SOCKETS

**SOCIETAL ENGAGEMENT
WITH KEY ENABLING TECHNOLOGIES**

eHEALTH

MAPPING OF KEY ENABLING TECHNOLOGIES INNOVATION ECO-SYSTEMS

eHealth applications in Bulgaria: towards societal benefits

TITLE	Mapping of Key Enabling Technologies innovation eco-systems. eHealth applications in Bulgaria: towards societal benefits
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DATE	10 March 2021
KEYWORDS	eHealth, KETs, IoT, AI, innovation, societal benefits
SERIES	This report is a part of a series on the mapping of Key Enabling Technologies Innovation eco-systems in the healthcare, circular economy, industrial automation sectors in selected EU countries. The full collection is available in "Deliverable 1.1. Report on innovation ecosystem maps for selected case studies" of the SocKETs project
PUBLICATION AVAILABLE AT	https://sockets-cocreation.eu/

Revision history

REVISION	DATE	AUTHOR	ORGANISATION	DESCRIPTION
Version	28 February 2021	Tzvetanka Angelova, Prof. Alben Vutsova	Centre for Research and Analysis	Title: eHealth for society benefits: applications of new technologies
Comments	8 March	Andrea Porcari		Comments and recommendations reflected in the text
Version	12 March	Tzvetanka Angelova, Prof. Albena Vutsova	Centre for Research and Analysis	eHealth applications in Bulgaria: towards society benefits
Comments	17 March	Lucie Steigleder, L.S.E.Augustijn		Comments and recommendations reflected in the text
Version	22 March	Tzvetanka Angelova, Prof. Albena Vutsova	Centre for Research and Analysis	eHealth applications in Bulgaria: towards societal benefits

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1. Introduction

SocKETs brings together six European partners with the aim to test and develop methods and tools to align the development of innovations based on Key Enabling Technologies with societal values and needs. SocKETs will facilitate co-creation between industry representatives, researchers, policy makers, end-users, civil society representatives and citizens, and will develop tools for societal engagement in innovative technologies. Co-creation in SocKETs is intended as a form of collaborative innovation, in which ideas are shared and improved together toward the joint development of new value.

This report is part of a collection of case studies on co-creation and KETs based innovation developed by the project, and is focused on KETs based innovation for eHealth application toward societal benefits in Bulgaria. It provides an analysis of the innovation eco-system of this sector in Bulgaria, including considerations on the innovation context, the barriers and opportunities for the introduction of new technologies, the key actors, relations and networks involved, and the relevant actions and interactions taking place. It aims to inform the design of a participatory process to discuss about the most relevant technologies and innovations that could support the transition towards eHealth in Bulgaria.

To elaborate our case study, we have carried 6 interviews and performed a desk analysis, as well as drawn from our experience at the Centre for Research and Analysis. During interviewing and study work we met several challenges including lack of inclination for eHealth services (research development and market realization); low level of introduction of eHealth services and devices in the country; lack of systematized information and data and statistics on the topic, as well lack of research on how people perceive and what they expect from eHealth. We had to rely on the few interviews, and mainly on the desk analysis to build on our case-study.

The panel of our interviewees included 6 leading experts from the different stakeholder groups, of which 5 males and one female, including 1 NGO, 1 R&I actors, 2 business, 1 policy and 1 social media actor.

2. Technologies and application scenario

a. Opportunities and challenges

For succesfull implementation of eHealth in Bulgaria this sections lists the opportunities and challenges with regard to KETS applications in eHealth - the Internet of Medical Things, Mobile devices for health indicators monitoring and Telemedicine.

Over 57% of the world's population are now connected through the World Wide Web, easily accessible through an expanding set of technologies including wearables, smartphones, computers, sensors and tablets (Statista, 2019). (Snowdon, 2020)

The availability and affordability of internet access enables information to flow freely across global borders, connecting people and populations to health experts, health teams and organizations anywhere in the world. Global populations are emerging as informed consumers of healthcare, striving to make health decisions autonomously, with the support of provider teams, rather than relying on prescribed care pathways which may not be aligned with personal health needs and goals. One has only to look at the 318,000 different health applications in the consumer market to understand the drive toward health and wellness enabled by the many consumer devices and technologies in this rapidly growing market (IQVIA, 2017).

Digital health has been described as an era (Rawlands, 2019), a progression along the evolutionary path of information and communication technologies (ICT) in healthcare, one that constitutes a great leap forward and transcending technologies rather than just the next technological step. Digital health as an "era" is embedded in what is widely accepted as the fourth industrial revolution — the use of big data, analytics, and artificial intelligence, all of which are evolving across virtually every business sector. While the fourth industrial revolution is well underway in many sectors — finance, travel, online retail, communications — it has not evolved as quickly in the health sector.

Digital health[1] is now emerging in health systems, building on the strengths of the **eHealth era** where an industrial approach to digital technologies has created the necessary foundational infrastructure.

b. Technologies

The most important finding and result of KETS in eHealth is the opportunity for health system transformation — enabled by digital health technologies - to achieve transformation of care models, whereby individuals are empowered, connected and informed, and care delivery prioritizes health and wellness.

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[1] "Digital health" as a term has been discussed widely, yet an agreed upon definition of digital health remains elusive. A variety of terms and concepts are used interchangeably in reference to digital health, including "mHealth" (mobile health), "eHealth" (e.g. technology and digital applications to assist patients in their health), virtual care, and telehealth, to name just a few.

Some of the most significant advancements offered by the new technologies into the eHealth area have started with the development of Information and communications technologies (ICTs). ICT are at the basis of eHealth and play a critical role in improving health care for individuals and communities. They provide new and more efficient ways of accessing, communicating, and storing information, help bridge the information divides that have emerged in the health sector in different countries and regions —between health professionals and the communities they serve and between the producers of health research and the practitioners who need it. Through the development of databases and other applications, ICTs provide the capacity to improve health system efficiencies and prevent medical errors.

Telemedicine, Health Portals, Cloud Computing, Virtual reality can also be listed here.

IoT (Internet of Things) (Rodrigues, 2018) **-** A new network infrastructure to connect devices, IoT offers intelligence to objects by adding them the capacity to collect and store data from different types of sensors, to perform actions autonomously based on actuators, coordinate functions, and share information considering the connectivity among nodes.

Healthcare industry is among the fastest to embrace IoT based solutions. It is being considered one of the key industry drivers and a special concept for it, considering the IoT application on eHealth, are Internet of Health Things (IoHT).

A 2020 projection made for IoHT "MarketsAndMarkets" predicts that IoHT will be worth US$ 163.2B, commercial report claims a spending of $117B, and McKinsey estimates an economic impact of more than US$ 170B. All this caused by cost savings, quality of life improvement for patients with chronic disease, and health monitoring, which prevents disease complication. It is a fact that IoHT will create a big economy impact in the world.

Big data[2] - The growing use of electronic health information systems and digital patient data in both research and clinical practice has led to the generation of huge volumes of data worldwide. Over the past few decades, the types of healthcare data collected has changed significantly in volume, variety and velocity. The term 'Big Data' evolved to reflect the fact that the data generated today is often too large and heterogeneous and changes too quickly to be stored, processed, and transformed into value by traditional technologies. Health data now comprises large and complex digital datasets, including proteomic and genomic data, and more recently, widespread use of mobile devices has enabled the collection of citizen and patient data on a range of health parameters.

The advantages of Big Data analyses go beyond simply improving profit margins and reducing resource wastage but will also be of value in predicting epidemics, improving quality of life, providing better outcomes, and avoiding preventable deaths, particularly from chronic diseases. The large amount of data from the considerable range of different sources provides significant opportunities to stratify patients' diagnosis and treatment on a more individual level and therefore provide a more personalised level of care.

Advanced analytics and algorithms (e.g. AI, machine learning, deep learning, neural networks) further advance the transformation from the current disease management, to a more proactive and predictive strategy focused on keeping people healthy and well. Analytics are the new trend in digital health, able to transform data

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[2] eithealth.eu/eit-health-think-tank - Think Tank 2018: The use of existing Big Data to improve healthcare

into knowledge, insights, evidence of value and impact that informs new models of care within a digitally-enabled environment. Electronic Health Records (EHRs), Personal Health Records (PHRs) can be filed here.

According to one of our interviewees "*It is more and more believed that there should be a link between the patient and his doctors – a permanent distant link related to monitoring the condition of patients who are at risk; to have remote smart devices that monitor health indicators. But macro data analysis is most important for personalized medicine. We cannot apply personalized treatment if we do not carry large-scale studies. Cancer for example - we want to study all its mutations, find those that may be affected by existing drugs and identify patients who would be affected by one or another drug.*

When asked about the trends of development and the issues in eHealth technologies' implementation, our **interviewees express a** common opinion that first we should start working in the direction of e-health.

"… The process has started but with very cumbersome steps. The problem is that the processes that are currently available as communication processes between patients, doctors, hospitals - these processes are outdated and the way they are implemented in eHealth is wrong. They try to adapt the old processes to the new electronic reality. The result is not good."

Interviewee said *"… we need first to build the basis - to digitize all medical records. Once these standard nomenclatures for information exchange are created by us, they can then be linked in a system and upgraded with additional services. Then the new technologies such as IoT, AI, Big Data will be applicable, once the foundation is created. Internet of things will be used to gather additional information about a person's health, Big Data and Artificial Intelligence will be used for monitoring and prognosis".*

"Basically the eco-system should deal with the hospital systems and their data bases and their connection to the data base of the Health insurance fund. These blockchain databases will allow access to the patient's health record, provide better administration, assist pharmaceutical companies and laboratories in the preparation and implementation of the production process; the doctors will have real access to the patient's medical record" [interviewee].

Finally, they summarized that it is not possible to say which of the listed technologies is more important. The one we shall use depends on the task we are solving. If we talk about medical records - software is important, in sensors which are working with enzymes – it is biotechnology; the mobile monitoring devices; macro-data analysis; Artificial intelligence - all of them have their respective applications.

But in spite of the different opinions, there were common trends that stood out:
- Non-invasive testing and treatment - because it is less painfull due to smaller incisions, shorter hospital stays, and return to normal daily activities more quickly.
- Telemedicine – because of lower costs, convenience and remote service, accessibility for disabled patients, preventive care, no risk for infection;
- Health status monitoring devices – offering possibilities for testing, monitoring and early detection of diseases, infections and various chronic conditions, etc.

During the next stages of the project, we will focus on implemented innovations (innovative devices and practices) in the health system and the latest achievements in diseases monitoring, innovative devices and practices, ICT applications and platforms especially such that are user-friendly, non-invasive and can be applied in a non-hospital environment.

The activities will involve technology products and services offered by private owners - mainly startups having emerged in the period after 2015 using KETs applications such as the Internet of Medical Things, Mobile devices for health indicators monitoring and Telemedicine. Our examples include devices for health indicators monitoring in real life, offering channels patient – doctor/hospital, wearable devices for athletes' performance measuring, telemedicine through a platform offering accessible virtual contact.

3. The innovation eco-system

a. Context, values and principles

It is assumed that the key to improve health systems is the transformation of today's healthcare system toward a digitally enabled system focused on health and wellness. Innovative care models using eHealth could address the rising demand for better healthcare, helping to shift progressively towards integrated and personalized care systems.

The use of digital health applications and devices throughout the chain of medical products and services is expected to introduce efficiency, time-saving, accessibility, equality, affordability and better quality of life.

These values are clearly stated in the National Health Strategy 2030: prevention of diseases and the promotion of healthy lifestyles, improvements in the quality of life of citizens and more effective ways of organizing and providing health services and care, changing the model of healthcare so as the patient be at the center of the health system.

The **main principles** in the eHealth system applications retell the main values and principles of medicine and health care. Main requirements for the digital health information and use correspond to:

- Reliability and truthfulness – a leading principle for information providers.
- Quality – information data should be culturally adapted, easy to use, unbiased, timely;
- Informed consent, data protection and confidentiality;
- Protection and prevention from commercial practices;
- Use of best practices;
- Application of EC standards in the professional relations' regulations.

In confirmation of the above, and specifically used by the interviewees along their work on eHealth, are the rules developed by the State Agency for e-Government, *"…one of the most important being, according to the laws on personal data protection, the creation of electronic identification or electronic identity card with which a person can identify himself in the electronic space and to have the right to access the services that are provided,*

including eHealth. In eHealth, each document being unique, must be signed as such in order to have among others a regulatory value".

Another principle, important for the Media stakeholder is that *"companies producing monitoring devices should describe very accurately the characteristics of their product and not, for advertising purposes, mislead the customer with false information.*"

b. Market description

The draft budget for 2021 and prognosis for 2022 and 2023 of the Ministry of healthcare[3] shows the 12 programs' priorities and funds dedicated to them: BGN 6,5 billion for 2021 for the whole system.

It is the program **"Development of a unified health-information system and eHealth"** that includes plans for information provision of the management of medical activities through optimal use of existing sources of information and their logical synthesis and analysis, as well as accelerated development of eHealth.

In the following table, the Ministry gives records for previous years and next years' plans for expenditures for the "Development of a unified health-information system and eHealth" programme:

	Records	Records	Law	Project	Prognosis	Prognosis
Year	2018	2019	2020	2021	2022	2023
Total MHB departmental expenses in thousands of BGN	8 119,2	9 939,4	9 837,0	18 091,8	18 291,8	18 291,8

Table 2: Plans for expenditures for the "Development of a unified health-information system and eHealth" programme

The National Health Insurance Fund of Bulgaria

Bulgaria has a mandatory health insurance system with a National Health Insurance Fund, which covers a package of activities determined by regulations of the Ministry of Health. The Fund acts as an independent institution with full autonomy and has 28 regional structures (regional health insurance funds), through which it concludes contracts with the providers of medical care. Voluntary health insurance is provided by private health insurance companies, which provide an additional package of services that are not covered by the state health insurance package. Their market share is currently relatively small.

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[3] Draft budget for 2021 and updated budget prognosis for 2022 and 2023 in program format. Ministry of Healthcare of Bulgaria
https://www.mh.government.bg/media/filer_public/2021/01/21/biudzhet_za_2021_g_v_programen_format_na_ministerstvo_na_zdraveopazvaneto.pdf

The main sources for financing the health system in Bulgaria are the obligatory health insurance and the national budget. It is important to underline that the mandatory health insurance is very low – 7% of the person's salary and it reflects negatively upon the health system services. To a lesser extent, voluntary health insurance contributions, municipalities, user fees, paid services and funds from external sources provided by donor organizations are involved.

Around the world

In all countries around the world, the main issue for the growth of eHealth is solving the problem of reducing the rapidly rising costs of medical care with ever-increasing quality requirements.

More and more countries adopt a state policy to attract private investors in healthcare, the so called public-private partnership. A market for private companies and investors is created, improving healthcare quality. But the new expectations require the conservation of very detailed information about patients, previous medical consultations, nutrition, habits, etc. i.e. whole e-dossiers and their protection. To increase incomes, health establishments in some countries reached the conclusion to provide personalized medical services, a model which has been already implemented by banks, telecoms, retailers. Thus, healthcare turns into one of the pillars for economy.

The "Healthcare Information System Market, 2013–2019" [4] report findings show that personalizing the attitude towards patients is a worldwide trend as an element of the business strategy for improving clients' loyalty. This trend is related to serious requirements for the IT infrastructure, whose setting up wants serious investments. In many countries this problem is solved through outsourcing and public-private partnerships.

Technologies market

The modernization of medical care systems imposes automation of medical information flows, telemedicine, ICT implementation, part of which are also the Business Intelligence systems providing precise information on expenses, profitability, services search. Data from MarketsandMarkets for 2018 about the BI systems value in Healthcare show that it reached $4,74 billion. Laboratories become hi-tech companies. Transparency Market Research analysers prognosticated that in 2019 the volume of the global market of laboratory information systems will be $2,16 billion. The price of these systems is quite high and not affordable for all health providers. Thus, medical laboratories have emerged as a separate business, where high tech infiltration led to formalized processes, automatic equipment and minimal personnel.

The mHealth applications market (mobile devices used by doctors and patients), according to the Allied Market Research, will reach $58,8 billion in 2020.

Other information sources predict that in 2020 the mHealth market will reach $46 billion and the global market of tele-medical applications will reach $41,2 billion.

The number of patients using telehealth applications is also growing very fast - from 0.35 million in 2013 to 7 million in 2018. Telemedicine is the second and mobile health applications are the fourth highest funded category in the field of health information and internet technologies in the first half of 2018. $ 701 million and $ 535 million have been set aside for them, respectively.

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4 https://cio.bg/digitalizacia/2015/01/23/3439445_it_v_zdraveopazvaneto_tendencii_i_perspektivi/

In 2020, the digital health market is expected to reach $ 200 billion, primarily due to the mobile health market. Telemedicine means distance medicine but lacks a popular organizational and technological model, due to the different reasons:

- unrealistic expectations are placed on technology.
- assumption that the patient enters a capsule or room and with minimal instructions and appropriate equipment manages to collect enough information in electronic form to be sent and analysed by a doctor, i.e. to minimize live contact between doctor and patient, which is especially valuable in regions with low population density, which is often technologically challenging and economically and medically unjustified.
- requires complex expertise - legal, technological, medical.

Regulatory restrictions make the problem even more complex.

A document on "Market study on telemedicine" published by the European Commission, Directorate-General for Health and Food Safety, 2018 provides insight into the telemedicine market figures. According to Statista, the global telemedicine market was valued at €16.3 billion in 2015, and is expected to reach more than €37 billion by 2021, with a CAGR of 14% during that period. This dynamic sector therefore has the potential to drastically influence the delivery of efficient patient care at a lower cost for healthcare markets worldwide.
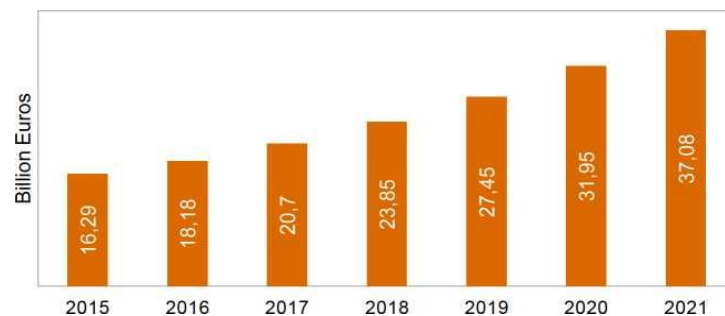

Figure 1: Global telemedicine market size from 2015 to 2021 (in billion Euros)

According to Statista's "Digital Market Outlook"[5], the "number of users" covers users in three main telemedicine product categories:

- Connected medical devices ("smart devices"[6]);
- Digital tracking and monitoring applications for smartphones and/or tablets ("apps"); and
- Telemedical services for patients at risk ("telemedical services"). Hardware and software solutions for healthcare professionals (e.g. medical equipment for hospitals and doctors' surgeries) are not included.

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[5] Statista (2015). Digital Market Outlook. Available at https://www.statista.com/outlook/digital-markets

[6] The "Smart Devices" segment covers medical devices (hardware) that are equipped with dedicated interfaces or SIM cards that serve to transmit measurement data across a wireless connection (e.g. via mobile networks, WiFi, Bluetooth, M2M technologies, NFC, BLE). The selection of suitable equipment is dependent on the individual health status of the patient and the severity and presence of other conditions (e.g. a combination of severe heart failure and cardiac arrhythmia).

In Bulgaria, telemedicine dates back to 1974 and is still developing today. Many clinics and hospitals have implemented partial software solutions that allow for remote medical consultations, but most patients are still reluctant to accept it.

Given the data above, the case study that we are developing can be a promising and relevant initiative to start talking about Internet of Medical Things, Mobile devices for health indicators monitoring and Telemedicine: what KETs are involved in the mHealth devices, how these products work and could be improved. "*The consumer needs to be educated about the benefits of new technologies*", according to the interviewees.

The implementation of the national eHealth system in the next years will need the support and involvement of the whole society.
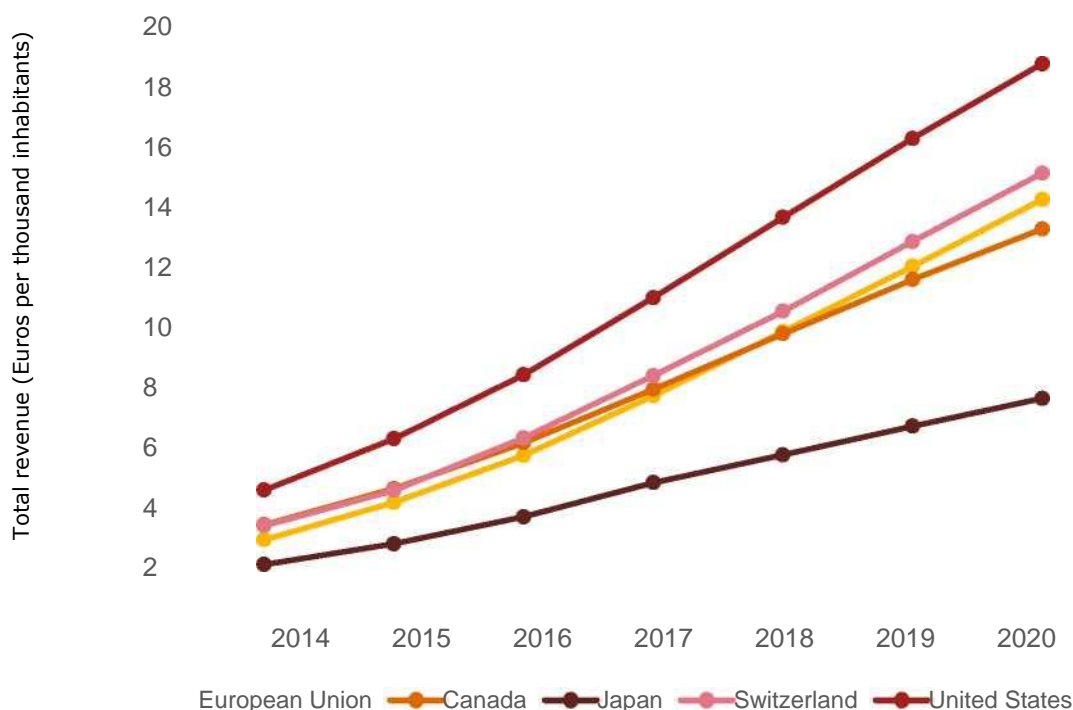
 and involved with

Figure 2: eHealth market outlook. Total number of users in the market (millions) by geographical region

Source: Statista estimates - trends include per population for three principal diseases (diabetes, hypertension and heart failure) and World Bank data on total population

c. Policy frameworks, normative and regulatory regimes

The current state policy on eHealth is directly aimed at the implementation of the measures set out in the existing strategic documents - National Healthcare strategy[7] and the Concept for development of the emergency medical care system 2014-2020, and are in line with those planned in the draft national health strategy for the period 2021-2030 for the development of the sector.

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[7] Ministry of healthcare of Bulgaria. National Health Strategy 2021 – 2030

https://www.mh.government.bg/media/filer_public/2020/12/29/proekt_na_natsionalna_zdravna_strategiia_2021-_2030.pdf

eHealth is in the basis for the implementation of the strategic goals and priorities of the National Health Strategy 2030[8]. Innovative solutions in the field of eHealth will provide support for the prevention of diseases and the promotion of healthy lifestyles, lead to improvements in the quality of life of citizens and enable more effective ways of organizing and providing health services and care, is written in the strategic document.

The main priority of eHealth in the document is to carry out a digital transformation in the sector, based on the development of the three technological pillars: cloud technologies, development of wireless communications networks (4G / 5G), the mass introduction of high-speed optical data networks.

In order to ensure coherence of the measures and activities in the field of eHealth, a sectoral Strategy for eHealth in the Republic of Bulgaria for the period 2021-2027 will be developed with relevant action plans, the document proposes.

The Ministry of Health's program "Development of a unified health-information system and eHealth" is implemented by the following structures:

- 3 Directions at the Ministry – Budget; Medical activities and eHealth.
- Executive agency "Medical Supervision". EAMS exercises control over healthcare institutions, healthcare activities, and the quality of healthcare, and is the competent organ for transplantation management, coordination and control in Bulgaria.
- National Centre of Public Health and Analyses. Performs activities related to public health protection, healthcare promotion, disease prevention and information support for healthcare management.
- Regional health inspectorates.
- The Bulgarian Drug Agency - whose competences, functions and activities include to supervise the quality, effectiveness and safety of medicines; the operation of medical institutions in sampling, diagnosis, processing, storage, use, distribution, quality assurance and safety of blood and blood components and for transfusion.

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
- Health Insurance Act
- Medical Establishments Act
- Healthy and Safe Working Conditions Act
- Medical Products in Human Medicine Act
- Medical Devices Act
- Recognition of Professional Qualifications Act

For 2021, the Ministry plans to develop 10 new and updated regulations in order to introduce the National Health Information System. In 2021, with the development of a National Strategy for eHealth for the period 2021-2027

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8 https://www.investor.bg/analizi/85/a/i-novata-zdravna-strategiia-do-2030-g-s-fokus-vyrhu-e-zdraveopazvaneto-318949/

and its implementation, a concept for the development of telemedicine through mobile devices (mHealth) will be defined. It also plans to introduce a system for assessing the quality and safety of medical care.

National programs and strategies also contribute to the normative and regulatory regimes relevant in the field, mainly:

- National Health Strategy
- Strategy for Smart Specialization
- National Strategy for the Development of Research 2020
- Concept for the Development of Emergency Health Care
- Concept for "Aims for Health 2020"

National health policy is formulated by ensuring synchronization with the trends and recommendations formulated in European and international strategic documents:

- European eHealth Action Plan 2012-2020[9]
- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. 2018[10]
- Patient Summary Guidelines [11]
- ePrescription Guidelines [12]
- NCPeH Organisational Framework [13]
- eHDSI Governance Model [14]
- International health rules formulated by the WHO – strategic documents, programs, action plans on e-health [15].

Recently the "assessment of health technologies" mechanism whose main indicators are the electronic patient dossier, e-prescription, and real time monitoring of the health status has been discussed at the Regular discussions of the "Investor.bg" Business platform and accepted by the innovation industry as an instrument to establish the clinical and economic benefits of new technologies.

d. CSR, open innovation and co-creation practices

CSR practices are seen as a world tendency to impact certain trends of development, with the aim to improve the working environment, working conditions, social rights protection, better remuneration etc. But CSR has also

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[9] https://ec.europa.eu/health//sites/health/files/ehealth/docs/com_2012_736_en.pdf

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52018DC0233

[11] https://ec.europa.eu/health//sites/health/files/ehealth/docs/guidelines_patient_summary_en.pdf

[12] https://ec.europa.eu/health//sites/health/files/ehealth/docs/eprescription_guidelines_en.pdf

[13] https://ec.europa.eu/health//sites/health/files/ehealth/docs/ev_20151123_co01_en.pdf

[14] https://ec.europa.eu/health//sites/health/files/ehealth/docs/ev_20151123_co02_en.pdf

[15] http://www.who.int/ehealth/about/en/

the potential to impact the whole society and to create positive images and attitudes towards the different branches of industry[16].

On national level, the dissemination, encouragement and adoption **of CSR practices** are within the mandate of the Ministry of Labour and Social Policy. A CSR National strategy for the period 2019 – 2023 and Action plan have been adopted. The government's political commitment is to improve the quality of life of the population through transparent, socially responsible business practices and in the implementation of the government's Management Program.

The vision of the strategic document on CSR was developed in partnership with a number of stakeholders such as universities, NGOs, the business, social partners, citizens. The aim was to outline the role of the state and the other stakeholders, which in partnership to create and support the best conditions for a socially responsible behaviour of the side of the business for the interest of the whole society.

A good practice was introduced to have annual competitions for CSR best achievements to stimulate their application and recognition.

On the other hand, there are several initiatives, with the same purpose:

- Global Compact Bulgaria - www.unglobalcompact.bg. The initiative unites, on a voluntary basis, over 130 companies and organizations, which have accepted the ten principles of the responsible corporate citizenship in the field of environment, working standards, human rights and anti-corruption.

- The "CSR Bulgaria" Association, an NGO whose mission is to help the development of the socially responsible business in Bulgaria focusing on social projects, good practices, publications in CSR, education and training.

In addition to international standards and certificates the Bulgarian companies are developing their own national codes for voluntary adoption of CSR-related principles and rules in their work. The most wide-spread are the codes of ethics which are tailored to the specificity of the sector and concern for the general public interest.

As a general rule, CSR still remains a mostly 'imported' management product which has not established itself firmly on the national landscape.

Concerning the working environment, conditions and remuneration in the Bulgarian healthcare system, one can underline the territorial disproportions for the provision of medical specialists. A negative tendency is observed in relation to emigration of qualified healthcare specialists compared to young people joining the medical profession. Discontent is shown on the rules for specialization and lack of policy to retain young medics in the country. Measures in this respect have been taken in the strategy for the development of healthcare 2020 – 2030.

The analysis of Bulgarian practice shows that CSR practices have the power and potential to destroy the existing negative clichés and to revive the interest of young people in the key professions of valuable industries. Positive impact on young people and their families to a change in attitudes and assessments of professions in the main industries can be achieved, among others, by the good practices that exist now in the Bulgarian innovation eco-system:

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[16] "Manual for implementation of corporate social responsibility in the pilot industries", developed by Association of Industrial Capital in Bulgaria, project BG05M9OP001-1.011 - 0002

- "Innovations meet schools" project started by the PARA company with the aim to take innovation to the school and show what skills students need for creativity and solving problems through high technologies.
- The Healthtech innovation program by Eleven and Sopharma which organized a competition for the most mHealth innovative companies; after selection, companies are trained and receive funding for their projects.
- Digital Health and Innovation cluster, jointly with Junior Bulgaria are organizing a Digital Heath and Innovation course for students of the Medical University of Sofia.
- Digital Academy for Continuing Medical Training organized by the Bulgarian Doctors Union

A very important factor for the development of a strong and innovation-based ICT sector for example is the work of many training academies, organized by the enterprises themselves in the sector, as well as other training initiatives of leading companies, such as Musala, Telerik Academy, SoftUni, LeanPlum Bulgaria etc.

The **Open innovation** approach is discussed in a number of articles, thesis, manuals that one can come across in the Bulgarian public space. These treat its importance to company competitiveness, the possibilities to react in a swift and flexible manner to changes in business environment, benefits and disadvantages etc. However, in our review, few Open innovation practices in Bulgaria were detected. For example the Technical University of Sofia is working on Interreg funded project "DA-Space Open Innovation to raise Entrepreneurship skills and Public Private Partnership in Danube Region".

A good example is an Open Innovation Competition launched by the Association for the development of Sofia. The idea is that the participants suggest innovative ideas for the solution of parking issues in the Ljulin district of Sofia, which later can be applied for other Sofia districts. Participants receive necessary information as well as mentors' support. The competition is held online.

An interesting article by (Netoff & Semova, 2010) treats the Open innovation and the Academic Entrepreneurship. The paper reviews the opportunities for academic entrepreneurship and technology transfer to the real sector through the model of open innovation.

The authors describe a number of practices available for researchers working on fundamental studies and which are far from the corporate R&D activities, for example:

The http://innocentive.com platform which offers possibilities for companies to publish their problem and for researchers to offer solutions. The conditions for the partnership, the remmuneratios are regulated in advance.

The http://www.researchgate.net/ platform permits, through a number of instruments, researchers to present themselves, their achievements and interests, to build partnerships with colleagues workig on similar and complementary ropics.

Other entities using Open innovation are the **NGOs**, through their setting up and participation in different networks that support the exchange of ideas, creation of transparent and fair rules for the transfer of intellectual property. Many such networks exist in Bulgaria. Ex. Labor market research https://labormarketresearch.eu/bgn/.

Clusters are also specific networks that are NGOs with legal bodies status. Their activity is directly related to the competitiveness of their members. This is achieved through the development of a joint brand, through the economy of scale effect. In Bulgaria there are dozens of clusters (according to Investor.bg they are 261), but

only a few of them are potential places for open innovation, where university research is present and technology transfer, innovation and competitiveness are the basis.

Still another opportunity to implement the Open innovation model are the **technological centers, parks and incubators**. One of them – the Sofia Tech Park is engaged in the project through its laboratories, incubators and work and exhibition space.

e. Actors of the innovation eco-system

The innovation ecosystem **structure** is presented below by some of the main actors and their role and significance for eHealth development and implementation in Bulgaria.
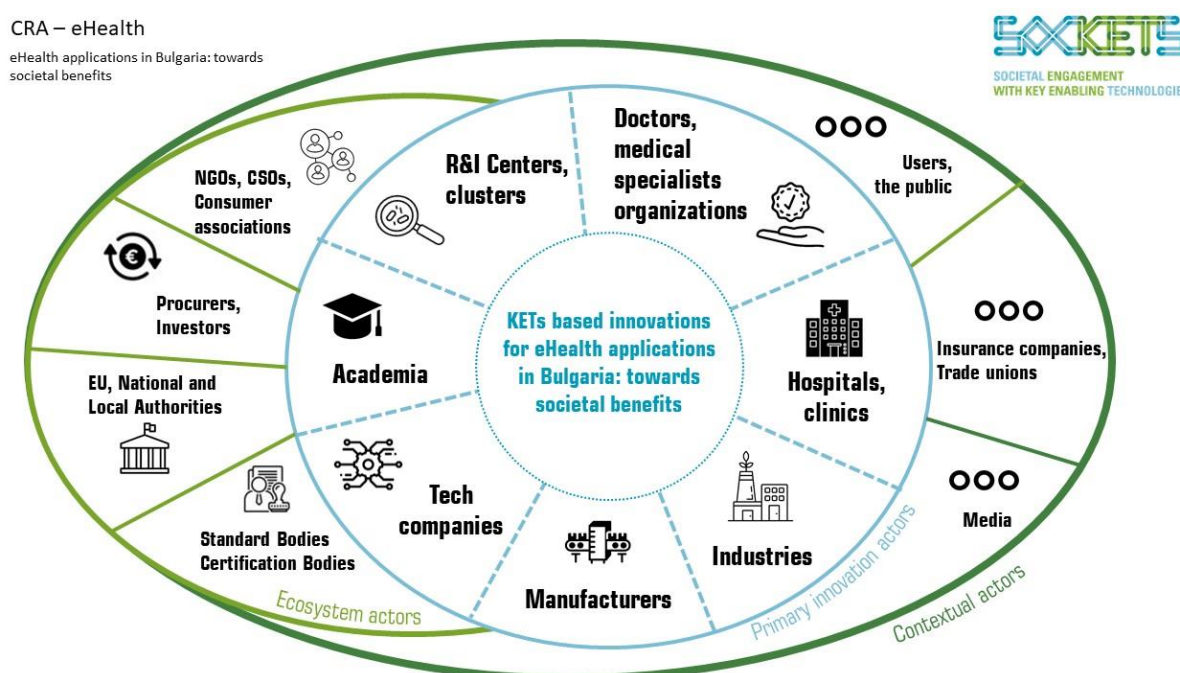
Figure 3: The innovation eco-system stakeholders

- **Research** – the Bulgarian Academy of Sciences and its ICT institutes, the Medical Universities,
- **Public bodies** – the Ministry of Healthcare, hospitals, clinics
- **Business -** start-ups, ICT – IoT - AI companies producing/launching software, platforms; manufacturers - producers of medical devices, wearable devices, clothes;
- **Industry** and sectoral associations, tech parks, clusters;
- **Other** - Funds – Health Insurance Funds, other sources of funding the system; Non-governmental organizations - doctors' and medical personnel associations, patient organizations for protection of patients and customers, specialized NGOs for personalized medicine; for eHealth; for medical education etc.; Trade unions; Media; The Public, etc.

Research

The Framework of the **National Strategy for the development of AI[17]** , 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 fulfill 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."

In 2019, a **National research program eHealth** was initiated. The program was funded by the Ministry of Education and Science with the amount of BGN 2 mln[18]. 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.

Public bodies

There are 8 **main priority areas** for the healthcare system in Bulgaria as described in the **National Healthcare strategy** elaborated by the Ministry of Healthcare. The one that deals with eHealth is Priority area 2. "Introduction of a unified integrated information system through the development of eHealth for full transparency and efficient use of available resources, which is explained in detail in the net chapter".

The Bulgarian eHealth system includes the following **public eHealth projects**: E-prescriptions, eHealth files, eHealth card, eHealth portal, Hospital information systems, Telemedicine. The idea of eHealth began to be discussed in Bulgaria in 2005. Since then, it has often been identified as a priority, but a number of obstacles have impeded its implementation: the lack of funds, low level of computer literacy of many medical staff, the need to introduce new regulations, incomplete system of standards and codes, insufficient and obsolete computer base partial and infrequent use of Internet.

The eHealth development in the next few years as seen by the public authorities, and the priority tasks that will be worked on from 2021 to 2024 include:

- Information data base or the system for the control of medical expertise.
- National Unified Health Information system.
- The Specialized Electronic System for Monitoring and Analysis of Medicinal Products.
- National eHealth strategy 2021 – 2027.
- eHealth National Nomenclatures – elaboration and implementation.

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[17] Framework of the National Strategy for the development of AI. Preliminary vision http://www.bas.bg/wp-content/uploads/2020/07/Towards-AI-Strategy-BAS-Vision-1July2019.pdf

[18] The exchange rate of the BGN is 1 BGN = 0,51 euro

- Trans-border exchange in the EU of health data.

Business

Our interviews analysis provided some good examples of Bulgarian innovation companies or start-ups in automation systems, Internet of tings, 3D printing in the eHealth system. A few examples of products these have developed are listed here:

- Robots for medical assistance;
- Home automation and wearable devices – watch trackers for kids; touchable watch trackers; control of home appliances, lights and consumption through mobile phones;
- 3D model of patient's bone using the information from the computer tomography scan used in personalized care;
- Intelligent capsule - a new non-invasive method for gastroenterology tests;
- Wireless home sensors that can measure movement, respiration, heart rate, sleep and behavior of patients by using low power radio waves.

What is important to mention is the **lack of cooperation** between the different sectors – public, research, business to work in synchrony or on joint projects. To remedy to this weakness, with the support from the EC, Bulgaria adopted an **Innovation Strategy for Smart Specialization**, with the aim to stimulate the cooperation between the business and research and redirected public resources to set up regional innovation centers. In 2021 the Strategy was updated for the new program period till 2027.

The case-study involves several of the actors, namely:

- The national health provider currently introducing the e-prescriptions, patients' dossiers, nomenclatures and standards which are the foundation for the eHealth system on national level. It is an important actor on which depend many of the functions of the other actors in the system.
- Technology owners. Two companies have been interviewed that are producing/launching software, medical devices, wearable devices using ICT, IoT and AI.
- A Tech Park which will play several roles in the study. On the one hand it is developing KETs with its several laboratories, on the other it is also involved with an innovation cluster. And finally it will be a partner and the location for the exhibition/installation that will be developed further in the project.
- An NGO which involves researchers, inventors, patients, medical and health care professionals, health care and educational institutions, service units and commercial structures in health care and fosters the better understanding and adoption of the concepts, services, and products of personalized medicine for the benefit of patients and the health care system. It will help with involving the medical specialists that some of the technology owners need.
- A social media company – which is interested in raising awareness on eHealth and its principles in ethics, truthfulness, patient data protection and reliability of devices.

The interviewees suggested to involve in the co-designing multi actor engagement process some other stakeholders such as:

– Clothing companies and device producers that hold the software and sensors of the monitoring system and who are partnering with the ICT and software owners;

- Financial and strategic partners in the area of investments, technology and telemedicine software developers, ICT companies, clothes producers, researchers, beta testers.
- Various actors in the eco-system, incl. the hospitals, the ministries and the public agencies' administrations, the National Parliament Committees members and the legislators, the Health Insurance Fund should be engaged to discuss the good practices, to raise awareness on important eHealth issues.
- Non-governmental organizations, such as the National patient organization, who are also involved in building the national eHealth system.
- Companies that provide medical and laboratory and pharmacy software.
- the DHI cluster.

4. Societal and ethical aspects

a. Ethical and social conditions and implications

In Bulgaria there is a central ethics commission at the Council of Ministers - The Central Ethics Committee which gives opinions on deontological and ethical issues in the field of clinical trials when these are referred to the Ethics Committees.

The commission operates in accordance with the basic principles which ensure the rights, safety, health and human dignity of trial participants as set out in the Declaration of Helsinki on Ethical Principles for the Conduct of Clinical Trials on Humans. The following duties are part of their work:

1. Respect the principle of confidentiality and the absence of conflicts of interest.
2. Provides with statements and recommendations for clinical trials.
3. Carries out current control over developmental tests.
4. Exercises control over applications of medical devices.
5. Validates the documentation for testing of medical devices.

Some of the interviewees shared views about the main interactions with society after introduction of new technologies. Quotations are given below, in groups:

New conditions and implications

- *An entirely new way of thinking, a new approach to medical care. Everything is happening online. For this new system to work properly we need rules and investments.*
- *New many challenging devices and processes - At the background there is the computing power – the operators monitor the data; At the foreground – the consumer for whom it is important to know how easy to use the devices will be, how interactive, what real access they will give, will there be a human touch; how his data will be processed:*
- *Sensors – how to integrate them, how to make them widely accessible.*

Stakeholders

- *There are many target groups. The system consists of many moving parts, many interested parties with their own agenda. Some of them will be motivated by the technological development, others - to make money, still others – to protect people.*
- *The state is conservative. It chooses the easiest way - not to change things, be passive. There is no disease prevention system. Although in the long-term prophylaxis comes cheaper.*

Interactions

- *Citizen and their data protection - Who will be responsible for this data protection and how will it be organized?*
- *The effects on society – there should be a balance of benefits and risks by introducing new technologies;*
- *The funds that the state will give for research will have no direct return. These funds on the other hand could be directed to education, or other goals. Here lies the issue of the balance – how much should go for research and how much for practical development of e-products.*
- *The ethical balance is also a difficult issue. To what degree will we monitor people, who will have access to their data. How to avoid commercialization and taking advantage of the data?*

Legal aspects

Currently, the National health information system is legally regulated by the Health Act. An ordinance describing all processes is to be developed. The modules that are being worked on for eHealth are regulated in Ordinance 4 of the Council of Ministers on Access to Medical Information and in the National Framework Agreement for Medical Activities.

The national regulations for the Health Insurance System do not provide for payment for medical devices, it does not pay for software. It pays for treatment and medicine. In England and Germany, there are regulations that allow an application to be approved, recommended and paid for by insurers.

Threats and Risks

- *The main risks for people would be 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 risk 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.*
- *"Pseudoscience and lack of data reliability. People consult Google and a number of crazy theories invade the social media".*
- *Medical specialists and researchers voice controversial information and advice on the most popular media and people are confused.*

- *Hospitals have been transformed into business enterprises, according to changes in the Healthcare Act from 2015.*
  "The hospital does not try to heal you; it tries to get money from you. Because otherwise without incomes from the state, it cannot function. Thus useless treatment procedures and surgery are performed, fake hospital stays are registered, etc. "[interviewee]
- *There is lack of nomenclatures (systems or codes) and standards related to eHealth. Much of the medical information at the moment, all documents are on paper, there are missing or incomplete parts. Data needs to be centralized and consistent so that it can be later upgraded and have greater transparency for the monitoring at national level. Another example is that we do not collect specific data for ex. rare diseases and have it in adequate registers, that could serve as a basis for analysis, prognosis and better treatment.* – this is a summarized opinion from several of the interviewees.

Recommendations

- *Need of targeted investment.*
- *Comprehensive legal framework setting up - rules on how to operate with personal data, bio-data, how to protect personal medical data, 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 the new technologies.*
- *Define and share responsibilities.*
- *Not to allow technologies to take advantage and rule out human relations.*
- *Competent and knowledgeable people should be involved.*
- *Trust should be created between patients and doctors, which is now lacking. Dialogue is important to return the trust. Strict rules should be observed as to who can pronounce himself in the media on specific specialized topics.*
- *Promote the new technologies, educate people on their benefits.*

b. Public and stakeholder awareness

Our interviewees stated that there are definitely more benefits for society - better analysis of medical records when visiting the General practitioner (GP), presence of medical history, more adequate decisions and treatment.

The introduction of new technologies in eHealth, especially the connection of GP, hospitals, pharmacies, the health insurance fund, the different medical services, in a common national system would be a great achievement and welcomed by all. This will bring efficiency, quality and better access to healthcare.

And people react positively to these new applications. The feeling is that people support eHealth as a way to optimize processes, saving costs and time.

On the other hand, we do not know how doctors will react to that. Doctors are not accustomed to monitor their patients online. The GPs are overloaded nowadays with thousands of patients, heavy documentation and

constantly changing requirements. Many of them resign. In order for the system to work, we need to adopt such monitoring practices and the eHealth new methods and techniques in a way that will alleviate the doctors work. People should be informed about such possibilities; applications should be explained. The system should have an option for notification of the doctor and assist the doctors in their tasks.

c. Cultural aspects

The Analysis of the socio-economic status of Bulgaria after joining the EU reveals several main issues and potential for improvement. Those that concern the healthcare system and the implications can be summarised as follows[19]:

- Unfavorable **demographic trends**, such as declining birth rates, population aging and increased urbanization;
- Alarming signals about the **quality of education** at all levels. It is especially urgent to overcome the low level of computer and digital skills of human resources in the country, which hinders the widespread use of ICT and services based on them and the achievement of digital growth.
- In recent years, **life expectancy** has been rising steadily, albeit with regional imbalances and remaining the lowest in the EU. Public spending on health remains low and direct payments to consumers are the highest in the EU, with significant implications for access to health services.
- The **emigration of qualified specialists** cannot be compensated by the small number of people joining the labor force in the healthcare system.
- Frequent regulatory changes and slow implementation weaken the effectiveness of legislation and discourage investment. The country remains in the group with the weakest indicators of good governance in the EU. However, an ongoing development is visible of authentic Bulgarian companies in the field of microelectronics, communication equipment, sensors, industrial automation, robots, optical products, etc. (ex. Datex, Samel-90, Optics, Daisy Technology, etc.). The same trend is even more clear in the field of development of software products where since the early 2000s, multinational ICT leaders have begun to establish R&D centers in the country mainly through the purchase of their long - standing Bulgarian subcontractors (ex. VMWare Bulgaria, Software AG, SAP, DevexePerts, Progress, Bosch Software Innovations Sofia, IDT Bulgaria, LeanPlum Bulgaria, etc.), while authentic Bulgarian companies are established as world innovative leaders, albeit in "narrow" specialized markets or niches (e.g. Chaos Software, Ontotext, Interconsult Bulgaria, Mobile Systems, Software Air Group Bulgaria, Sirma Medical Systems, etc.).
- Bulgaria lags behind in terms of **e-government**, but in the last few years there has been an improvement as a result of the consolidation of the functions and processes related to e-government into a single structure and the measures taken to improve e-public services.

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[19] Bulgaria 2030 – Part 1. Analysis of the socio-economic development of the country after joining the EU, retrieved from https://www.minfin.bg/upload/41549/Bulgaria%202030%20analiz.pdf

– **Economic growth** increasingly depends on the extent to which drivers for competitiveness are used - innovation, high value-added products and regional specialization. Despite the marked improvement in the private sector's innovation capacity in recent years, the country's innovation system is operating below its potential, with all the ensuing negative consequences in terms of striving to build a knowledge-based economy. The R&D sector in Bulgaria faces some serious challenges that require policy change.

Additional analysis of the ICT sector, provided in the publication Innovation.bg 2019[20] (Georgieva, Georgieva, Galev, Yalamov, & Koleva, 2019) gives hope for a positive development. In 2018, the number of people employed in research and development in Bulgaria increased by more than 10% on an annual basis. The business sector has a leading role in the growth of the R&D staff. For comparison, the medical sciences have a share of 18% and an annual growth of 13%, followed by a 17% share for the natural sciences and a growth of only 2%. Along with the increased innovation activity of enterprises, including on a project basis with the support of operational programs, this process is influenced by the research and development structures of foreign companies discovered in the country in a number of high and medium high technology activities.

The system needs funding, better interaction between business and research, improved higher education system, better applied research capacity and modern infrastructure to meet modern requirements. These factors affect the quality and applicability of the research undertaken and the ability to compete with science at European and global level.

The **information and communication technology** sector in the country is developing dynamically, increasing its contribution to added value, employment and exports. ICTs are a major driver of the digital revolution globally. For the period 2010 - 2019, the fastest growing ICT sub-sectors, measured but in terms of revenue, are "Computer programming and IT activities" and "Wholesale of computer and communication equipment", the former reaching € 2.9 billion and the latter € 1.5 billion in revenue for 2018. The almost threefold increase in revenues in the subsector "Computer manufacturing and communication equipment, electronic and optical products" for the period 2010 - 2018 is a strong sign of the positive trend in the entire ICT sector related to the imposing of Bulgaria as a destination for R&D development, intensive and innovative technologies not only in software but and in hardware.

For the last ten years the Bulgarian ICT sector has undergone significant transformation with diverse major effects on the economy and socio-political processes. Exports of ICT products and services has tripled from 2010 to 2019 and for the first time it will exceed BGN 10 billion and will reach 17% of the total export (goods + services) of Bulgaria. The ICT sector is already contributing for almost 6% of the gross value (in 2017) and a growth of over 30% of business costs for research and development of activity since 2016.

The cultural identity of Bulgarians has suffered extremely strong and prolonged influences from external factors (five centuries of Ottoman rule, centralized planned economy), which led to its forced change, did not allow its natural development and ultimately created a distorted model of national culture with many internal

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[20] Innovation.bg 2019 http://www.arcfund.net/arcartShowbg.php?id=18492

contradictions. However, under the influence of external factors, the cultural identity of societies continues to change. With the membership of Bulgaria in the EU and with the goals set by the country, a shift of cultural values in the direction of more pronounced femininity and individualism, less uncertainty and power distance. Despite the challenges in the Bulgarian cultural frames, the country on the basis of its own cultural identity, creates and implements approaches to increase the competitive potential of the national economy, i.e. to develop its own innovation culture. Practical steps have been taken in the following areas

- Human resources development - entrepreneurship education is introduced in the first stages of the educational process aimed at development of initiatives, to stimulate the readiness for lifelong learning and the skills for creative application and dissemination of the acquired knowledge in the practice;
- Dissemination of good innovation practices - striving to saturate the public space with information about implemented innovation projects, results of their implementation, reasons for the achievements/failures. The relationships between the participants in the innovation system, incl. Public-private partnerships are trying to be improved within the framework of organizational and social innovation, affecting the principles and mechanisms of functioning of the partnering institutions;
- With Bulgaria joining the EU in 2005, and the generation of millennials born after the socialist system, a number of practices have been introduced trough projects, programs and initiatives, benefitting a new entrepreneurial culture, a new gender dimension and new educational methods, that change the cultural environment.

Some views expressed by the interviewees, support the following ideas - It is important that more and more people hear about the new technologies in eHealth. Who are the technology owners, who is implementing the transformations, what are the benefits? Those that make real science should be heard, not the pseudo-specialists [interviewee].

Bulgarian media often publish discussions, articles and opinions on the development of new technologies (databases, applications, mobiles, wearables) and their implementation in medicinal products and services. Opinions are voiced that:

- Consumers and businesses alike are beginning to realize the potential of the partnership between technologies and the health industry]
- eHealth will improve access to health services by putting the patient at the center of the system and increasing its efficiency.
- New skills, consumers and citizens' habits and behaviour will likely need change, and new ways of interaction will emerge, enhancing synergies, symbiosis and giving value to peculiarities of organisations and local communities.
- During a webinar on "E-solutions for better health" Prof. Asena Serbezova, Chairman of the Board of the Bulgarian Pharmaceutical Union said: "With digitalization we will achieve improved access to health services, greater empowerment of patients, longer duration of life".

The digital landscape of labor

Another transformation occurring as a consequence of digital technologies is the future of work and professional skills. Automation, big data and artificial intelligence can affect 50% of the world economy. There is also

anticipation and apprehension about what lies on the other side of the threshold of this change. More than 1 billion jobs and $ 14.6 trillion in salaries are automated by today's technologies, that open the door to new ways to use human energy, shove out routine jobs, all this can lead to an increase in social inequalities (World Economic Forum, 2017)

High-speed changes will require safety mechanisms and training systems to help withstand "megatrends", changing the nature of the work. New markets opened by technology along with increased productivity will benefit some, but others will suffer - the young, the low-skilled, the part-time workers, temporarily employed and others.

Despite concerns about the 'destructive' role of technologies in the labor market, "total employment does not seem likely to fall sharply" – on the place of the old jobs, appear new ones.

The Future of Jobs Report, 2018, says, "*As technological breakthroughs are rapidly shifting the line between man- and machine-performed tasks, global labor markets are undergoing major transformations. These transformations, if managed smartly, could lead to a new era of good work, good work places and improved quality of life for all, but if poorly managed, they represent a risk of widening skills gaps, greater inequality and wider polarization.*" (World Economic Forum, 2018)

The IT that have the strongest impact on the transformation of the labor market are - Big Data, Robotics, Information Security, Virtualization, Mobile technologies, Programming, Cloud Computing, Cognitive Computing and Artificial intelligence. The top five most sought-after soft skills are: creativity, persuasion, cooperation, adaptability and time management, followed by emotional intelligence, flexibility, work with data, cognitions skills, social and emotional skills, technological orientation. The top five most sought-after hard skills are: cloud computing artificial intelligence, analytical justification, human management and UX design.

5. Interest in co-creation and SocKETs activities

The co-creation method in Bulgaria is not a very familiar concept. Especially when mentioned in Bulgarian language, the interlocutor always asks „ … co-creation of what? " The expression needs additional explanation to be understood.

The **interviewees for the case-study**, regard co-creation as a positive initiative that they will join.

Some of them reflect that the goals of the co-creation initiative should be to engage the various actors in the eco-system in order to discuss the good practices, to raise awareness on important eHealth issues, involving the hospitals, the ministries and the public agencies' administrations, the National Parliament Committees members and the legislators, the Health Insurance Fund. Special attention should be paid also to journalists who need to have adequate information to transfer to audiences. A lot of work is necessary with the participation of many people at different levels so as to educate and engage society.

Others comment that it is good to start the SocKETs engagement and co-creation talks – to set a frame, to have a common strategy, a general direction to follow, the energy to be steered in a more purposeful direction.

So far, they have not used the co-creation method, although their products [interviewee] have feed-back channels and the products have undergone changes due to customers' involvement. It will not be difficult to switch to a more targeted discussion.

They are willing to participate in a discussion format regarding a new product, for which they think there must be communication, everyone's vision must be clear and should be considered, there will be pros and cons and risks, etc., but this is positive.

One of the interviewees shares that at the moment they are developing a base system for personal medical dossier. On this basis they want to introduce more specialized applications that will monitor chronic diseases, as well as some pediatric issues. They need them to have a more specific focus, therefore it will be good to know what other chronic diseases exist that can be regularly monitored from a distance. Here the views of medical unions, doctors' and patients' associations will be very valuable.

Other considerations that they expressed are:
- How to schedule the event – co-creation discussions should take place at the beginning, before work on a product starts; co-creation discussions should take place after the company product is at prototype stage, so as to know that it will work;
- The needs of the target group should be investigated, as well as whether the patients will be willing to take advantage of the new product/technology;
- The choice of other participants is vital for a successful co-creation event;
- Company's own interest and capacity are main considerations for participation in co-creation.

Other states that it could contribute as a media partner to the case study underlying that awareness is important and it can participate in this study by disseminating information, by giving the floor to genuine specialists and researchers to explain the benefits of new technologies in eHealth. It can make visible the people that are involved in eHealth, and include more people who make real science. Interviewee has heard about co-creation, but has not used it and shares the following thoughts:

"*The practice shows that a small group of 2-3 people invent something and then it begins to spread. When a topic is discussed with many people, it is difficult to have them join a unified idea*".

"*We are not just working on what we think is right. We make meetings, have communication channels, share what we intend to do, expect comments. We publish projects on the national health portal, e.g. rules for information exchange and the processes of the electronic prescription and the electronic exchange. We would join a co-creation event, but it depends on the choice of the target groups.*"

In conclusion a professor stated that "*We should gather the right target groups, choose the correct formats, find the appropriate language. Select the right partners and act in coordination*" [interviewee].

A desk research of Bulgarian sources reveals the following results about co-creation implementations:

- It is used in the business terminology as co-creation of value which implies the existence of a platform where consumers can give feedback information to the producer, can express their opinions and views and recommendations about a specific product/service of a company[21].
- A co-creation project[22], led by Unione degli Assessorati with Bulgarian participation, funded by Erasmus+ is on the internet. The project represents a study of the method, what needs and expectations it covers. The project makes a survey of the current attitude, knowledge and opinions about the model of co-creation in the public administration activities, namely to show the level of cooperation of civil servants with citizens, their expectations in the cooperation with private organizations, the level of their knowledge and awareness of the model.

The Centre for Research and Analysis has implemented the Fit4Food[23] project as Ecsite TP, during which it implemented co-creation methods and produced modules for training of school children and journalists.

6. Conclusion

During the case study analysis, we gradually narrowed our interest for further co-creation activities to KETs applications in diseases monitoring, innovative devices and practices and ICT applications and platforms that are user-friendly, non-invasive and can be used in a non-hospital environment. The activities will involve technology products and services offered by private owners - mainly start-ups having emerged in the period after 2015 using Internet of Medical Things, Mobile devices for health indicators monitoring involving also Artificial Intelligence and telemedicine.

The discussion on eHealth will provoke a shift in the way we regard healthcare services and the technologies involved. It will engage citizens in dialogue and co-creation based on their priorities, expectations and concerns. The main values and principles that should be put forward are:

- Reliability and truthfulness – a leading principle for information providers
- Quality – information data should be culturally adapted, easy to use, unbiased, timely
- Informed consent, data protection and confidentiality
- Protection and prevention from commercial practices

During the co-creation events we shall try to put forward the following main issues:

- The interactions with society, mainly the impacts on society, the benefits and risks.
- The evident barriers and opportunities to introduce KETs based innovations in Bulgaria that have been identified.
- Other risks to consider:
  - o The lack of regulations for ethical issues and personal data collection and protection

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[21] Co-creation of value for a trade mark through a company platform. Boryana Dimitrova, PhD, Brendt Smith, Assoc. Prof. , Trina Andras, Prof., PhD

[22] https://www.cocreated.eu/bg/

[23] https://fit4food2030.eu/

- o   Insufficient computer literacy of citizen, but also of the medical staff
- o   The harmful effect of pseudoscience, fake news, lack of data reliability, controversial information
- o   Lack of trust in medical doctors and institutions.

The opportunities however, are outstanding. Health systems will benefit from innovative care models that use eHealth to address the rising demand for healthcare, and the shift towards integrated and personalized care systems. The use of KETs applications and devices throughout the chain of medical products and services will introduce efficiency, time-saving, accessibility, equality, affordability and better quality of life.

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Annex

List of other organizations and specific products to consider for the case study

Our interviews provided some good examples of Bulgarian innovation companies or start-ups in automation systems, Internet of tings, 3D printing in the eHealth system:

- The company name is **PARA (Professional Association of Robotis and Automation),** led by Kristiyan Mihailov https://www.facebook.com/KrisMihailov89/- Co-Founder and Robotics activist, who states - I believe Bulgaria is a great place for innovations. The copmpany develops robots for medical assistance.
- **Allterco Robotics** https://allterco.com/en/PRODUCTS aims to make the life of the today person easier. The team of young talented developers, is devoted to produce competitive and easy to use products and developed a whole new trend in the Home Automation and Wearable devices. In December of 2015, Allterco Robotics introduced the first GPS/GSM watch trackers for kids, called MyKi Watch, for pets - MyKi Pet, a device helping pet owners monitor their pets' location at all times through an application; - MyKi Touch - the touchable watch tracker for children with more functions. Today, over 50% of the children in Bulgaria wear MyKi. Another line of development is Shelly, the first of its kind automation system which helps the end customer controll all their appliances, lights and consumption simply by using their mobile phones.
- **OS Implants** surgical models https://osimplants.com/surgical-models/ help doctors to apply personalized care and planning by issuing products created through realistic 3D model of the patient's bone trauma using the information from the patient's Computer Tomography scan. All bones of the patient can be recreated and printed.
- A new non-invasive method for gastroenterologic tests was developed by MD Ivan Lyutakov. He created an **intelligent capsule – the EnhanCAP,** that reaches the small intestine, relieves drugs on the site and takes extracts from the microbiome to be tested. The main challenge is the size of the capsule and the appropriate material – issues that are being gradually overcome.
- Rumen Hristov is an Olympic winner for informatics and ranks 6 in the list of world competitors in informatics. He falls in the Forbes classification "30 under 30" as a co-founder of the **Emerald Innovations company**. The company is producer of wireless home sensors that can measure movement, respiration, heart rate, sleep and behavior of patients by using low power radio waves. This allows the device to capture valuable patient home data through walls, without touching or disturbing the patient.

During the case-study we identified three main products that will be considered for further co-creation and engagement activities:

- device for health indicators monitoring in real life, offering channel patient – doctor/hospital.
- wearable device for athletes' performance measuring;
- telemedicine platforms.

The first device **Medrec:M** is being developed by the Sirma Group company. Like other products of the company, techniques from the field of A**rtificial Intelligence** will be integrated here as well as the **Internet of things**. This technology will ensure that consumers are better informed, it will assist doctors in better diagnosis and treatment. It will monitor for dangerous conditions and warn of trends in the change of important health indicators over longer periods of time, which would otherwise go unnoticed.

Medrec: M provides a channel for communication with the health authorities - an opportunity for the user to provide anonymous information for the purpose of assessments and predictions related to the health status of the population. The product provides an opportunity to participate on a voluntary basis in surveys and studies for the transition to better health.

How does Medrec: M work?

The user uses the mobile application to collect and record their medical data, symptoms, test results, medications taken, diagnoses, epicrisis, etc. If necessary, the user can easily share his data with a doctor. For this purpose, he uses the "sharing" function in the mobile application, indicating the doctor only by entering the e-mail address with which he registered in Medrec: M. One of the features of the system is that the doctor may not accept the invitation to access the patient's data. The patient sees if his invitation to share has been accepted.

Using the application and filling in the health status data on a regular basis will be useful for both users and health authorities, who will have a look at up-to-date statistical information provided to them on the basis of anonymized data. By regularly filling out the surveys in the application, users contribute to building a better health care, and in a pandemic - to more adequate responses. The application uses and will use Sirma's vast expertise and diverse technologies in the life sciences and healthcare.

The second device is developed and implemented by **Barin Sports**. The device monitors the physical condition of professional athletes, the work they have performed, the loads they take, how fast they run, their pulse speed, their recovery process.

The system allows to accumulate large data – over 12000 data points per second. A serious massive, that is processed by machine learning and AI. The process allows to offer advice to coaches, incl. possible risks of contusions, overloads etc., to decision making and management of athlete performance and involvement in the games.

The company is looking for investments to develop two new directions - a new device for the wider public especially elderly people for monitoring health indicators linked to a medical center; develop a base-layer under the t-shirt with the device integrated into it – to follow still more indicators of the body – sweating, hydration.

The Covid pandemic greatly accelerated the development of telemedicine.

The company **Healee** is a leader in this field. The use of the platform has increased 10 x in 2020. The Healee chatbot is based upon artificial intelligence.

The **Superdoc** platform is also very popular and has gained in popularity lately.

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