/gender-mainstreaming/toolkits/gear/legislative-policy-backgrounds/bulgaria

with 68% of women compared to only 8% of men reporting that they carry out household tasks alone or mostly alone. This results in a gender gap of 60 percentage points, which is 14 points higher than the EU average. [29]
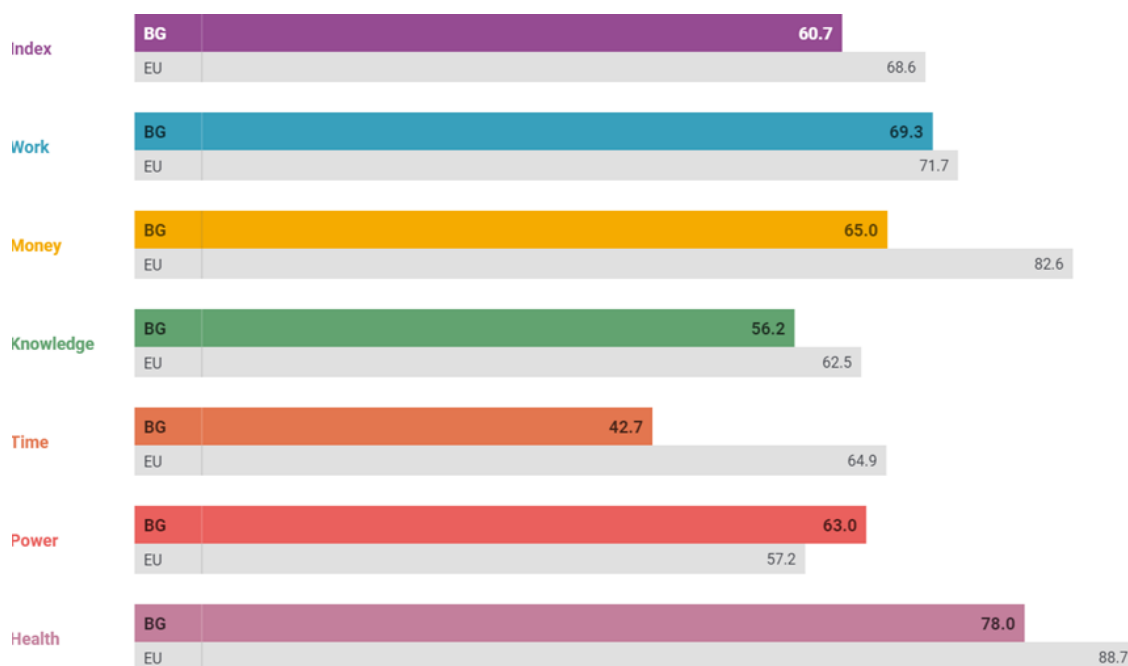

		BG	EU
Index		60.7	68.6
Work		69.3	71.7
Money		65.0	82.6
Knowledge		56.2	62.5
Time		42.7	64.9
Power		63.0	57.2
Health		78.0	88.7

Figure 10: EIGE, Gender Equality Index Bulgaria 2022. Source: https://eige.europa.eu/lt/gender-equality-index/2022/country/BG

And yet the country has made some progress worth highlighting: Bulgaria's Gender Equality Index has shown a significant improvement of 5.7 points since 2010. Since 2019, Bulgaria's score has increased by 0.8 points, mainly driven by improvements in "power", which measures gender equality in decision-making positions across the political, economic and social spheres[30] (+17.2 points and 9th position among all Member States). The improvement was driven by a score increase in the sub-domain of economic decision-making, in which it ranks 6th in EU. Significant progress "knowledge" is also worth to mention (+5.8 points since 2010), with improvements in the sub-domain of gender segregation in education powering this change. Bulgaria has demonstrated notable advancements in other two specific domains since 2010.

Several good practices can be identified. The section below describes some examples, notably in the areas of research and innovation.

6.2 – Good practices

Bulgarian Centre of Women in Technology (BCWT)

The Bulgarian Centre for Women in Technology (BCWT) is dedicated to inspiring, motivating, and supporting girls and women in Bulgaria to pursue opportunities in the digital world. The BCWT's primary objective is to promote women's leadership and enhance their professional involvement in the digital industry, science, and entrepreneurship.

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[29] *https://eige.europa.eu/lt/gender-equality-index/2022/country/BG*

[30] https://eige.europa.eu/gender-equality-index/2019/domain/power/BG

Their main objectives are to:

- Encourage women to choose careers in the digital industry
- Support women to start their business and ventures
- Provide a secure environment for exchange and mutual support between women professionals and leaders in the digital world

To achieve these goals, the BCWT has implemented several strategies:

- Building and developing professional networks in the fields of technology, entrepreneurship, science, and arts, through regular networking events and conferences.
- Showcasing different aspects of the digital industry to inspire young women in choosing a career path in those industries.
- Organizing specific trainings to help women from different social groups to acquire skills needed in the digital industry.
- Striving to be a competent center for questions regarding the professional and personal progress of women in technology, by conducting research, collecting and sharing information, and good practices among BCWT members.
- Strengthening connections with Bulgarian and international industries, institutions, and associations, and with governmental bodies, in order to provide support or recommendations.

Programs of the Bulgarian Center of Women in Technology:

SHEleader@digital is an international conference held in Sofia, Bulgaria. The conference aims to foster a focused discussion on the role of women in the digitally connected world and how to attract more women and girls to take on professional and leadership roles in the ICT and digitally empowered economy. The conference strives to identify solutions to bridge the gender gap in the technology industry.

Entrepregirl is a competition designed for young women entrepreneurs between the ages of 16 and 25. Initially held in Bulgaria, the competition has expanded to an international level. Entrepregirl seeks to identify women with innovative ideas and offers a platform to showcase and develop their ideas. Over the course of five editions, nearly 200 participants with diverse ideas have joined Entrepregirl.

Women Founders Forum[31]
The Women Founders Forum took place between 12-13 May 2022 in Sofia, Bulgaria, an initiative of the Bulgarian Commissioner Ms. Mariya Gabriel, with the participation of women from 19 EU Member states. The first European network of European Women Founders was created, to deal with challenges and opportunities for women in the fields of innovation and entrepreneurship.

Female general practicioners and e-health use
Kilova et al.[32], performed a survey to 381 health practitioners to identify attitudes regarding the application of e-health in Bulgaria. The survey was completed by 240 women (63%) and 141 men (37%), which

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[31] https://ied.eu/blog/health-hub-at-the-women-founders-forum-in-sofia/
[32] Kilova, Kristina & Branzalov, N & Alakidi, Adolf & Kitova, Tanya & Kasnakova, Petya & Bakova, Desislava & Mihaylova, V. & Mihaylova, Anna & Davarski, A & Mateva, Nonka. (2022). ELECTRONIC HEALTH IN THE

correspond to the actual distribution of general practitioners by sex (55.9% to 44.1%). According to the respondents, the main goals for them of using e-health were: easier access to health care (n = 270; 70.9%), saving money (n = 217; 57.0%) and development of new services (n = 197; 51.1%). However, these results were not disaggregated by gender in this paper.

Use of mobile health applications by women in Bulgaria

A study also by Kilova et al.[33], explores the different attitudes towards the use of mHealth in Bulgaria through an online survey between July 2019 and February 2020. Amongst the 976 people that were interviewed, 591 (60.6%) were females and 385 (39.4%) were males. The results suggested a deviation in favour of female respondents. A huge majority claimed that they generally used mobile applications for monitoring blood pressure or pulse. The study suggests the essentiality of mobile health applications to be developed in Bulgaria, crucial for patients as this technology has the potential to open up several new possibilities for treatments and observations of diverse socially significant diseases. Special attention to developments for women health as they are the most likely e-health app users.

Additional information can be obtained from Statista[34] portal, about a disparity on internet usage according to gender. By 2020, 36% of female internet users in Bulgaria used the internet to look up health information. Among men, this share was lower (21%). Compared to 2019, two percent less men and two percent less women replied that they used the internet to inform themselves about health and related issues.
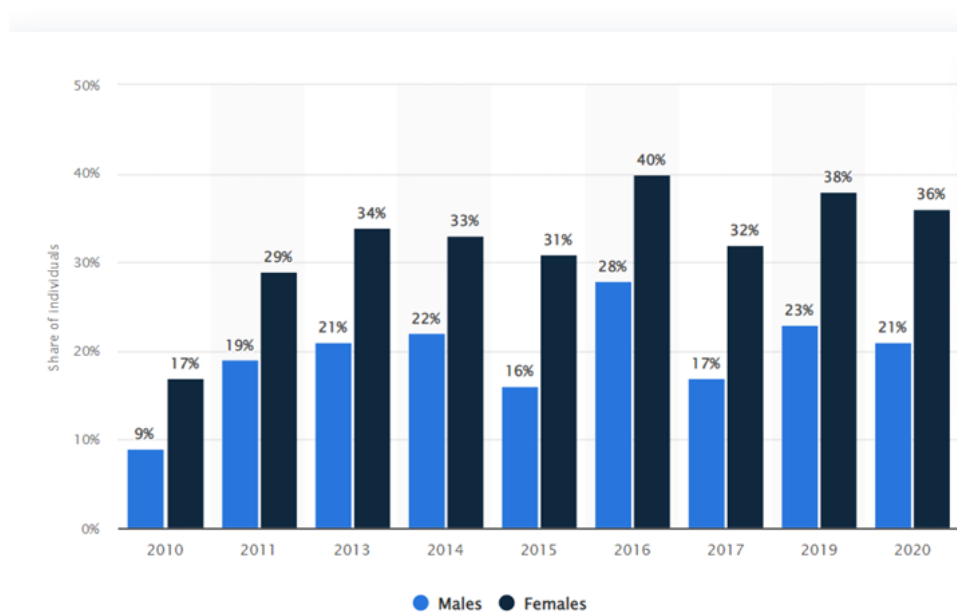

Figure 11: Share of people in Bulgaria that looked up health information online from 2010 to 2020, by gender. Source: statista.com 2023

- The most visited websites by Bulgarian women are related to fertility and nutrition[35]. Below, the top 5 list

PRACTICE OF GENERAL PRACTITIONERS IN BULGARIA DURING A PANDEMIC - A SURVEY. Journal of Environmental Protection and Ecology. 23. 344-351.

[33] Kilova, Kristina & Bakova, Desislava & Yaneva, Antonia & Mihaylova, V.. (2020). ATTITUDES TOWARDS THE USE OF MOBILE HEALTH APPLICATIONS IN BULGARIA. Proceedings of CBU in Medicine and Pharmacy. 1. 53-60. 10.12955/pmp.v1.98.

[34] https://www.statista.com/statistics/1247458/bulgaria-internet-users-searching-health-information-online-by-gender/

[35] https://www.similarweb.com/es/top-websites/bulgaria/health/womens-health/

- o mamaitati.com
- o sportkp.ru
- o fertilitydost.com
- o nutrition4change.com
- o Createfertility.co.uk

Women's health in social minorities

A good practice is the "Roma Alert!" project, helping Romani population in Bulgaria and Greece to use public health systems and trains them on health issues, hygiene and health system procedures. The European Commission set a target for 2023 regarding the participation and empowerment of Roma communities[36]. The project was addressed to improve their health and quality of life, cut infant mortality and increase life expectancy. An action plan was developed setting out hygiene and health measures required in the medium and long term. The project website became a knowledge repository on Roma health issues. Some blogs for health information were created at its behest (ex: https://www.mothersblog.gr/tag/roma-alert)

Another project, "RTransform" benefitted from the fact that regarding conquering the online space, many Roma women were very active. This was proven during the 19th RWSG (Roma Women Students' Gathering). In its 19th edition[37], this democratic space aimed at tackling the challenges the pandemic has raised and its impact on the Roma communities. Women actively disseminated the main conclusions of the event on Twitter. This evidence <u>might contribute to bridging the digital gap</u> that the Roma community has experienced, and which was exacerbated because of COVID-19.

Image from https://www.swissinfo.ch/eng/innovation-in-women-s-health-comes-in-small-doses/46302328

More initiatives on Women and health[38]

Currently in Bulgaria, there is a set of separate structures and institutions addressing gender equality issues (including women's health). These are:

- o Institutional Mechanisms to the Legislative (Human Rights and Religious Affairs Committee at the National Assembly - sub-committee on Women's Rights and Gender Equality;
- o Commission for Protection against Discrimination, reporting to the National Assembly;
- o Parliamentarian Ombudsman, reporting to the National Assembly);
- o Institutional Mechanisms to the Executive (National Council on Equality between Women and Men to the Council of Ministers;
- o National Commission on Combating Trafficking in Human Beings;

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[36] https://scholar.google.com/scholar_lookup?title=A+Union+of+Equality:+EU+Roma+Strategic+Framework+for+Equality,+Inclusion+and+Participation&publication_year=2020&

[37] https://pubmed.ncbi.nlm.nih.gov/35564919/

[38] https://eurohealth.ie/eu-parliament-study-report-bulgaria/

- - - Equal Opportunities Department at the Demographic Policy, Social Investments and Equal Opportunities Directorate at the Ministry of Labour and Social Policy;
  - Consultative Commission on Equal Opportunities to the Minister of Labour and Social Policy);
  - Institutional Mechanisms at the Local Level (Gender Specialists to the Municipalities;
  - Public Councils to the Municipal Councils;
  - Local Commissions on Combating Trafficking in Human Beings; Local Public Mediators).

An example of well-functioning practice in the field of women's healthcare is the Maternal Health Programme, securing free access for each woman to systematic healthcare activities from the beginning of the pregnancy till 42 days after birth delivery

Other Legislative initiatives: Women and health issues are specifically treated in a number of legal documents, such as the

  - Law on Health of the Nation
  - the Health and Work Safety Act
  - the National Labour Code
  - the National Framework Contract
  - Ordinances for preventive check-ups, dispensation, healthcare activities guaranteed by the insurance fund budget, specific regulations of human reproduction, family planning, human rights and research activities, etc.

Health care system activities provision: Services developed specifically for women are essentially limited to reproductive needs, especially childbearing, referring to expanding and improving maternal and child health systems. Sexual health education and promotion of the reproductive health of women are important elements in the obligatory package of activities of the Public Health Care system but are not fully implemented.

Research and surveillance initiatives: There are studies and surveys on women and cancer, women's sexual and reproductive health; medical aspects of trafficking in women; occupational health and women, and others are carried out by state or scientific institutions or within international project activities. Data from the existing System of Vital Registration[39] is also used in epidemiological studies in women's reproductive health.

Projects, campaigns, seminars, round tables, local initiatives, etc.: The Bulgarian Sexual and Reproductive Health Peer Network is part of the 'Strengthening the National Reproductive Health Programme' funded by United Nations Population Fund for Bulgaria[40], involving a comprehensive combined health, sexuality and life-skills educational package for students aged 12-18 delivered at youth clubs and education centres across the country.

Projects supported by the PHARE Programme of the EU[41] (to strengthen public administrations and institutions to function effectively inside the European Union) and several international organisations, sexual education and health promotion work with young girls and women is performed.

National Breast Cancer Awareness Campaign[42], seeking to raise public awareness for prevention and cure of breast cancer, and funding for educational and preventive activities and the provision of equipment (mammographs) for the more remote parts of Bulgaria.

7 – Synergies with other EU regions

Bulgaria has identified the following main areas of interest to collaborate in the digital area with other European countries:
- European Health Data Space

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[39] https://eurohealth.ie/wp-content/uploads/2012/08/eu-reports/bulgaria.pdf
[40] https://www.unfpa.org/sites/default/files/resource-pdf/bulgaria.pdf
[41] https://www.europarl.europa.eu/enlargement/briefings/33a1_en.htm
[42] http://www.cwsp.bg/en/htmls/page.php?category=400

- Citizen Electronic Health Record
- Predictive analytics and algorithms
- Genomic and personalized Medicine
- Medical devices and wearable sensors
- Inclusive Connectivity Infrastructure to Enable the Broader Health Ecosystem

Here is a sample of some of the ongoing multi-country initiatives.

MEGA Alliance and 1+MG[43]

Bulgaria is one of the countries which are part of the MEGA Alliance (The Million European Genomes Alliance) to give access to 1 million genomes in Europe by 2020.

The declaration of cooperation "Towards access to at least 1 Million Genomes in the EU by 2022" was promoted by the European Commission within the scope of its digital strategy, with the aim of promoting the sharing of genomic and health data from the populations of Europe. Signed on Digital Day on April 10th, 2018 by 13 Member States, the declaration now has a total of 24 signatory European countries, plus Norway and UK, as well as some observer countries.

Sharing the genomic data of 1 million European citizens, associated with their health data, is expected to have a huge clinical and scientific impact. The knowledge generated represents a vast potential for the advancement of clinical and public health research and will create opportunities for gains in key areas of health, in particular personalized medicine.
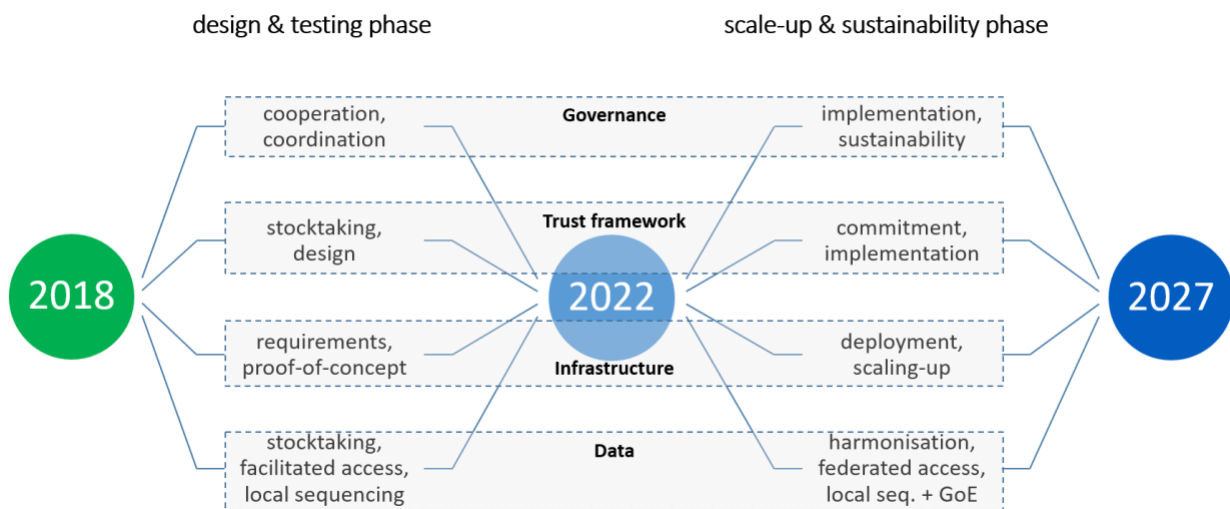

Figure 12: The 1+MG Roadmap. Source: https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes

In 2020, the Roadmap for the implementation of the **1+ Million Genomes (1+MG)** initiative was approved by representatives of the European signatory countries. The roadmap envisages the creation of a European data sharing infrastructure, with a federated model interconnecting a network of genomic and health databases from the 24 participating countries. In order to allow the sharing of interoperable data between countries, the initiative is currently analysing the associated ethical and legal issues in detail, defining guidelines and standards for the quality of data to be shared, including health data and genomic data, as well as such as the development of models and tools for the use of these data by health services and research projects in the signatory countries.

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[43] https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes

EDIH on cybersecurity - CYBER4All STAR[44]

In the framework of "Digital Europe" and the "Programme for Scientific Research, Innovation and Digitization for Intelligent Transformation", a series of so called "European Digital Innovation Hubs - EDIHs" has been launched at the beginning of 2023.

EDIHs are one-stop shops set up to support companies in responding to digital challenges and becoming more competitive. While EDIHs have a regional presence, they also benefit from being part of a pan-European network. Owing to their regionality, EDIHs have first-hand knowledge of the needs of local companies and can provide services in their own language, tailored to their innovation ecosystem. The European coverage of the Network of EDIHs also facilitates the exchange of best practices across hubs in different countries as well as the provision of specialised services between regions within the same country.

For the territory of Bulgaria, four project proposals have been approved:

- AgroDigiRise dedicated to agriculture
- EDICS dedicated to the construction sector
- SynGReDiT dedicated to green transformation
- CYBER4All STAR dedicated to cybersecurity to all sectors, including healthcare

To bridge the "Cybersecurity divide" in the EU the CYBER4All STAR Project will offer expertise, access to experimentation facilities and services, access to finance and ecosystem networking with disruptive technology suppliers. The hub is expected to cooperate with other Cybersecurity EDIHs across Europe via the European Corridor of Cybersecurity EDIHs, initiated by the European Cyber Security Organization.
The ultimate goal is to make it easy, cost-efficient and technologically-friendly to learn and adopt Cybersecurity as well as HPC and AI on a mass and integrated scale, targeting in particular SMEs and Public Sector Organisations.

VELES Excellence Hub project on Smart Health

This project, starting in 2023 and funded under Horizon Europe, aims at strengthening the South-East Europe Smart Health Regional excellence and boosting its innovation potential.

The Excellence Hubs actions focus on strengthening regional innovation excellence by creating innovation ecosystems that connect academia, businesses, governments, and civil society in Widening countries and beyond. By forming strong linkages between these groups, the Excellence Hubs aim to promote robust and sustainable innovation in the region.

In this specific case, the RIS3 strategies of the participating countries in the region, namely Bulgaria, Romania, Greece, and Cyprus, prioritize the use of Big Data, Artificial Intelligence, and Internet of Things technologies in healthcare to promote personalized medicine, informed decision-making, and better disease prediction. A coordinated cross-country approach is necessary to ensure that all the separate efforts are aligned towards the creation of an Excellent South-East Europe Smart Health Innovation Ecosystem, enabled by a Regional Smart Health Data Space.

VELES aims to improve innovation excellence by creating a sustainable innovation ecosystem based on a Regional Smart Health Data Space. This initiative includes the development of a transformational framework, research and investment strategies, and an action plan for the adoption of innovative and secure digital solutions that promote sustainable healthcare services. The Regional Smart Health Data Space will be demonstrated through the implementation of four interrelated pilots on cancer treatment in Greece, personalized/precision medicine of Alzheimer's disease in Bulgaria, cerebral tumors in Romania, and dementia in Cyprus.

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[44] https://european-digital-innovation-hubs.ec.europa.eu/edih-catalogue/cyber4all-star

In addition, VELES aims to foster health data sharing regional and national strategies, to secure improved clinical practice, to preserve patient's privacy and to empower citizens' smart healthcare through access to innovative, cyber secure and data driven digital health services.

The SocKETs (Societal engagement with Key Enabling Technologies) project

This project received funding from Horizon 2020 (grant agreement No.958277) to develop and use co-creation, as a form of collaborative innovation to develop shared new values, to shape KETs-based innovation towards the needs of all stakeholders and for the benefits of society. The Bulgarian Center for Research and Analysis in Sofia is one of the partners of the project, setting up the Bulgarian lab with the goal of discussing on eHealth and provoking a shift in the way the Bulgarian society regards healthcare services and the technologies involved. The lab engaged citizens in dialogue and co-creation based on their priorities, expectations and concerns. The project will finish on September 2023.

NOTE ON REFERENCES AND SOURCES

This report has been elaborated with inputs from available public sources published on the Internet. All the main sources used for information or assessment are mentioned in the text or listed as foot notes or as links to the text.

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