

D1.2

Panorama of the digital health landscape in the EU and in the Strategic Partner Countries

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Abstract

This deliverable "Panorama of the digital health landscape in the EU and in the Strategic Partner Countries" provides an overview of the digital health research and innovation (R&I) landscape in each country/region: EU, Canada, China, Japan, South Korea, USA. It demonstrates for each region the priorities within digital health and active and healthy ageing, as well as the challenges, relevant key programmes, most important players in the field, strengths and weaknesses, and provides an overview of international collaboration and success stories in digital Health between EU and the Strategic Partner Countries.

Keywords

Digital health, eHealth, healthcare, information technology, health technology, active and healthy aging, electronic medical records, connected care, age in place, health information exchange European Union, USA, South Korea, Japan, China, Canada

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Abbreviations and Acronyms

Abbreviation, Acronym	Description	
AARP	American Association of Retired Persons	
ACCRA	Agile Co-Creation of Robots for Ageing	
АНА	Active and Healthy Aging	
AI	Artificial Intelligence	
AIST	National Institute of Advanced Industrial Science and technology (Japan)	
AMCs	Academic Medical Centers	
AMED	Agency for Medical Research and Development (Japan)	
САВНІ	Centre for Aging and Brain Health Innovation (Canada)	
CDHI	Center for Digital Health Innovation	
CEF	Connecting Europe Facility	
CFN	Canadian Frailty Network	
CFM	Joint Research and Innovation Funding Mechanism (EU and China)	
CHRONIC Care Act	Creating High-Quality Results and Outcomes Necessary to Improve the Chronic Care Act (USA)	
CFREF	Canada First Research Excellence Fund	
CHRP	Collaborative Health Research Projects	
CIFAR	Canadian Institute for Advanced Research	
CIHR	Canadian Institutes of Health Research (project partner)	
CITRIS	University of California Center for Information Technology Research in the Interested of Society	
CLSA	Canadian Longitudinal Study on Aging	
CMS	Center for Medicaid and Medicare Services (USA)	
CRCC	Canada Research Coordinating Committee	
CSA	Coordination and Support Action	
DEP	Digital Europe Programme	
DG Connect	Directorate General for Communications Networks, Content and Technology of the European Commission	
DNRS	Dementia National Responsibility System	
DSM	Digital Single Market	
Dx.x	Deliverable x.x	
ECG	Electrocardiogram	





Abbreviation, Acronym	Description
eHealth	Electronic Health
EHI	Electronic Health Information
EHR	Electronic Health Record
EIT	European Institute of Innovation and Technology
EIP AHA	European Innovation Partnership on Active and Healthy Ageing
EMR	Electronic Medical Record
ENISA	European Union Agency for Network and Information Security
epSOS	Smart Open Services for European Patients
ERDF	European Regional Development Fund
ESF+	European Social Fund Plus
ESRC	Economic and Social Research Council
EU	European Union
FDA	Food and Drug Administration (USA)
GDHP	Global Digital Health Partnership
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
НСО	Health Care Organization
HE	Horizon Europe
HHS	Department of Health and Human Services (USA)
HIE	Health Information Exchange
ніт	Health Information Technology
H2020	Horizon 2020
HSCIC	Health and Social Care Information Centre (USA)
IA	Canadian Institutes of Health Research Institute of Aging
IAH	Independence at Home
ICT	Information and Communication Technologies
IFA	International Federation on Ageing
IHSPR	Institute of Health Services and Policy Research
Inno-Hub	Healthcare Innovation Hub
InvestEU	Invest EU Programme
IoT	Internet of Things
IT	Information Technology





Abbreviation, Acronym	Description
12M	Innovation to Market
KRW	South Korean Won
LCT	Long Term Care
Link-J	Life Science Innovation Network Japan
MA	Medicare Advantage
MAFEIP	Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing
M&A	Merger and Acquisition
MEDISO	Medical Innovation Support Office (Japan)
METI	Ministry of Economy, Trade & Industry (Japan)
MFF	Multiannual Financial Framework
mHealth	Mobile Health
MHLW	Ministry of Health, Labor & Welfare (Japan)
MIC	Ministry of Internal Affairs and Communications (Japan)
MOHW	Ministry of Health and Welfare (Korea)
MoST	Ministry of Science and Technology (China)
MoU	Memorandum of Understand
NCE	Networks of Centres of Excellence
NHC	National Health Commission (China)
NHS	National Health Service (England)
NIA	National Institute of Aging (USA)
NIH	National Institute of Health (USA)
NHIS	National Health Insurance Service (Korea)
NRC	National Research Council Canada
NRC IRAP	National Research Council of Canada Industrial Research Assistance Program
NSC	National Seniors Council
NSERC	Natural Sciences and Engineering Research Council
NSFC	National Natural Science Foundation of China
OECD	Organisation for Economic Co-operation and Development
ONC	Office of the National Coordinator for Health Information Technology (USA)
PACE	Program for All-Inclusive Care for the Elderly (USA)
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)



Abbreviation, Acronym	Description
Pre-Cert	Software Pre-Certification Program
R&D	Research and Development
R&I	Research & Innovation
SaMD	Software-Based Medical Devices
S&T	Science and Technology
SMEs	Small and Medium Enterprises
SSHRC	Social Sciences and Humanities Research Council
S2i	Steinbeis 2i GmbH (project partner)
UKRI	UK Research and Innovation
US	United States
VITO	Flemish Institute of Technology
WASS	Well Aging Society Summit
WHO	Word Health Organisation







Executive Summary

This "Panorama of the digital health landscape in the EU and in the Strategic Partner Countries" is part of the International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living (IDIH) project funded under the European Union's (EU) Horizon 2020 Research and Innovation Programme.

The present report has been elaborated as deliverable 1.2 (D1.2) in the framework of work package 1 *"Preparatory Work: Analysis of the international collaboration landscape in AHA"*. Its findings mainly feed into Objective 1 "To support the definition of common priorities to enhance strategic international collaboration in digital health for active and healthy ageing in line with policy orientations" of the IDIH project and provide an overview of the digital health research and innovation (R&I) landscape in the EU and the Strategic Partner Countries - Canada, China, Japan, South Korea, USA.

Firstly, in *Chapter 1 Introduction*, the report provides an introduction on the IDIH project and its objectives, background information on Digital Health and Active and Healthy Ageing and the vitality of constructing a roadmap for global digital health development, for which the current deliverable is important.

Secondly, in *Chapter 2 Methodology and Concept of the Study*, the report explains the 5-step methodology through which the current report was constructed. As a first step, in-depth desk research was conducted for each country/region by IDIH consortium partners – and experts in the field - from the respective countries, under the coordination of S2i and GAC, and preparation for interviews took place. As second step, in Europe 10 interviews, while in each Strategic Partner Country 5+ interviews were conducted with key stakeholders who have extensive knowledge on the national context (strategy, technology, market...) related to digital health, to bring a qualitative element in addition to the desk research. As a third step, the analysis and integration of the interviews in the report took place, cross-checking the information derived from the desk research with that from the interviews, resulting in one coherent text. Fourthly, additional analysis took place, such as the creation of SWOT analysis, definition of main challenges, lessons learnt, and gathering additional qualitative data from external experts. As a final step of the methodology, conclusive remarks for the report were made.

Thirdly, in *Chapters 3-8*, the report provides a detailed overview of the Digital Health and Active and Healthy Aging Landscape in each country/ region (in alphabetical order), through the methodology described above). The reports clearly illustrate each region's/country's priorities and challenges, amongst other aspects. Each nation (geographical region) has its own approach towards care delivery and the use of health technology. Numerous players and stakeholders are building networks on a national and international level with the aim to address the demands of AHA and eHealth and to promote collaboration and support at multiple levels.

The key elements for each report are:

- Digital health R&I priorities
- Main challenges related to digital health
- Specific challenges for the ageing population





- Relevant key programmes and funding agencies
- Most important players and networks in the field
- Strengths and weaknesses in the regions (SWOT analysis)
- International S&I collaborations in digital Health between EU & strategic partners
- Good practices and outlook for further international collaboration

The two last elements present an international collaboration aspect, and as such to make it more convenient for the reader, are placed separately from the country reports, in *Chapter 9 International S&I collaborations in digital Health between EU & strategic partners*. There is no separate section here for EU, as the collaboration with EU is found in the sections of the Strategic Partner Countries.

Finally, the report finishes with *Chapter 10*, in which some of the main conclusions are drawn. Overall, it can be stated that active and healthy aging is a global challenge and the improvements of the conditions of the aging population should be a common goal. This requires a common set of priorities, among others in the field of digital Health. Whilst this Panorama Report in its descriptive nature had for purpose to provide an overview of the current landscape in each country / geographic region and to describe the state of the international collaboration frame, the Report D1.3 "Recommended areas to consider for international cooperation in digital health' research and innovation, including priority matrix", will illustrate where shared priorities between the EU and the international partner countries could foster collaborations. As such, this Panorama Report (D1.2) is, together with (D1.1) report on trends and drivers and (D1.3) provides the analytical basis for the consultative work with expert groups from research, user groups and policy and for the final development of a joint Roadmap to design international collaboration in active and healthy ageing.

It is worth noting that the R&I landscape, including strategies, involved key players and interaction modes among them is widely varied both in the strategic partner countries analysed in IDIH in comparison to the EU and within the member and associated states of the EU. Accordingly, the report aims at providing an overview of each countries' particularities, strengths and weaknesses and future opportunities. A further study of the converging themes and disparities will be subject matter of the sequel report under deliverable D1.3, to elaborate on commonalities and highlight priorities shared by all countries/regions and the overall aim of the Digital Health Transformation Forum to validate these through an expert-driven approach, involving also Funding Agencies during the lifespan of the IDIH project





1 Introduction

The International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living (IDIH) is a 36-month Coordination and Support Action (CSA) (May 1st, 2019 – April 30th, 2022), co-funded by the European Commission (EC) under the EU's Horizon 2020 research and innovation programme, aiming to promote and increase international cooperation to advance digital health in the EU and five Strategic Partner Countries to AHA through innovation. To this purpose, IDIH will identify shared priorities in all regions and set up a Digital Health Transformation Forum as a long-lasting and expert-driven catalyst to foster collaboration between the EU and the Strategic Partner Countries (i.e. USA, Canada, China, Japan and South Korea).

In more detail, IDIH has set the following high-level objectives:

- Objective 1: Support the definition of common priorities to enhance strategic international cooperation in digital health for AHA in line with policy orientations
- Objective 2: Provide specific contributions to the international dialogue in digital health for AHA
- Objective 3: Facilitate the exchange between research, technology and innovation (RTI) stakeholders from the EU and Strategic Partner Countries in digital health
- Objective 4: Foster international collaboration for digital solutions for healthcare benefitting the society and industry.

The growing ageing population worldwide has unique implications for health services and, in recent years, has stimulated demand for innovative technologies that support active and healthy ageing (AHA). As individuals continue to experience longer life spans, this will be accompanied by an increased prevalence of medical conditions that will strain healthcare systems and economies, however it will also open up market opportunities and boost the creation of innovative technologies, which will ameliorate the lives of such individuals. Indeed, digital technologies find a vast and rich application field in the health sector.

Advancements in medicine, technology, and social systems have expanded the life expectancy which is accompanied by age-related often chronic and sometimes even multiple forms of diseases. Prevention of disease and promotion of healthy living are recognised as essential principles for reducing the health burden related to both communicable and non-communicable diseases, requiring cooperation across borders, as different countries can rely on different strengths in terms of technology. The IDIH report on "Trends, drivers and enablers of a digital health transformation" (D1.1) illustrates this and this report (D1.2) provides an overview of the digital health Panorama in the EU and in selected strategic international countries.

The potential of digital solutions facilitate access to healthcare including improved access to electronic health (eHealth), accommodating diverse needs, improving digital health literacy, integrating eHealth into the overall health and social care system policy, evaluating the impact of eHealth solutions and building up an evidence base, giving specific consideration to empower patients with disabilities or specific diseases, and considering financial subsidies for the purchase of eHealth equipment / information and communication technology (ICT) access.





Without cross border secure access to datasets, a shared computing and storage capacity and an appropriate regulatory framework that allows for secure access to data-sets across borders, it remains difficult for healthcare organisations to optimise their services and for researchers to reach the scientific achievements that are needed to support early disease diagnosis, coordinate response to epidemics and accelerate therapy development on a national and international level.

Digital health adoption is gaining traction but is heavily reliant on support and funding from a variety of healthcare stakeholders – governments, regulatory bodies, insurers, investors, and the consumers themselves. The interaction between these players vary from country to country largely due to different regulations and priorities. However, with the global population ageing rapidly, each country will share a common interest in promoting active and healthy societies. Hence, it is vital for international partners to convene and construct a roadmap for global digital health development that will support citizens in living and ageing well.

This is why the IDIH project team has set itself a vision:

To develop a Roadmap to design international collaboration of the digital transformation in active and healthy ageing.

As such, the present "Panorama of the digital health landscape in the EU and in the Strategic Partner Countries" (D1.2) is one of the analytical cornerstones IDIH builds upon, setting the frame together with D1.1 on trends and drivers and complemented through the preliminary priority matrix that shows commonalities between EU and international countries' priorities in the field of digital health (D1.3). This initial priorities' matrix is then validated by three expert groups (policy, user associations, R&I experts) with the aim of creating a Digital Health Transformation Forum for sustainable collaboration in AHA which provides expert input to the Roadmap design. The ultimate aim being the development of international collaboration in digital health, to promote and support active and healthy ageing.

This report has been elaborated as deliverable 1.2 (D1.2) in the framework of work package 1 "Preparatory Work: Analysis of the international collaboration landscape in AHA". The report mainly feeds into Objective 1 and provides an overview of the digital health research and innovation (R&I) landscape in each region. The report provides a "static overview" of the landscape, whilst further IDIH project activity aims at fostering international collaboration through active support schemes, notably the expert-driven consultation and validation mechanism of the Digital Health Transformation Forum which is an important step-stone for the project vision implementation.





2 Methodology and Concept of the Study

For the current report, data collection and analysis were performed in several steps, detailed below.



Desk research by IDIH partners involving their respective countries, and preliminary draft	Conducting overall 37 interviews with key actors from	Analysis of the interviews and their integration in the report	Supplementary analysis: Challenges SWOT analysis, Additional	Drawing final conclusions
Preselection of interviewees per country and preparation of support materials	Strategic Partner Countries	(cross-check with the desk research)	qualitative data gathered from external experts	

Figure 1: Methodology steps

First step – Desk research and preparation for the interviews

Desk research

Firstly, materials were compiled through a **comprehensive desk research by all involved IDIH partners** – the partners from the strategic partner countries being in charge of their respective countries as the local experts, with the guidance by project partner GAC, while European partners in charge of the EU report, guided by S2i. Guidance included ensuring that the partners conduct research in the same manner and on the same elements and topics and that the outline of the country reports is standardized. Each report focuses on the following key elements:

- Digital health R&I priorities
- Main challenges related to digital health
- Specific challenges for the ageing population
- Relevant key programmes and funding agencies
- Most important players and networks in the field
- Strengths and weaknesses in the regions
- International S&I collaborations in digital Health between EU & strategic partners
- Good practices and outlook for further international collaboration

The two last elements present an international collaboration aspect, and as such to make it more convenient for the reader, are placed separately from the country reports, in *Chapter 0*





International S&I collaborations in digital Health between EU & strategic partners. There is no separate section here for EU, as the collaboration with EU is found in the sections of the Strategic Partner Countries.

Out of the plenty of resources, data has been retrieved according not only to its actuality but also and most importantly because of its validity over time and availability at the time of the search. Therefore, even though data might stem from early days, it does not dispense on its validity nor its corroborative power to underline the statements at hand¹. Following the desk research, preliminary drafts of the landscape per country/ region were made.

Preparation for the interviews

In parallel, **preparation for the planned interviews took place**. Interviews (10 in the EU and 5 in each of the strategic partner countries) were going to be conducted in order to complement the desk research and obtain qualitative information and feedback from relevant funding authorities, R&I stakeholders and other key actors. The preparation included the selection of interviewees based on certain modalities and preparation of support materials.

• Modalities and selection of the interviewees:

The interviews were planned to be conducted with key stakeholders or "super-informants", who have participated in international R&I collaborations in the field of digital health, have an extensive knowledge on the national context (strategy, technology, market...) related to digital health, or who are directly involved in policy design at the respective funding agencies or are key R&I players in the field of digital health. The interviewees were selected in two different manners. Firstly, some interviewees were directly selected by the IDIH consortium based on personal connections and due to their knowledge on the subject and as such relevance to the aim of the study. Secondly, other interviewees were selected based on recommendations given by the persons interviewed in the first round, following a snowball technique sampling. To avoid bias and ensure external validity of the interview analysis, the IDIH consortium tried to select people and structures bringing different visions. In particular, it was important to be able to compare views by triangulation, in order to have a correct interpretation.

• Preparation of the interview guidelines and consent forms:

Two "uniform" interview guidelines were developed: one for the interviewees from the strategic partner countries and another one for interviewees from the EU – however the general outline is the same for both to **ensure that the information collected is as homogenous as possible**. Both interview guidelines consisted of twelve questions respectively and addressed questions that are related to the key sections and elements of the report, e.g. national priorities for digital health, main challenges and trends related to digital health and active and healthy aging in the respective countries, international

¹ <u>Some of the resources related to future policies are evolving during the time of drafting this report e.g. the transition of governments in the targeted countries or the funding programmes e.g. Horizon Europe pending financial ratification. The same goes for some statistical data with census reports expected in 2021.</u>





cooperation between EU and the strategic partner countries within this field, and so on. The Guidelines for the EU interviews can be found in *Annex 11.1.* and Guidelines for the interviews in Strategic Partner countries can be found in *Annex 11.2.* A key principle in the development of an interview guideline was the avoidance of 'interviewer bias', such as reflexivity-interviewee, which is the tendency to give what the interviewer wants to hear, or the tendency to exaggerate successes and minimize failures.

In addition, a process for sharing results and handling any personal data was put in place: an Information Sheet and an Informed Consent Form, in which the interviewees were informed about the purpose of the study, and modalities of participation, were prepared to be sent to the participants before the interviews, according to the General Data Protection Regulations (GDPR). The interviews are anonymous, as such names of the interviewees are not disclosed in this report.

Second step – Conducting interviews

In a second step, **37 interviews were conducted: ten interviews in the EU and five interviews per Strategic Partner Country** (except in the case of Canada, where 7 digital health stakeholders were consulted). The IDIH consortium conducted interviews in Europe and in each of the targeted countries between October 2019 and May 2020.

The main strength of the interviews is their focus on the research questions – they enabled interviewees to provide insights, and personal views not reflected in the literature.

The interviews were conducted in a semi-structured and in-depth manner. The interviews more so resembled a guided conversation rather than structured queries, for the following two reasons. Firstly, it allowed the consortium to establish trust and create a friendly atmosphere with the interviewees. Secondly, it allowed the interview to be fluid rather than rigid, and to better incorporate the line of reflection with the interviewee's own personal experience. The time of the interviews ranged from **30 to 90 minutes**.

While the guideline and the questions remained identical for all interviewees, they still had the chance to give most insight and contribution in the field of their expertise:

- As, such, the semi-structured interviews directed towards key actors who have extensive knowledge on the national context (strategy, technology, market...) related to digital health aimed to uncover the context, the actors, and the motivation in the development of digital health in the EU and the Strategic Partner countries.
- The semi-structured interviews directed towards key actors who are directly employed by funding agencies aimed to examine what the main R&I programmes are, who the actors implementing the programmes are, and how they were implemented.
- The semi-structured interviews directed towards key actors who have participated in international R&I collaborations in the field of digital health aimed to investigate the existing and ongoing international R&I collaborations, to identify success stories, best practices and lesson learnt, and to understand the motivation for further collaborations.

While the desk research enabled to gain an insight to the digital health landscape through facts, data and academic papers, the interviews complemented the desk research in a qualitative way – they enabled to gather not only facts, but also rich information about the attitudes, opinions and experience





of authorities, funding agencies and other R&I stakeholders involved in a digital health in national and international context. As such they provide a perspective from a different angle and give a "human touch" to better understand the situation in the different countries, which is very relevant for the topic of healthy ageing. Furthermore, and importantly, through these qualitative exchanges, the pertinence of the information gathered from the literature review could be validated in a meaningful framing addressing the needs of the current report.

Third step – Analysis and integration of the interviews in the report

The analysis of the inputs from the interviews followed an **analysis and synthesis process**. Minutes of the interviews were typed in a word file. This allowed to keep Verbatim for fuelling the report. A synthesis for each of the interview was made, which allowed to identify the key points and main insights. An Excel File was built, with one sheet per country, to analyse in a transversal way convergence, divergence and main patterns per questions.

The findings from the desk research and the interviews have been summarised in the following EU and Strategic Partner Country sub-sections. The interviews provide in-depth information on some aspects of the deliverable, and in particular: (i) confirm the main trends identified through desk research regarding digital health in national context (deductive analysis); and (ii) identify the pattern to setup a conceptual framework regarding digital health in international context (inductive analysis).

Since information was obtained both, through desk research and interviews, it was then **cross-checked in order to ensure coherence and accuracy of information.** As such, one coherent text was created based on both type of inputs to avoid repetition, due to which at times it cannot be distinguished what exactly was derived from the interviews and what from desk research. Nevertheless, to make the contribution and the personal views of the interviewees more visible, quotations and sections in which the interviewees are paraphrased were added to the report.

Quotations from the interviews are highlighted with a specific sign and blue coloured box, as in the following example:



"xyz"... -Expert in Digital Health from China

In other places, the interviewees were paraphrased in order to summarise their views. In such cases the following sign and box is used in the reports to signal that this is derived from the interviews:



As the interviews are anonymous, only the stakeholder type and the country of the interviewee is indicated in the report.





Fourth step – Supplementary analysis: main challenges outlined, SWOT analysis, lessons learnt defined, additional qualitative data gathered from experts

- At a fourth step, the main challenges faced through the digital transformation in health and those specific to AHA were identified in each country report (boxes in purple). The findings of D1.1. especially those elements relating to key driving enablers and the challenges in channelling AHA solutions into policy design and future implementation have been taken up and integrated to verify these assumptions against expert response and literature reflections.
- a **SWOT analysis** for each targeted country has been drawn to highlight the respective strengths and weaknesses and how they could translate into possible threats to avert and potential opportunities to snatch for sustainable international cooperation in the AHA field.
- As a complementary source of qualitative data to the interviews, Experts within the IDIH Digital Health Transformation Forum, as well as several external experts² from the EU and Strategic Partner countries were asked to provide statements on the current state of Digital health and active and healthy ageing in their countries. These are marked in the reports with blue boxes, as those of the rest of the interviewees, as indicated above.

Fifth step – Conclusions

Finally, conclusions were drawn based on the content of the entire digital health landscape in the EU and in the Strategic Partner Countries report.

² The IDIH project has organised a webinar, in collaboration with the SENET project (EU-China health collaboration), on « Artificial Intelligence applied to Health » on December 3rd, 2020. Expert speakers and participants have provided statements on their view on « How digital technology (artificial intelligence and others) can support specifically active and healthy aging » and what they « consider to be the main challenges related to digital health and active and whether this can be seen as a barrier or an opportunity to international collaboration ».





3 Digital health and AHA: Panorama and priorities in the EU

According to the 2018 Ageing Report³, the demographic old-age dependency ratio (people aged 65 and above relative to those aged 15 to 64) in the EU is projected to increase in the coming decades from 29.6% in 2016 to 51.2% in 2070. One out of three Europeans will be over 65 by 2060. Moreover, while in 2016 the largest cohort for both males and females was 45-49 years old, in 2070 the largest cohort will be 70-74 years old for women and 50-54 years old for men.

The projected changes in the population structure reflect assumptions on life expectancy and other influences like fertility rates and migration flows. In the EU, life expectancy at birth for males is expected to increase by 7.8 years over the projection period, from 78.3 in 2016 to 86.1 in 2070. For females, life expectancy at birth is projected to increase by 6.6 years, from 83.7 in 2016 to 90.3 in 2070 implying a convergence of life expectancy between males and females.



EU28 - Population by age groups and sex

Figure 2: Population by age group and gender, 2016-70 (thousands)⁴

Europe's health and care systems face serious challenges. These are ageing, multiple chronic conditions or illnesses, health workforce shortages, and the rising burden of preventable non-communicable diseases caused by risk factors such as smoking, alcohol, and obesity, and other diseases including neuro-degenerative and rare diseases. Furthermore, the threat from infectious diseases due to increased resistance to antibiotics and new or re-emerging pathogens is growing.

⁴ https://ec.europa.eu/info/sites/info/files/economy-finance/ip065 en.pdf



³ https://ec.europa.eu/info/sites/info/files/economy-finance/ip079 en.pdf

Infectious diseases rank among the top ten risks over the next 10 years according to the World economic forum long term risk outlook 2020^5 .

Public spending on health and long-term care is steadily rising in the EU Member States and is expected to continue to do so.⁶ In the EU, between 2010 and 2060, total government spending on pensions, healthcare, long-term care, unemployment benefits and education will increase by almost 20% of the Gross Domestic Product (GDP), while expenditures for long-term care will double. Therefore, improved health and care at less cost not only in digital health, but also in digital health will contribute to resolve this dilemma. Then, Health4.0 in analogy to Industry4.0 would not only mean less cost and better quality but also a possible solution to the demographic change leading to decreasing contributions against increasing costs, says a former EC officer and senior business development manager.

Without the consideration and evaluation of health data, an increase in both process and performance quality as well as in organisational and economic efficiency is intangible. Thus, according to a seasoned researcher and entrepreneur from Germany, there is and urgently need to agree on a definition of regulation mechanisms and an ethical framework without slowdown innovative processes. Furthermore, there shall be better mechanisms for data protection and simultaneously sharing of patient data.

3.1 Digital health R&I priorities

An older population means more efforts to maintain a healthy, active and independent life. It is a challenge shared by all European countries, but also an opportunity for Europe to be a global leader and provide innovative solutions.

As digital health equipment and processes have the potential to contribute to higher quality therapeutic decision-making and treatment as well as to an increase in the process and performance quality of health services, the expert panel on an effective way of investing in health highlighted the central importance of digitalisation in the healthcare sector in its recommendations to the European parliament⁷.

In line with the Commission's Digital Single Market (DSM) strategy and after analysing the results of an Open Public Consultation, the EC published a Staff Working Document and a *"Communication on Digital Transformation of Health and Care in the Digital Single Market"*, empowering citizens and building a healthier society. These policy documents give direction to EU activities in this field for the coming years.⁸

⁸ <u>https://ec.europa.eu/digital-single-market/en/policies/ehealth</u>





⁵ WEF Global Risk Report 2020.pdf (weforum.org)

⁶ Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability – Country Documents 2019 Update [European Commission (europa.eu)

⁷https://ec.europa.eu/health/sites/health/files/expert_panel/docs/022_digitaltransformation_en.pdf

The "Communication on Digital Transformation of Health and Care in the Digital Single Market" identifies **three priorities** that should be implemented through R&I:

- 1. Citizen's secure access to and sharing of health data, also across borders;
- 2. Personalised medicine through shared European data infrastructure;
- 3. Digital tools for citizen empowerment and person-centred care.

Other areas of law or policy initiatives are directly relevant for the development of a DSM for health and care. They include the protection of personal data, interoperability and R&I funding.

The provision and use of digital health data are enormously important for research and science, particularly in the medical and nursing fields. Research on health data can bring targeted and personalised interventions, enhance prevention and helps to better understand and improve the functioning and efficiency of complex health systems.

Sharing of digital health data leads to improved and faster availability of medical information while digitalisation supports progressive laboratory and diagnostic equipment. Especially patient documentation or invoicing electronic support systems are routinely used today and there are promising applications in the field of telemedicine or telemonitoring.

The Commission Staff Working Document *"Digital transformation of health and care in the Digital Single Market"*⁹ describes the digital health R&I priorities in a national and international context.

Priority #1. Citizen`s Secure Access to Electronic Health Records (EHRs) and the Possibility to Share Health Data across Borders

Citizens requiring medical care when traveling or moving residence to another EU Member State are often confronted with the lack of access to their own medical records or medication. Access is particularly crucial when citizens seek emergency treatment while travelling outside their Member State of origin or residence or when they might be obliged to repeat procedures because they cannot access or re-use information from procedures completed recently in another healthcare institution.

A recent report adopted by the eHealth Network¹⁰ provides a snapshot of the current state of play of patient access to their EHRs in the EU:

- Nine countries have implemented systems at a national level providing patients with online access to their eHealth data for some time now. What patients can access can be quite narrow e.g. health information only (Hungary), patient summary only (Finland).
- Seven countries stated that they had national level EHR projects that included patient access to EHR information in development.

¹⁰ EUR-Lex - 52018SC0126 - EN - EUR-Lex (europa.eu), COM, 2018 -233 final





⁹ <u>https://ec.europa.eu/digital-single-market/en/news/staff-working-document-enabling-digital-transformation-health-andcare-digital-single-market</u>



• Ten countries stated that they provide access to patients to their eHealth data through multiple regional, local or speciality systems. Of this group, nine countries described current projects to develop a national system with patient access functionality, and the Netherlands are preparing guidelines for the development of regional systems that provide patients access to EHR data.

The three countries that selected "no EHR systems" (Cyprus, Czech Republic, Ireland) are planning to provide patient access to eHealth data "within two years", "within four years", and "in five years or more" respectively. Malta has an online portal for doctors and their patients that fulfils much of the functions of a national EHR in terms of patient access to EHR information but is also planning a national project to begin within two to four years.

Despite over a decade of EC recommendations and voluntary cooperation in the definition of EHR standards, the market has so far not delivered EHR solutions that are interoperable across borders, mainly due to the prevalence of EHR systems based on closed proprietary solutions. It clearly undermines the full realisation of a DSM for digital health and care solutions and disadvantages European companies, notably small and medium enterprises (SMEs) that are unable to compete with the established commercial vendors of closed proprietary EHR systems.

Priority #2. Personalised medicine through shared European data infrastructure

At EU level, there has been a wide recognition that the use of health data to advance research and develop personalised medicine has the potential to offer significant benefits for patients and healthcare systems¹¹. Personalised medicine relates to the broader concept of patient-centred care, which takes into account that, in general, healthcare systems need to better respond to patient needs.

Over the past years, personalised medicine has gradually gained recognition as a useful tool for healthcare organisations across different disease areas. Physicians increasingly welcome therapies supported by data analytics which have the potential to replace trial-and-error with precision diagnosis and treatment, benefiting both the provider and recipient of health and care services. **An estimated 70% of citizens in the EU would be ready to share their personal health and wellbeing data (medical and care data, lifestyle, physical activity, nutrition, etc.) to support scientific research or improve treatment and early diagnosis of disease¹². However, for the time being, there is no secure and commonly accepted infrastructure at EU level to enable federated access to health data that can support personalised medicine across the EU.**

Over the past decade the volume of data generated from medical research and healthcare has grown exceptionally fast. The annual data generation was estimated to a 4,300% annual growth between 2012 and 2020¹³ projected to as much as 2,314 exabytes of new data generated globally

 ¹² <u>https://ec.europa.eu/digital-single-market/en/news/attitudes-towards-impact-digitisation-and-automation-daily-life</u>
 ¹³ <u>https://e-health-com.de/fileadmin/user_upload/dateien/Downloads/redesigning_health-eu-for2020-ehtf-report2012_01.pdf</u>





¹¹ <u>https://www.rand.org/pubs/research_reports/RR1972.html</u>

in 2020¹⁴ Big data in health encompasses high-volumes, high-diversity biological, clinical, environmental, and lifestyle information collected from single individuals to large cohorts, in relation to their health and wellness status, at one or several time points. The amount of data produced by sequencing, mapping, and analysing genomes is considerable. Each human genome has six billion 'letters' and when sequenced generates approximately 100 gigabytes of data.

The scientific and research community is increasingly engaged in a debate about the merits and advantages of creating a sustainable and effective ecosystem that brings together cross-border access to data-sets, computing capacity to analyse and process that data, knowledge and scientific expertise needed to accelerate the translation of big data into real outcomes for citizens and healthcare systems across the EU. While substantial technological advancements have been achieved in automatization and miniaturisation, there is still room for more investment in research e.g. Al for health and big data sharing¹⁵. **The EU has invested over EUR 2.6 billion in personalised medicine R&I in Horizon 2020 (H2020) and its predecessor Framework Programme 7¹⁶.**

Several Member States agreed in March 2017¹⁷ to work together with the EC to support the next generation of computing and data infrastructures, within the framework of European collaborative projects. The plan is to establish the European High-Performance Computing Joint Undertaking for acquiring and deploying an integrated world-class high-performance computing infrastructure capable of at least 1,018 calculations per second (so-called exascale computers). This will be available across the EU for scientific communities, industry and the public sector, no matter where the users are located.

Priority #3. Digital Tools for Citizen Empowerment and Person-Centred Care

The "Health at a Glance: Europe 2018" report¹⁸ revealed that across the EU deaths from major noncommunicable diseases translate into around 3.4 million potentially productive life years lost, or EUR 115 billion in potential economic loss each year for the EU economies.

Moreover, **large health inequalities persist in EU Member States between people with higher levels of education and income and the more disadvantaged**, largely due to different exposure to health risks, but also to disparities in health behaviour and access to high quality care. The grey digital gap (i.e., the lower proclivity of older adults to use personal computers or to communicate via the Internet), however, is deep; only approximately 48% of EU-28 population aged 65-74 according to community survey on ICT in 2017 compared to 45% a year before use the Internet the last 3 months or at least once per week respectively¹⁹. Low internet usage is due in part to lower education levels of older European citizens in these countries. The "Blueprint" initiative, which aims

¹⁹ https://ec.europa.eu/eurostat/web/products-statistical-books/-/KS-02-19-681





¹⁴<u>Healthcare data volume globally 2020 forecast | Statista: www.statista.com/statistics/1037970/global-healthcare-data-volume</u>

¹⁵ <u>https://genomemedicine.biomedcentral.com/articles/10.1186/s13073-016-0323-y</u>

¹⁶ https://www.futuremedicine.com/doi/full/10.2217/pme-2017-0003

¹⁷ https://ec.europa.eu/commission/presscorner/detail/en/IP 18 64

¹⁸ <u>https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe-2018_health_glance_eur-2018_</u>en

to implement prevention programmes among European older adults, will, therefore, take significant time to implement among elderly EU citizens.

Prevention of disease and promotion of healthy living are recognised as essential principles for reducing the health burden related to both communicable and non-communicable diseases, requiring cooperation across borders and coordination within the EU. Importantly, prevention comprises promotion of healthy lifestyles (individual lifestyle choices such as not smoking, eating healthy, avoiding alcohol and exercising more) underpinned by policy choices that help create school, work and community environments conducive to leading healthy lifestyles.

The need to shift the focus from sickness and cure to promoting health and disease prevention, including combating health inequalities, is well recognised at national and EU level. It has been highlighted in the Joint Report on Health Care and Long-Term Care Systems and Fiscal Sustainability²⁰, as one of the recommended policy options to enhance the fiscal sustainability and cost-effectiveness of health systems.

To realise the potential of digital solutions to facilitate access to healthcare in a fair and inclusive way, the eHealth Stakeholder Group²¹ has made a number of recommendations regarding "Health inequalities and eHealth"²² including: improving access to eHealth and involving all stakeholders; accommodating diverse needs; improving digital health literacy; integrating eHealth into the overall health and social care system policy; evaluating the impact of eHealth solutions and building up an evidence base; giving specific consideration to empowering patients with disabilities or specific diseases; and considering financial subsidies for the purchase of eHealth equipment / ICT access.



An expert in the field of Active and Healthy Ageing from Italy formulated his views on digitization as follows: "More focused and longer-term policies should be launched, capable of intervening in a structural way on the public health system, thus accompanying and supporting - beyond the duration of governments - the virtuous processes related to digitization in the sector: dematerialization of paper

processes, innovation of organizations, changing of operating procedures, and introduction of new professional skills integrating ICT. These aspects are now animating the debate around public administrations, and currently concern health services". Then, digital health solutions for AHA focusing on efficient prevention (primary or secondary) processes enhanced by digital technologies with a strong emphasis on providing low-trained workforce with temporary skills and capabilities for screening or disease management and prevention.

A showcase project that demonstrates an approach to the aforementioned identified priorities is ACTIVAGE, a European Multi Centric Large Scale Pilot on Smart Living Environments. ACTIVAGE's main objective is to build the first European Internet of Things (IoT) ecosystem across nine deployment sites in seven European countries, reusing and scaling up underlying open and proprietary IoT platforms,

²² http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=5170





²⁰ <u>https://ec.europa.eu/info/publications/joint-report-health-care-and-long-term-care-systems-and-fiscal-sustainability-country-documents-2019-update_en</u>

²¹ <u>https://ec.europa.eu/digital-single-market/en/ehealth-experts</u>

technologies and standards, and integrating new interfaces needed to provide interoperability across these heterogeneous platforms, that will enable the deployment and operation at large scale of AHA IoT based solutions and services, supporting and extending the independent living of older adults in their living environments, and responding to real needs of caregivers, service providers and public authorities.²³



Figure 3: Infographic on transformation of eHealth care in the DSM²⁴



Furthermore, an expert in the field of IA from the EU was consulted on digital health trends in the EU, who suggest that infectious disease, genomics and AI are being combined to explore how richer information on pathogens in hospital and the community can be provided, in order to aid clinical decision making (e.g. choosing the

right antibiotic to prescribe), identify outbreaks and new strains of concern. Modelling approaches to forecast the spread of resistance mechanisms and model the impact of different interventions are also being explored. Regarding the question on how digital technology (artificial intelligence and others) can support specifically active and healthy aging, she suggested that personalised risk assessments and health recommendations can fill the gap where focussed attention from a General Practitioner may not be available or practical in monitoring and recommending diet and exercise changes. An IoT approach to monitoring for signs of developing conditions such as Parkinson's and Alzheimer's also offers promising approaches to more proactive early treatment by regularly monitoring patients and capturing changes in their performance of daily activities that would be hard for a clinician to observe.

²⁴https://ec.europa.eu/digital-single-market/en/news/infographic-digital-health-and-care-eu





²³ <u>https://www.activageproject.eu/</u>

3.2 Main challenges related to digital health:

The main challenges are related to the following issues, as explained in this section:

- Exchange of data is limited, secure and interoperable ICT infrastructures and data networks are needed
- EU is not a fully functioning single market for digital health and care solutions
- Appropriate regulatory framework and data protection is needed

It is becoming increasingly clear that **exchange of data can contribute to raising the quality of care**. Yet large parts of the actually existing digital infrastructure in the healthcare system is not, or is only to a limited extend, suitable for data exchange outside of a specific organisation.

This affects in particular medical software used by doctors working in general practice, healthcare professionals in the outpatient sector and also many hospital information systems. Because health data is predominantly generated in out-patient care facilities and in hospitals, the overall goals of the health system is to focus on the numerous individual "data generators" to bring them up to date with a new generation of or updated digital infrastructure to establish an interoperable eco-system for digital health in Europe.²⁵

Despite the considerable potential of digital technology to contribute to better health and care outcomes and the cross-border dimension of digital health products and services, the EU is not a fully functioning single market for digital health and care solutions.

Barriers to access can be found at the level of individuals, health service providers and the health system. Access is also affected by public policy beyond the health system – especially fiscal policies, but also social protection, education, employment, transport and regional development policy. The ability to disaggregate data at sub-national level and by sub-groups in the population is essential. Policy responses need to reflect the multi-dimensional nature of access problems, the importance of intersectional action and the specificities of national and regional contexts. Indeed, adoption schemes that are also very specific as most of the validation processes, reimbursement model, collaboration between players schemes can hardly be replicated in different countries within Europe, admitted a French EU program manager. This concurs also with a globally agreed consensus on standardisation as one of the major bottlenecks beside data protection and interoperability.

Digital technologies can be employed in mobile health (mHealth) surveillance, prevention, and intervention efforts that will become more affordable and easier to use. These solutions can help citizens and professionals to address preventable risk factors associated with chronic diseases. They can also support AHA, and facilitate early detection of symptoms and timely treatment, thus reducing the need for more burdensome treatments later on. However, the citizens' ability to access their personal health data remains differentiated across and within the Member States. It ranges from non-existent in some, partial in others, to full access in certain Member States. Often, the personal

²⁵ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co922_en.pdf





data concerning the health of a given citizen is scattered across different local and national data repositories.

Over the last years, **there has been a remarkable increase in the amount of health data generated by new devices and technologies.** At the same time, improvements in computing capacity and performance and the emergence of other digital technologies allow large data storage and advanced data analytics. Still access to varied datasets located across different Member States remains difficult or inexistent, because data is subject to different taxonomies and standards and therefore scientific research invariably builds on relatively limited population regiments.

Without cross border secure access to data sets, a shared computing and storage capacity and an appropriate regulatory framework that allows for secure access to data-sets across borders, it remains difficult for healthcare organisations to optimise their services and for researchers to reach the scientific achievements that are needed to support early disease diagnosis, coordinate response to epidemics and accelerate therapy development across the EU.

Free transmission of health data across borders need secure ICT infrastructures and data networks. The European Union Agency for Network and Information Security (ENISA) has acknowledged the significance of digital health networks as critical information infrastructures and has developed actions focusing on the security challenges and risks faced by the health sector in the Member States. Healthcare organisations need to increase security measures to protect their infrastructure and data networks.

In addition to the GDPR, which introduces security requirements applicable also to healthcare organisations, the EC is working to assist Member States and healthcare organisations to meet the requirements set out in the Directive on Security of Network and Information Systems.²⁶

Standards and reference schemes for age-friendly environments are needed, integrating a multidisciplinary and bottom-up approach at policy level that may ensure real accessibility and fruition of infrastructures and buildings based on health and wellbeing. This may be possible only through a real synergy between the industrial, health and ICT communities, as well as final users, covering the whole value chain, from the conception to the delivery of facilities.



Furthermore, European interviewees referred to the fact that there are a lot of companies active in the field of digital health, but their commercial structure is still very weak. Many eHealth companies are start-ups but access in the public market is challenging. Furthermore, criticalities may arise from procurement rules especially as the issue of colutions distribution and liabilities.

while addressing the issue of solutions distribution and liabilities.

²⁶ <u>https://ec.europa.eu/digital-single-market/en/news/staff-working-document-enabling-digital-transformation-health-and-care-digital-single-market</u>





3.3 Specific challenges for the ageing population

On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the three main challenges related to digital health are:

- 1. Exponential growth of healthcare burden
- 2. Fragmented Reimbursement models in the EU
- 3. Data protection and acceptance by end-users

With populations ageing across Europe, pensions, healthcare and long-term care systems risk becoming financially unsustainable, as a shrinking labour force may no longer be able to provide for a growing number of older people. Active ageing is the EC's policy directed towards **"helping people stay in charge of their own lives for as long as possible as they age and, where possible, to contribute to the economy and society"**. Policymakers hope to address these challenges by turning them into opportunities, with a focus on extending working lives and providing older peoples' access to adequate social protection and, where necessary, supplementary pensions.

Living longer does not necessarily mean living a healthier, more active and independent life — this is all the more important given the growing number of older and very old people in the EU. The European innovation partnership on AHA was created in 2011 and aims to foster innovation that will promote active ageing and raise healthy life expectancy. 27

Furthermore, as an increasing number of older people reach an age where declining physical and mental health makes them dependent on help from others, there are considerable implications for long-term care expenditure. **The European pillar of social rights stresses the right to affordable long-term care services of good quality**, in particular home-based care and community-based services. It also underlines that everyone in old age should have a pension that is commensurate with their contributions and the right to resources that ensure living in dignity.

The economic old age dependency ratio (inactive 65+ year olds vs. employed aged 20-64) is projected to rise significantly from 43.1% in 2016 to 68.5% in 2070 in the EU. This implies that the EU would go from having 3.3 working-age people for every person aged over 65 years to only two working-age persons.²⁸ Consequently, in the future fewer people will contribute to finance public healthcare, while a growing share of older people may require additional healthcare goods and services. Longer working lives accompanied by a healthier working population can mitigate the impact of ageing.

The overwhelming majority of older people continue to live in private households (either alone, with their spouse or with other persons)²⁹. In 2018, 33.9% of households where single person households in Europe.³⁰ Nevertheless, some older people move into institutional households, such as retirement or nursing homes. This may occur out of choice (e.g. not wishing to live alone) or because it is no longer

³⁰ https://ec.europa.eu/eurostat/statistics-explained/index.php/Household composition statistics





²⁷ <u>https://ec.europa.eu/eip/ageing/home_en</u>

²⁸ <u>https://ec.europa.eu/info/sites/info/files/economy-finance/ip079_en.pdf</u>

²⁹ <u>https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Ageing_Europe_-</u>

looking at the lives of older people in the EU

possible for older people to carry on living at home (e.g. due to complex long-term care needs). The very old are more likely to be frail and therefore to need services such as those provided within institutional households as family and patient face high barriers on the use of digital technology at home: In the words of one of the experts:



"User interfaces are a major barrier to enabling digital technologies for patients, families and clinicians to empower aging gracefully at home based on support services" – Digital Health expert from the EU

While most healthcare costs in the EU are covered by social protection systems, long-term social care is usually treated in a different manner. Indeed, it is rare that such services are covered to the same extent as healthcare. This means that the responsibility for financing institutional care often resides with the older person needing such care (or with their family).

As set out in the World Health Organisation preamble to its constitution (WHO)³¹, **health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity**. While Europeans are generally living longer, many face multiple health conditions or mobility problems in their later years.

Relatively high rates of chronic illness, mental health conditions, disability and frailty may be reduced if structural, economic and social drivers of poor health are tackled at an early stage e.g. through healthcare services investing more in education and screening services, or individuals making changes to their lifestyles.

Aging people need more frequent visits to consult both general and surgical practitioners. In 2017, 86.5% of people aged 65-74 years and 91.8% of people aged 75 years or more had consulted a general practitioner during the 12 months. In a similar manner, older people also made a greater use of prescribed medicines. In 2014, 87.1% of people aged 75 years or more reported that they made use of prescribed medicines during the two weeks. The use of prescribed medicines by older people across the EU Member States ranged from a low of 68.0% in Romania up to a high of 96.3% in the Czech Republic³².

Chronic diseases can restrict the independence of older people and may require considerable health and social resources for care and/or treatment. According to **Health in the European Union – facts and figures** Eurostat online publication providing recent statistics on health, some of the most common chronic diseases in people aged 75 were high blood pressure, arthrosis and back problems.³³

explained/index.php?title=Health in the European Union %E2%80%93 facts and figures





³¹ <u>https://www.who.int/about/who-we-are/constitution</u>

³²<u>https://ec.europa.eu/eurostat/statistics-explained/index.php/Medicine_use_statistics [It is worth noting that the Data presented in this article refer to year 2014. A third wave of the European health interview survey (the source of these data) will be conducted in 2019. Planned article update: December 2021]</u>

³³ https://ec.europa.eu/eurostat/statistics-

That raises the question what kind of health organisations and care should be developed to preserve the quality of life of an ageing population and sustain the European healthcare systems in the long run.³⁴ Europe needs to find solutions for sufficient care to look after the aging population. Maintaining a healthy ageing population has the potential to lower demands for healthcare services. According to a European funds manager, "overall funding opportunities, entrepreneurial skills, disparities in health and care models make it difficult to replicate a success - even with cash - and the overall risk-avoidance regarding new payment models, service implementations ask for projects or pilots with clear milestones towards economic viability if they deliver their promise, need clearly phased projects, clear outcomes and relevant money to ensure the company's viability when they deliver."

3.4 Relevant key programmes and funding agencies

In the Communication *eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century*³⁵, the EC announced the areas where R&I would be supported for the period 2014-2020, under the societal challenge 1 **"Health, demographic change and wellbeing" of H2020**:

- An ICT, computational science and engineering framework for digital, personalised, and predictive medicine, including advanced modelling and simulation;
- Innovative instruments, tools and methods for unlocking the value of data and for advanced analytics, diagnostics and decision making;
- New digital media, web and mobile technologies and applications, as well as digital instruments that integrate healthcare and social care systems and support health promotion and prevention;
- eHealth systems and services with strong user involvement, focusing on interoperability and the integration of emerging patient-centric technologies for cost-effective healthcare.

The multiannual financial framework (MFF) sets the EU's long-term budget planning. Recent MFFs usually covered seven years. The proposals for the EU's next MFF for the period 2021-2027 is under negotiation and includes a number of funding instruments which could support targeted investment in the area of eHealth.

Financial instruments under the MFF can be divided into two main categories:

1. Shared management funds: Instruments whose management is shared between the EU and the Member States. In practice, Member States assume a large part of the responsibility for managing and distributing these funds via national implementing programmes, which are agreed and supervised by the EC. The bulk of EU funds fall under this category.

2. Direct/indirect management funds: Instruments which are managed centrally and directly/indirectly by the EC, e.g. for research.

³⁵ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52012DC0736:EN:NOT





³⁴ <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5946166/pdf/fmed-05-00123.pdf</u>

Main Financial Instrument or Programme	Relevant Sub- Instrumental Programme	Types of Investments / Activities under the Programme
Shared management funds under the new MFF are managed by the Member States,	European Regional Development Fund (ERDF)	Investments in: Infrastructure, access to services, productive investments in SMEs; equipment; software and intangible assets; information; communication; studies; networking; cooperation; exchange of experience and activities involving clusters; technical assistance
through their managing authorities.	European Social Fund Plus (ESF+)	Section for the European Social Fund Plus Section for Health: Analytical activities; policy implementation; capacity building; communication and dissemination activities
	The Digital Europe Programme (DEP)	High performance computingArtificial Intelligence (AI)Cybersecurity and trustAdvanced digital skillsDeployment, best use of digital capacity andinteroperability
Direct / Indirect Management Funds	Connecting Europe Facility (CEF)	Digital connectivity infrastructure
	The Invest EU Programme (Invest EU)	Sustainable infrastructure Small business Research, innovation and digitisation Social investment and skills
	The Reform Support Programme	Financial and technical support to implement reforms
	The Horizon Europe Programme (HE)	Open science Global challenges in industrial competitiveness Open innovation

Table 1: Overview of management funds r	elevant for eHealth under the new MFF ³⁶
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On the national level, depending on the EU Country the Ministry of Health, the Ministry for Education or the Ministry of Economic Development as well as national "Aging Networks" or "Academic Institution Networks" might provide different key programmes and funding on R&I in AHA.

³⁶ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co922_en.pdf





3.5 Most important players and networks in the field

Several initiatives across Europe have promoted collaboration of a wide range of stakeholders in developing, testing and replicating innovative approaches to health and care services, in the field of disease prevention, integrated care and new ways for managing non-communicable diseases and comorbidities, often with the use of digital solutions such as telehealth and mHealth. The European Innovation Partnership on Active and Healthy Ageing (EIP on AHA)³⁷, the Active and Assisted Living Joint Programme (AAL)³⁸, the EIT Health³⁹, and the Joint Action CHRODIS⁴⁰ are such examples of transnational, inter-regional and inter-sectoral collaborations. These have brought to light good practices, produced tools and guidance and have been supporting mutual learning and knowledge exchange with the purpose of facilitating the deployment of innovative solutions for health and care⁴¹.

The EIP on AHA

The EIP on AHA is an initiative launched by the EC to foster innovation and digital transformation in the field of AHA. The EIP on AHA platform is a communication and information hub for all actors involved in AHA throughout Europe. It aims to encourage partner engagement, promotes news and events, meets and exchanges ideas with peers, and looks for potential partners for innovative projects. The EIP on AHA overall target is to increase the average healthy lifespan of EU citizens by two years by 2020.

The EIP on AHA has, as its foundations, two main pillars: Action Groups and Reference Sites. The Blueprint, Innovation to Market (I2M) and Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing (MAFEIP) are three further initiatives that feed the EIP on AHA:

- The Blueprint aims to innovate health and care in Europe. It is the follow-up of the former EIP on AHA Scaling Strategy. It reflects the policy vision of the EIP on AHA partners and is their channel for giving and receiving policy inputs. A "back-and-forth" mechanism operates between the EC and stakeholders (policy makers and other key opinion leaders) to evolve, update and implement the Blueprint.
- I2M targets the scale-up of digital health and care solutions in a cross-border context. This horizontal action is part of the EC strategy on digital transformation of health and care in the DSM.
- MAFEIP was initially developed in response to the EIP on AHA's specific monitoring needs. It
 is used as an impact assessment tool to support evidence-based decision-making process for
 all institutions and users in the health and care sector.

The AAL programme

The AAL programme funds projects in public-private partnerships in the field of ICT for AHA. The programme started in 2014 and is co-financed by the EC – under the H2020 umbrella – and 19 countries until 2020. The overall objective of AAL is to enhance the quality of life of older adults while

⁴¹ <u>https://ec.europa.eu/eip/ageing/repository_en</u>





³⁷ <u>https://ec.europa.eu/eip/ageing/home_en</u>

³⁸ www.aal-europe.eu

³⁹ https://www.eithealth.eu/

⁴⁰ http://chrodis.eu/

strengthening the industrial base in Europe through the use of ICT. The AAL projects aim at introducing their solution to the market within two to three years after the end of the project.

The EIT Health

The EIT Health is a consortium of over 140 partners from leading businesses, research centres and universities from across 15 EU countries. EIT Health was designated as a European Institute of Innovation and Technology (EIT) Innovation Community by the EIT Governing Board in 2014. The goal of EIT Health is to contribute to increasing the competitiveness of the European industry, improve the quality of life of Europe's citizens and to increase the sustainability of healthcare systems. The network is promoting innovations that enable European citizens to live longer and healthier lives.

EIT Health is doing so by connecting the relevant stakeholder and the right topics across European borders, so that innovation is evolving at the intersection of research, education and business. Adopting an investor approach, EIT Health will drive the integration of business, research and higher education, boost innovation, and be a catalyst for new solutions for Europe. The consortium aims to overcome the fragmentation of different healthcare systems in Europe and give companies easier access to markets across the EU. EIT Health has formed six Innovation Hubs across Europe, with Headquarters based in Munich.

The second EU Joint Action for addressing chronic diseases CHRODIS Plus

The second EU Joint Action for addressing chronic diseases CHRODIS Plus includes 42 partners from 18 EU countries plus Norway, Serbia and Iceland. Spain is the coordinator supported by Lithuania for the scientific coordination. The joint action runs for three years (September 2017- August 2020) and has a total budget of €6.8 million, of which €5 million come from the 3rd Health Programme. CHRODIS PLUS focuses on implementing and pilot testing the results of CHRODIS, notably:

- Transferring five good practices in health promotion (three on children's health, one on workplace health promotion and one on healthy ageing) to more EU countries;
- Field-testing the new care model for people with multi-morbidities in primary care and tertiary care hospitals in Lithuania, Italy and Spain; and
- Field-testing the recommendations to improve the quality of care for people with chronic diseases in primary care and secondary care hospitals in Slovenia, Serbia, Croatia, Finland and Greece.

eHealth Hub

eHealth Hub is an EU-funded initiative that is cross-border and exclusively focused on the digital health vertical. eHealth Hub's goal is to provide high-quality, vertically-focused and business-oriented services tailored to the needs of European eHealth SMEs and stakeholders, and to secure their continuation after the project end via a sustainable support structure.⁴²

DigitalHealthEurope

DigitalHealthEurope provides comprehensive support to the Digital Health and Care Innovation initiative in the context of the DSM Strategy. The project's approach involves a number of actions that

⁴² https://www.ehealth-hub.eu/





will boost innovation and advance the DSM priorities for the digital transformation of health and care, as outlined in the EC's 2018 communication on the topic.⁴³

Many companies and organisations such as Phillips, IBM-Europe, SAP, Engineering Ingegneria S.P.A, Samsung Electronics, Fraunhofer, ATC-Greece, ATOS Origin, CNR, CERTH, Novartis, GlaxoSmithKline and many SMEs are also involved in specific areas of IoT and home-based care.⁴⁴

3.6 Strengths and weaknesses in the EU

The 28 Member States of the EU have a clear mandate to ensure equitable access to high-quality health services for everyone living in their countries. This does not always mean making everything available to everyone. Rather, it means addressing an unmet need for healthcare by ensuring that the resources required to deliver relevant, appropriate and cost-effective health services that are relevant to need.

Strengths	Weaknesses
 Strong individual research and innovation infrastructures Considerable industrial and public data sets Health support services and systems 	 Fragmented policies, reimbursement models Uneven internet access and usage and lower digital skills (senior adults and practitioner alike) very few investors, low willingness to risk capital to support innovations and disruptive business models
Opportunities	Threats
 Not yet saturated and growing market Digital push through health challenges Innovation leadership in future & emerging technologies 	 Complex market esp. for start-ups Ambiguous legal basis and regulation for digital health Disparity of research investments

The need for a new generation and regulation of data collection for effective, accessible, resilient and accountable health systems is well-known. Better monitoring to access problems in a timely manner, measure changes over time and across groups of people and enhancement of international comparability are the targets to be met.

⁴⁴ <u>https://www.research.ibm.com/haifa/dept/vst/HI-EUProjects.shtml</u>





⁴³ <u>https://digitalhealtheurope.eu/</u>

4 Digital health and AHA: Panorama and priorities in Canada

4.1 Digital health R&I priorities

There are a number of research and innovation funders in Canada, including those focused on healthrelated research, such as the **Canadian Institutes of Health Research (CIHR)**.

The R&I priorities in Digital Health set by CIHR in Canada are:

- Ensuring the adaptation of healthcare and services to an aging population (set by the Institute of Aging)
 - o supporting research that integrates appropriate and effective eHealth solutions
- Four priorities set by the Health Services and Policy Research (IHSPR)'s Strategic Plan, many of which include supporting research focused on advancing digital health innovations:
 - Accelerate the discovery of innovations that transform health care delivery systems to achieve the Quadruple Aim and improve health equity for all
 - Modernize the health care system with digital health solutions and data science
 - Integrate evidence into health services and policy decisions for improved health care system performance and outcomes
 - Strengthen capacity for solution-oriented research and evidence-informed health care system transformation

CIHR is Canada's federal funding agency for health research. In its most recent Strategic Plan (CIHR Strategic Plan 2021-2031

A Vision for a Healthier Future⁴⁵, Priority E: Integrate Evidence in Health Decisions, has the goal of ensuring research evidence will be integrated seamlessly with Canadian health policy and practice.

CIHR has a dedicated **Institute of Aging (IA)**, which focuses on supporting research to promote healthy aging and to address causes, prevention, screening, diagnosis, treatment, support systems, and palliation for a wide range of conditions associated with aging. Its goal is to improve the quality of life and health of older Canadians by understanding and addressing or preventing the consequences of a wide range of factors associated with aging.

⁴⁵ https://cihr-irsc.gc.ca/e/52331.html





CIHR's IA recently launched their refreshed strategic plan (2019-2021) <u>Living Longer, Living Better⁴⁶</u>. This strategic plan identifies a three-pronged approach for CIHR's IA research priorities. Under its *Strategic Direction 2: Solutions for the Complex Health Challenges of Older Populations*, IA has identified **Ensuring the adaptation of healthcare and services to an aging population** as a key priority, which includes **supporting research that integrates appropriate and effective eHealth solutions**.

Furthermore, CIHR has a dedicated Institute of **Health Services and Policy Research (IHSPR)**, whose mission is to **foster excellence and innovation in health services and policy research and to catalyze the application of research findings to policies**, practice and programmes that provide real-world benefit and enhance the provision of high-quality care for Canadians. IHSPR's vision is to position Canada as a global leader in optimizing the health and health outcomes in the population through the provision of evidence-informed healthcare services.

IHSPR's Strategic Plan, 2021-26 – Accelerate Health Care System Transformation through Research to Achieve the Quadruple Aim and Health Equity for All,⁴⁷ outlines four strategic priorities: Accelerate the discovery of innovations that transform health care delivery systems to achieve the Quadruple Aim and improve health equity for all, Modernize the health care system with digital health solutions and data science, Integrate evidence into health services and policy decisions for improved health care system performance and outcomes, and Strengthen capacity for solution-oriented research and evidence-informed health care system transformation.

4.2 Main challenges related to digital health

The digital health technology sector in Canada is expected to continue to grow rapidly in the coming years, driven by the nearly omnipresent access to the internet, the widespread adoption of mobile devices and increasing demand from patients and health care systems.⁴⁸

Another driver for the digital health sector is Canada's strength in artificial intelligence (AI). In 2017, Canada was home to the second largest tech sector outside Silicon Valley in the United States and solidified its position as a leader in the field of AI. A strong network of academic institutions, improving infrastructure through federal and provincial funding and availability of talent fueled the recent development of the AI industry in Canada. The increased number of research institutes and incubators has spawned many AI start-ups. However, despite being the sixth largest producer of top-cited scientific publications related to machine learning and representing 3.12% of world publication in AI, firms headquartered in Canada accounted for only 0.9% of all AI-related inventions from 2012 to 2014 (OECD, 2017c).

Despite the strong push towards digital health innovation, Canada's health care system faces persistent challenges in achieving efficient, coordinated, digital, patient-centred care.

devices/activities/announcements/notice-digital-health-technologies.html





⁴⁶ <u>http://www.cihr-irsc.gc.ca/e/51447.html</u>

⁴⁷ https://cihr-irsc.gc.ca/e/52481.html

 $^{^{48}\,}https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-services/medical-services/medical-services/drugs-health-products/medical-services/drugs-health-products/medical-services/drugs-health-products/medical-services/drugs-health-products/medical-services/drugs-health-products/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/medical-services/me$

On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the main challenges related to digital health in Canada relate to:

- 1. Transformation of the health system
- 2. Procurement system and regulation
- 3. Integration of digital health

Transformation of the health system

Many have acknowledged that a transformation of the health system is required to truly address the current needs of its citizens.⁴⁹ Canada's marketplace is small and with 13 individual health care systems in place, the marketplace is further divided making it challenging for small and medium sized enterprises to have their innovations commercialized in scale.

Procurement system and regulation

There is a risk-averse procurement culture prioritizes short-term focus on cost rather than broader considerations of value. In addition, the Digital health innovations are further challenged by a procurement system that is highly regulated, and reimbursement model not favorable, and impedes then commercialization.⁵⁰

Integration of digital health

The global analysis of potential cost-benefice of the of the digital health solutions has to be take into consideration, to improve the use of



"There are numerous cases where the validity and usefulness of digital health have been demonstrated but the overall efficiency and cost-benefit analysis of the digital health landscape remain to be demonstrated." – Digital Health expert from Canada

solutions. In order to do so, the involvement of the end-users at very early of the development of the solution is important. End-users could be the patient, but also healthcare and health service providers.

4.3 Specific challenges for aging populations

According to a 2012 report by the International Federation on Aging (IFA), there are **several challenges** to be addressed if Canadian seniors are to enjoy active and healthy aging and receive a quality end of life such as:

- aging in place (home and community care, staying at home, age friendly cities or communities, home care services, aging at home technology and housing);
- support to caregivers (informal careers, family careers, financial and psychological support);

⁵⁰ https://www.ic.gc.ca/eic/site/098.nsf/eng/00025.html





⁴⁹ <u>https://policybase.cma.ca/dbtw-wpd/PolicyPDF/PD10-05.PDF</u>

- supporting the aging workforce (pensions, retirement, workforce participation, older people's incomes);
- healthcare sustainability;
- ageism and discrimination (rights and responsibilities);
- keeping older people connected and active (falls prevention, mobility, health promotion, active aging, volunteering, lifelong learning, technology, intergenerational programmes, preventing social isolation); and,
- preventing elder abuse.

There are various conditions that impact health and quality of life for older adults. Neurodegenerative diseases causing dementia are the health conditions that have the most harmful impact on the quality of life of the individual, as well as that of their caregivers. Similarly, frailty is a driver of severe physical disability that increases the rate of institutionalization affecting quality of life. Multiple chronic conditions are also a common struggle for many older individuals, which need to be better understood, addressed and ultimately prevented. This challenge is exacerbated for new emerging aging populations, such as people living with HIV/ AIDS, cancer survivors, or those with an intellectual or neurodevelopmental disability, spinal cord injury, stroke or traumatic brain injury, require particular attention due to the multiple health challenges that these people face later in life.

The health and wellness of caregivers, in the context of an aging population, also needs to be considered. Some of the key challenges with late-life care and decisions include the frequent unpredictability of end-of-life in the context of multiple chronic conditions.⁵¹

4.4 Relevant key programmes and funding agencies

Canadian Institutes of Health Research (CIHR)

The Canadian Institutes of Health Research (CIHR) is composed of 13 Institutes, CIHR collaborates with partners and researchers to support the discoveries and innovations to improve the health of Canadians and strengthen Canada's health care system. The following is a selection of key CIHR initiatives that aim to improve the health of older adults:

• eHealth Innovations Initiative

CIHR's <u>eHealth Initiative⁵²</u> aims to develop, integrate, and evaluate eHealth innovations that will improve the cost-effectiveness of patient and population-centred care. The initiative facilitated partnerships between technology industries and health system players, researchers and end-users such as patients/families and clinicians to create innovative approaches to health care delivery that will increase Canada's competitive position in the health-related information communication technology (ICT) industry and improve outcomes and patient experience in priority areas of healthy aging at home and youth mental health.

• Canadian Longitudinal Study on Aging

⁵² http://www.cihr-irsc.gc.ca/e/47342.html





⁵¹ http://www.cihr-irsc.gc.ca/e/documents/ia strategic plan 2019-en.pdf
The Canadian Longitudinal Study on Aging (CLSA) $\frac{53}{23}$ is a large, national, long-term study/platform that follows approximately 50,000 men and women between the ages of 45 and 85 at study inclusion for at least 20 years. The CLSA collects information on the changing biological, medical, psychological, social, lifestyle and economic aspects of people's lives. The ultimate aim of the CLSA is to find ways to improve the health of Canadians by better understanding the aging process and the factors that shape the way we age.

 Collaborative Health Research Projects CIHR, in collaboration with the Natural Sciences and Engineering Research Council^[5] (NSERC), support the Collaborative Health Research Projects (CHRP) programme, which funds innovative, interdisciplinary, collaborative research projects that require participation from the natural sciences or engineering community together with the health sciences community.

• Canada-UK Artificial Intelligence Initiative

The three Canadian federal research agencies and UK Research and Innovation (UKRI)⁵⁴ launched the Canada-UK Artificial Intelligence Initiative⁵⁵ in 2019. The four UK research councils involved in this UKRI initiative are the Arts and Humanities Research Council, the Economic and Social Research Council (ESRC), the Engineering and Physical Sciences Research Council and the Medical Research Council. This is an interdisciplinary joint call aimed at building competitive, resilient and healthy economies and societies through responsible AI.

• Project Grant Program

The CIHR Project Grant program is designed to capture ideas with the greatest potential to advance health-related fundamental or applied knowledge, health research, health care, health systems, and/or health outcomes. It supports projects or programs of research proposed and conducted by individual researchers or groups of researchers in all areas of health.

Government of Canada - Canada First Research Excellence Fund

The Government of Canada's Economic Action Plan 2014 announced the creation of the <u>Canada First</u> <u>Research Excellence Fund</u> (CFREF). CFREF became is an initiative of the three federal granting agencies in Canada – the Social Sciences and Humanities Research Council^[4] (SSHRC), NSERC and CIHR. The fund is designed to help Canadian universities, colleges and polytechnics compete with the best in the world for talent and partnership opportunities, to make breakthrough discoveries, and to excel globally in research areas that will create long-term economic advantages for Canada. The two inaugural CFREF competitions were held in 2015 and 2016. In September 2016, Campus Montréal, an alliance of three Montréal universities, was awarded \$93.6 million through CFREF for cutting-edge research in AI (spearheaded by the Institute for Data Valorization ()).

⁵⁵ https://mrc.ukri.org/funding/browse/canada-uk/artificial-intelligence-initiative/





⁵³ http://www.cihr-irsc.gc.ca/e/18542.html

⁵⁴ https://www.ukri.org

CFREF has also provided the following funding related to aging and digital health:

- **Vision: Science to Applications (VISTA)**⁵⁶ is an alliance between perceptual and behavioral neuroscience, computer vision, robotics, digital arts and media, and the social sciences.
- The Montreal TransMedTech (MT2) Institute initiative ⁵⁷ seeks to shape the future of diagnosis/prognosis, intervention, and medical technologies for complex diseases across all age groups, providing breakthroughs that will enable the development of medical technologies to transform health care, and to create an attractive model of excellence for Canada.
- BrainsCAN: Brain health for life ⁵⁸ at Western University, along with their national and international academic and commercial partners, will deliver evidence-based assessments and interventions for the diagnosis and treatment of disorders of the brain.

Canada Excellence Research Chair in Human-Centred Robotics and Machine Intelligence

The Canada Excellence Research Chair in Human-Centred Robotics and Machine Intelligence will launch an ambitious multidisciplinary research program, integrating theory, computation and experiment. International collaborations will bring together expertise in mathematics, engineering, health science, social science and philosophy to pioneer a new range of intelligent technologies that will forever change how we live, work and play for the better.

National Research Council Canada

The National Research Council Canada (NRC) is the Government of Canada's largest science and research organization. The NRC partners with Canadian industry to take research impacts from the lab to the marketplace, including in the area of digital health. The National Research Council of Canada Industrial Research Assistance Program (NRC IRAP) provides advice, connections, and funding to help Canadian small and medium-sized businesses increase their innovation capacity and take ideas to market.

Health Canada

In 2018, Health Canada established a new division within the Therapeutic Products Directorate's Medical Devices Bureau to allow for a more targeted pre-market review of digital health technologies, to adapt to rapidly changing technologies in digital health, and to respond to fast innovation cycles. Areas of focus include AI.

In August 2017, federal, provincial and territorial Ministers of Health agreed to the *Common Statement of Principles on Shared Health Priorities*. The federal government is providing \$11 billion over ten years specifically targeted at home and community care and mental health and addiction services. Of this, \$6 billion is dedicated to support priorities for home and community care, which include enhancing home care infrastructure such as digital connectivity and remote monitoring technology.

New Frontiers in Research Fund

⁵⁸ https://www.cfref-apogee.gc.ca/results-resultats/abstracts-resumes/competition_2/western_university-eng.aspx





⁵⁶ https://www.cfref-apogee.gc.ca/results-resultats/abstracts-resumes/competition_2/universite-york-university-eng.aspx

⁵⁷ <u>https://www.cfref-apogee.gc.ca/results-resultats/abstracts-resumes/competition_2/Polytechnique_montreal-eng.aspx</u>

In 2017, the federal government created the Canada Research Coordinating Committee (CRCC) to advance collaboration among the federal research granting councils – CIHR, NSERC and SSHRC – and the Canadian Foundation for Innovation. The CRCC is working to achieve greater harmonization, integration and coordination of research-related programs and policies and to address key priorities for Canadian research. It is leading the design and implementation of the New Frontiers in Research Fund (NFRF) which is investing \$275 million over 5 years beginning in fiscal year 2018-19, with \$65 million ongoing, to fund international, interdisciplinary, fast-breaking and high-risk research.

Provincial Health Research Funding Organizations

Many provinces in Canada have their own provincial health research funding organizations that support health research and innovation capacity across Canada through traineeship awards and operating grants, through the administration of world-class peer review systems, and by funding and implementing the translation of knowledge into innovative health products, services, technologies and solutions.

4.5 Most important players and networks in the field

The following are the key players in the field in Canada (including most active FP7 and H2020 participants):

Government of Canada

The Government of Canada works hard to help seniors enjoy a high quality of life and plays a leadership role in supporting health care innovation to improve patient care. Its policies, programs and initiatives for seniors are also designed to support the people around them—their families, caregivers, employers and communities⁵⁹. In addition, since 2018, Canada has had a federal Minister of Seniors, whose mandate⁶⁰ includes:

- Work with the Minister of Health and the Minister of Families, Children and Social Development on initiatives to **promote healthy aging**.
- Support the Minister of Health in the delivery of health care commitments of relevance to seniors and aging.

Government of Canada Agencies and Programmes:

• The Canadian Institutes of Health Research (CIHR)⁶¹ is Canada's federal funding agency for health research. CIHR's mandate is to create new scientific knowledge and to enable its translation into improved health, more effective health services and products, and a strengthened Canadian health care system. CIHR supports research concerning older adults, the life trajectory, and digital health, and this topic area is prioritized within the activities of the CIHR Institute of Aging and the CIHR Institute of Health Services and Policy Research.

⁶¹ https://www.canada.ca/en.html





⁵⁹ <u>https://www.canada.ca/en/employment-social-development/campaigns/seniors.html</u>

⁶⁰ https://pm.gc.ca/en/mandate-letters/minister-seniors-mandate-letter



- AGE-WELL⁶² is Canada's Technology and Aging Network. AGE-WELL aims to help seniors live independently and safely at home by creating technologies and services that benefit older adults and caregivers. Launched in 2015 through the federally funded <u>Networks of Centres of Excellence</u> (NCE) program, AGE-WELL addresses a wide range of complex issues in technology and aging through receptor-driven transdisciplinary research, training programs, partnerships, knowledge mobilization and the commercial development of technologies. In 2019, a new AGE-WELL National Innovation Hub was launched at Simon Fraser University to address aging challenges though digital health solutions⁶³.
- Canadian Frailty Network⁶⁴ (CFN) is also funded through the federally-funded <u>Networks of</u> <u>Centres of Excellence</u> (NCE) program. As a research network, CFN collaborates with industry, health care, academic, non-governmental organizations and private partners to improve the care of older adults living with frailty, and to support their families and caregivers.
- The National Seniors Council⁶⁵ (NSC) advises the Government of Canada on matters related to seniors' health, well-being and quality of life. Members include experts on seniors issues and aging, individuals with experience working for organizations that represent the interests of seniors, and seniors themselves. The NSC is currently focusing on four priorities: identifying measures to reduce crimes and harms against seniors; providing advice on gaps that could potentially be addressed if a national seniors strategy were to be developed; providing advice on the development and implementation of government initiatives using an age-friendly/healthy aging perspective; and identifying measures to counteract ageism.
- The Federal/Provincial/Territorial Ministers Responsible for Seniors Forum ⁶⁶ is an intergovernmental body which shares information, discusses new and emerging issues and collaborates on key projects. The Forum meets annually to determine shared priorities. In 2013, they agreed on specific foci that included supporting the active participation of seniors, particularly older workers seeking to balance work and care responsibilities and assisting seniors to plan for "aging in place".
- The Public Health Agency of Canada⁶⁷ (PHAC) empowers Canadians to improve their health. PHAC monitors and reports on the health of older Canadians, and promotes their health and wellbeing. PHAC's healthy aging activities focus on dementia, fall prevention, age-friendly communities, mental health, surveillance and elder abuse.

⁶⁷ <u>https://www.canada.ca/en/public-health.html</u>





⁶² https://agewell-nce.ca

⁶³ <u>http://www.sfu.ca/sfunews/stories/2019/01/new-national-innovation-hub-to-address-aging-challenges.html</u>

⁶⁴ https://www.cfn-nce.ca

⁶⁵ https://www.canada.ca/en/national-seniors-council.html

⁶⁶ https://www.canada.ca/en/employment-social-development/corporate/seniors/forum.html

- •>
- **Health Canada**⁶⁸ is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks for all Canadians including older adults.

Non-Government Agencies

- **Canada Health Infoway**, an independent, not-for-profit organization funded by the federal government, was established in 2001. Infoway helps to improve the health of Canadians by working with partners to accelerate the development, adoption and effective use of digital health solutions across Canada. Through their investments, they help deliver better quality and access to care and more efficient delivery of health services for patients and clinicians.
- The **Canadian Institute for Advanced Research** (CIFAR) is a Canadian-based global charitable organization focused on addressing the most important questions facing science and humanity by supporting long-term interdisciplinary research collaboration and knowledge mobilization. In 2017, the Government of Canada appointed CIFAR to develop and lead the Pan-Canadian Artificial Intelligence Strategy, the world's first national AI strategy, and committed \$125 million over five years towards this end⁶⁹. For example, the University of Toronto's Vector Institute, which aims to significantly increase student training in Canada and support the development of an AI supercluster in Toronto benefited from this program. In collaboration with other AI hubs in Canada, the Institute seeks to ensure critical mass of AI research, funding, highly qualified personnel (HQP), and investment in development activities in Canada. This would address one of the main concerns raised by companies investing in AI research in Canada, namely to ensure that sufficient AI expertise will be available in the future to justify the long-term prospects of their investments (i.e., critical mass of talent).
- The **Canadian Orthopaedic Foundation**, in collaboration with **Bone and Joint Canada**, to promote best practices in hip fracture care, improve access to surgery and enhance post-operative support for hip fracture patients when they return home.
- The Association of Canadian Community Colleges to develop and distribute national educational standards for Personal Support Workers (PSWs), who provide the majority of personal support care to seniors in home, community and long-term care facility settings. Ensuring that PSW graduates across Canada have a standard set of skills and knowledge makes recruitment and retention easier for employers, and promotes inter-provincial mobility for PSWs.⁷⁰
- The Centre for Aging and Brain Health Innovation (CABHI) partnership collaboration of healthcare, science, industry, not-for-profit and government partners that aims to drive innovation in the aging and brain health sector, including dementia. CABHI seeks to accelerate the development, validation, commercialization, dissemination and adoption of innovations

⁷⁰ https://www.canada.ca/en/employment-social-development/programs/seniors-action-report.html





⁶⁸ https://www.canada.ca/en/health-canada.html

⁶⁹ https://budget.gc.ca/2017/docs/plan/chap-03-en.html

that help older adults age safely in the setting of their choice, while maintaining cognitive, emotional and physical well-being. Innovative solutions to address brain health and aging include medical devices, therapeutic approaches, emerging technologies, wellness and digital health solutions, healthcare delivery practices, and practitioner/caregiver training and support.

- Cogniciti is a brain health company that is changing the way the world looks at brain health and aging. Through the provision of innovative, evidence-based brain health solutions, Cogniciti is engaging older adults in important conversations about their brain health, working to improve the quality of life of individuals living with dementia and supporting research efforts to prevent, treat and cure dementia. Cogniciti is a subsidiary of <u>Baycrest</u>, a global leader in residential living, healthcare, research, innovation and education for older adults, with a special focus on brain health and aging.
- **Digital Health Circle** supports the creation of innovative new digital technologies and highquality jobs in British Columbia that improve the lives of older people.
- **Bruyère Digital Health** is building an ecosystem of innovation to support the healthcare needs of Canada's aging population.
- **Telus Health** provides solutions to for Canada's healthcare industry. Telus Health is working to connect health teams, streamline workflows, and empower patients to manage their health.
- Ontario Telehealth Network (OTN) is providing a wide range of virtual services that are indispensable to people's well-being including unprecedented access to primary care and mental health care OTN is working with partners to modernize consumer access to care.





4.6 Strengths and weaknesses in Canada

Based on interviews with experts in the field of Digital Health in Canada, the following strengths and weaknesses were identified:

Strengths	Weaknesses
 Excellent capacity in all aspects of digital health Excellent capacity and international capacity including AI Public health and social systems are open to include digital health approaches 	 Challenge of integrating digital health solutions into the health and social system due to lack of cost- benefit analyses Challenges consistently integrating digital health solutions across Canada Weak entrepreneurial culture among academics in this area Access to health data can be challenging
Opportunities	Threats
 Relatively strong and innovative industry (SMEs) in this area Demonstrated ability to work collaboratively across institutions, sectors and countries 	 Regulatory challenges, such as procurement regulations impede commercialization of digital health solutions Geographical gap between urban and rural areas



Interviewees identified two main strengths in Canada as drivers for digital health. These include an excellent capacity in all aspects of digital health, including a strong AI sector as well as public health and social systems which are open to include digital health approaches. Weaknesses discussed included the challenge of integrating digital health

solutions into the health and social system due to lack of existing cost-benefit analyses, challenges consistently integrating digital health solutions across Canada's diverse health system, weak entrepreneurial culture among academics in this area, and a challenge with access to health data. As Canada moves toward becoming a super-aged country (over 20% of the population being 65 years and older), seniors are expected to comprise around 23% to 25% of the population by 2036, and around 24% to 28% in 2061⁷¹, the topic of digital health and aging will become of greater importance for the population.

⁷¹ https://www150.statcan.gc.ca/n1/pub/11-402-x/2010000/chap/pop/pop02-eng.htm





5 Digital health and AHA: Panorama and priorities in China

China already ranks second globally in digital health, reflecting the opportunities that exist there to lead an evolution in healthcare. There are three primary engines propelling this rapid growth in digital health:

- I. The Chinese middle class is growing fast. As frequent travellers, wealthy Chinese have a global outlook based on their interactions with people from other countries, and they look beyond China for information
- II. China has one of the world's highest rates of internet and mobile-phone use
- III. Chinese consumers place a strong emphasis on picking the right brand for their healthcare. Due to mistrust towards various media, consumers value credible information that can enable them to make decisions about finding the right hospital and the right doctor to provide the care they require.⁷²

With the rise of the digital economy, the health industry has also entered a new era of digitalisation. From the current industrial structure, the digital health market in developed countries such as Europe and the United States is relatively mature, but emerging markets in this field such as China are also developing and are expected to catch up with Europe and the US in the future. Although China's digital health industry started late, it is developing at a high speed. Especially in the fields of high-tech, AI, machine learning and other high-tech, China's digital health enterprises have shown extraordinary strength and great potential and have become a force to be reckoned with in the world's digital health management industry.

5.1 Digital health R&I priorities

The main priority in digital health in China is making the health system more sustainable and accessible, make health services more affordable, and strengthen health promotion, disease prevention, diagnosis, management, rehabilitation and palliative care.⁷³

The "Healthy China 2020" strategic study puts forward that "by 2020, the main health indicators would basically reach the level of moderately developed countries." At present, many provinces and cities in China have basically experimented with this goal. The "Healthy China 2020" strategic research has constructed a comprehensive health development target system that embodies the scientific development concept. These goals cover the protection and promotion of the national health service system and its supporting guarantee conditions, which are the monitoring and evaluation of the national health status and effective regulation of health. Based on the severity of the harm, the wide range of impact, clear intervention measures, fairness and forward-looking principles, the "Healthy

⁷³ https://apps.who.int/gb/ebwha/pdf_files/EB146/B146_26-ch.pdf





⁷² <u>https://www.clearstate.com/wp-content/uploads/2017/05/Digital-Health-China.pdf</u>

China 2020" strategic research screened out three priority categories for key populations, major diseases and controllable health risk factors. It further proposes 21 action plans for the above three priority areas and the realization of "health care" as key tasks in the future, including action plans for maternal and child health for key populations and improvement of poverty-stricken areas. These include: population health action plan, occupational health action plan; key infectious disease control action plan for major diseases, key chronic disease prevention and control action plan, injury monitoring and intervention action plan; environment and health action plan for health risk factors, food safety action plan, National Healthy Lifestyle Action Plan, Action Plan for Tobacco Harm Reduction; Promote the development of health, and realize the action plan for the construction of a medical and health service system that "can be treated", the action plan for the construction of health human resources, and the action plan for strengthening the basic medical insurance system. Action plan for rational drug use, action plan for ensuring medical safety, action plan for improving the efficiency of medical and health services, action plan for public safety and health emergency, plan for promoting technological innovation, action plan for national health information system, action plan for traditional Chinese medicine such as traditional Chinese medicine, development of health Industry action plan⁷⁴.

The *"Healthy China 2030"* Planning Outline issued by the State Council sets "co-construction and sharing, health for all" as the strategic theme. By 2030, the institutional system for promoting the health of the whole people will be improved, the development of the health field will be more coordinated, healthy lifestyles will be popularized, the quality of health services and health protection levels will continue to improve, the health industry will flourish, health equity will be basically achieved, and the main health indicators will be similar to high ranks of income countries. By 2050, it is aimed to build a healthy country compatible with modern socialist countries⁷⁵.

In relation with the government initiatives described above, China's **"National Planning Guideline for the Healthcare Service System"** (2015-2020) is a comprehensive plan with specific objectives and reforms, aimed at improving the shortcomings of its healthcare management and infrastructure by 2020⁷⁶. This Guideline is still valid for 2020 - the new edition will be published after the National People's Congress and the Chinese People's Political Consultative Conference will be held in March 2021. The priorities highlighted in the current report are still valid for 2020 and after). This guideline includes objectives such as engaging more with technological and internet-based healthcare solutions. The plan also substantially underlines the strategic need for the integration and fostering of the private sector. Pilot programmes are currently in place to test the viability and impact of both private as well as foreign-owned healthcare facilities.

It also vowed to provide more quality public services for senior citizens, as a way to deal with an aging society⁷⁷. Elderly care community centres will receive more government funding. Private capital and non-government organisations will have more access to the elderly care market, so that senior citizens can have more options in diverse services.

⁷⁷ http://english.gov.cn/policies/latest_releases/2017/03/06/content_281475586946296.htm





⁷⁴ <u>http://www.nhc.gov.cn/wjw/zcjd/201304/f70f8fc52d6a422494789f65c7ad134d.shtml</u>

⁷⁵ http://www.gov.cn/gongbao/content/2016/content_5133024.htm

⁷⁶ https://www.scio.gov.cn/32618/Document/1565200/1565200.htm

Finally, the strategy "Digital China" includes topics such as e-government, digital economy, big data, smart society, industrial Internet, network technology, digital ecology, **and digital health**.

The main R&I Digital health priorities⁷⁸⁷⁹ in China are outlined below.

Digital health R&I priorities in China:

- Main purpose in short: achieve a sustainable, accessible and affordable health care;
- Personalized digital health
 - Build up digital health community which is aimed at people's health and based on a digitalized platform (construction of a standardized population health information system)
 - Balance the supplementation of medical resources, optimize high-quality medical resources distribution and improve medical service
- Implementation of "Internet+ medical health" and remote medical care
 - With the coming of 5G era, remote medical and Internet medical have been booming
 - COVID-19 has highlighted the significance of remote medical and Internet medical

Personalised Digital Health

Health is a concept that varies from person to person. Even if different people suffer from the same disease, the treatment methods are not the same for each of them due to the effects of receptor quality, gender, age, etc. In the past, due to the limitation of technology level, the data acquisition of health management was limited to a narrow scope. Personal health data was not comprehensive and inaccurate, and the effect of health management was naturally not obvious. However, with the **development of science and technology**, especially the advancement of wearable device technology, accurate collection of personal health data is possible, and the digital health management industry naturally needs to develop in the direction of satisfying individual needs.

Personalised digital health management reflects the "patient-oriented" development philosophy that the medical industry has always adhered to. Technology should serve humanity. Digital health management introduces advanced digital technology into the health industry, not only to provide more advanced modern medical services to the citizens, but also to let the citizens experience intimate and thoughtful personalised services.

The true value of big data is not in the data itself, but the valuable information obtained through data processing and analysis. Digital health management is based on the detection, evaluation and guidance of individuals' health status based on the valuable information. Data processing capability

⁷⁹ http://field.10jqka.com.cn/20200625/c621349937.shtml





⁷⁸ https://www.jiemian.com/article/5277590.html

is the focus of R&D software development, and it is also necessary for the digital health management industry to respond to big data.

In this context, **China's hospital information standardisation construction** has experienced three development stages: exploration and research (2001-2005), key breakthrough (2006-2010) and rapid development (2011-2014). After more than 10 years of unremitting efforts, the population health information standard system is gradually improving. At present, **China has developed/revised more than 240 health information standards for basic, data, technical and management populations, of which more than 150 have been officially released.** Also, the norm laid the foundation for the standardisation of hospital informatisation. Following a \$9.5 billion investment by the Ministry of Health (now the National Health and Family Planning Commission) in 2012 to develop electronic medical records (EMRs) and improve hospital information systems, the Chinese government has intensified its efforts to boost digital healthcare. For example, the government has reduced the barriers in e-commerce, making it easier to register online pharmacies.

The "Healthy China 2020 Strategy Research Report" proposes that the special construction of seven major medical systems should be promoted in the future. In terms of medical informatisation, the state will launch **a national eHealth system project** with a budget of 61.1 billion yuan, including the information system of large general hospitals. Standardisation construction, the establishment of a national EHR and a regional medical information platform⁸⁰.

As such, the construction of a standardised population health information system has been of major importance for China since the start of the hospital information standardisation construction and continues to be crucial today, through the current national strategy which aims to further develop eHealth.

Implementation of "Internet+ medical health" and remote medical care

In 2020, China has put forward new requirements for the health development plan. In terms of digital health, China must build a strong public health system, improve professional capabilities, intensify the reform of the disease prevention and control system, and strengthen early monitoring and early warning capabilities, rapid detection capabilities, emergency response capabilities, and comprehensive treatment capabilities. At the same time, China also needs to attach great importance to the application of new generation information technology and accelerate the development of "Internet + medical health"⁸¹.

Internet-based medical diagnosis and treatment are important parts of digital health. The Chinese government actively promotes the **implementation of "Internet + medical health".** Especially in 2018, the General Office of the State Council issued opinions on promoting the development of "Internet + medical health" with aims to 1) develop "Internet +" medical services, 2) innovate

⁸¹ https://www.medsci.cn/article/show_article.do?id=3faa20186486





⁸⁰ http://en.lyxyhkj.cn/news/The-Ministry-of-Health-wants-to-invest-400-billion-to-promote-major-projects-in-the-sevenmajor-medical-systems-4.html

"Internet +" public health services, 3) optimize "Internet +" family doctor contracting services, 4) improve "Internet +" drug supply security services, 5) promote "Internet +" medical security settlement services, 6) strengthen "Internet +" medical education and popular science services, 7) promote "Internet +" artificial intelligence application services, 8) accelerate the sharing of medical and health information, 9) improve the "Internet + medical health" standard system, 10) improve hospital management and convenience services, 11) enhance the foundation of medical institutions facility guarantee capabilities, 12) strengthen medical quality supervision, and 13) ensure data and information security⁸². The above series of guidelines will beneficially guarantee the advancement of "Internet + medical health", which blossoms the development of digital health in China.



Interviewees from China referred to the fact that China has a large population of mobile Internet. Emerging markets such as India, Indonesia, and China have a large population base and high mobile Internet penetration, which is an important foundation for the successful launch of digital health products and services. At the

same time, emerging markets have a large population of people living in rural and poor areas, which means that successful healthcare solutions must be accessible and inexpensive. One of the big advantages of digital healthcare is the ability to provide remote services at low prices. With the paperless and electronic medical records, the chances of user data being damaged by cyberattacks are increasing. Data security issues can lead to the loss of users and negative public opinion.

5.2 Main challenges related to digital health

The opportunities and challenges facing digital health in China were discussed over and over again : the White Paper "2017 China Medical and Health Industry



"In China, one of the main objectives associated with digital health and healthy ageing is how to help individuals manage their health in a simple, efficient and cost-effective manner." – Academic stakeholder in Digital Health from China

Investment^{"83} covers the four sub-sector of the medical and health industry in 2017: medical and biotechnology, medical technology and medical devices, medical services, and digital medicine; the "*Digital Health Future Index Report 2019*⁸⁴" released by Philips focus on "Exploring the impact of digital health technology on healthcare professionals and patients"; at the Start-up Health Festival 2019, Marco Pish, MD, the general manager and chief medical officer of Ping An Global Traveler Fund, had a fireside conversation with Start-up Health's Katia Hancock; then on October 20-22, 2019, the 6th World Internet was held in China: more than 1,500 guests from more than 80 countries around the

⁸⁴ https://images.philips.com/is/content/PhilipsConsumer/Campaigns/CA20162504_Philips_Newscenter/Philips_Future_He alth_Index_2019_report_transforming_healthcare_experiences.pdf? ga=2.111714755.65401937.1590138521-1121912130.1590138521





⁸² http://www.gov.cn/zhengce/content/2018-04/28/content_5286645.htm

⁸³ <u>https://www.docin.com/p-2147812911.html</u>

world discussed 5G, artificial intelligence, and digital health issues. A consensus gradually come into building, confirmed by the interviewees conducted.



One of the interviewees from China suggested that the digital health industry will grow rapidly in emerging markets, surpassing mature markets. Health care providers must have technologies such as AI, machine learning and chat bots in the future. The healthcare industry will be highly integrated, as practitioners, technology giants and digital start-ups are hoping to gain a higher position in the growing healthcare arena.

On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the three main challenges related to digital health in China are:

- 1. Collection and management of health data in rural areas
- 2. Technological capabilities in management processing and application of health data
- 3. Ethical and security issues

Collection and management of health data in rural areas

Large part of China's national population lives in rural areas, which poses enormous challenges for the collection and management of health data. People in low-income areas have less understanding of healthcare and disease prevention, and there is no regular physical examination at the hospital. It is difficult for doctors to obtain long-term, stable data to manage the health of residents. Therefore, the government needs to invest more funds and primary healthcare service stations to increase the publicity and education of health management, so that more people can realise the importance and reliability of medical data collection, and thus enhance the popularity of digital health in China. Simultaneously, digital health requires a large amount of data circulation between individuals, equipment and institutions, requiring the relevant departments to issue clear policies and strong enforcement measures to ensure the safety of data usage. In terms of data usage, the public's concerns about data security can be reduced through appropriate technologies, monitoring and evaluation of security systems, transparency and accountability mechanisms such as legal compensation and privacy compensations caused by security breaches. The focus and difficulties of these digital health projects lie not just in China, but around the world.

Technological capabilities in management processing and application of health data

In the management, processing and application of health data, China's technology is less advanced than that of Western developed countries. In order to rapidly promote digital health in China, it needs to actively develop technology, improve data analysis and application capabilities, and truly apply digital health benefits to improve national health. Developed countries have relatively systematic and comprehensive policies and implementation experience from decades ago. China has only begun to develop digital health in recent years, and currently lacks a solid management system and application experience.

Ethical and security issues





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Furthermore, ethical and security issues cannot be ignored. The premise of applying digital health to clinical development is to create, collect and record massive amounts of sensitive information about individuals. In the process of digital health realisation,



"I believe that the public's trust in the use of health data and its privacy is a vital part of the development of digital health" -Expert in Digital Health from China

there are many problems in ethics and policy. For example, the process of using large repositories for data mining will challenge data management, privacy protection and monitoring mechanisms; how to better develop regulatory science to improve the security, effectiveness and cost-effectiveness of evidence evaluation; diversity; multidimensional, unstructured data and new evidence generation patterns for routine clinical measures.

5.3 Specific challenges for the ageing population

The over 60 population will grow from around 165 million in 2010 to 440 million by 2050, constituting 45% of the country's total population. China will have the largest amount of aged population in 2050 among the emerging countries. Not only will China have the largest percentage of elderly people in 2050, but it will also have the world's largest population. China's aging population presents a big challenge for the country in terms of Economic and Social Development.

- The most intuitive manifestation of population aging is the **relative decline in the proportion of working-age population, which means the relative reduction in labour resources** and the decline in labour supply, which affects the economic development potential. In the process of population aging in developed countries, the general shortage of labour supply and the aging of labour force have led to the result of weak economic growth.
- The **improvement of the old-age dependency ratio** is another important performance of the aging population. The increase in the dependency ratio of the elderly population means that fewer working-age populations need to support more elderly populations, which will inevitably increase the redistribution expenditure and increase the economic and social burden. The pressure on the working-age group will become heavier and intergenerational social conflicts might appear.
- The augmenting number of elderly groups not only increases the pension expenditure, but also their special medical and nursing needs will **increase the pressure on medical insurance and nursing insurance**, thus making a series of social policies face the challenge. With the development of economy and society and the advancement of medical technology, people's medical and health needs continue to increase, resulting in rapid rise in medical costs. However, the increase in medical expenses in the process of population aging also has the effect of the interaction of two factors: one is the expansion of the size of the elderly population, and the other is the rapid increase in the average medical expenses of the elderly.





On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the main challenges for ageing populations include:

- 1. The transformation of the ageing support arrangement: develop new elderly care system
 - a. Lack of adequate resources
 - b. Confidence and cultural barrier
 - c. "Stay at home" strategy
- 2. The development of a "smart pension industry

Demographic shifts such as aging population (extended life expectancy), gradually miniaturization of the family structure (the "one-child policy") and mass rural-urban migration, **led to reconsider the traditional old-age support system based on the family.** Families are increasingly dispersed and children have less time to take care of their parents.

- Thus, the needs of elderly disabled people's life care and nursing services will gradually expand, and constitutes a big challenge for the country's healthcare system, which currently lacks adequate resources: there is an urgent need for professional institutions and professional personnel to provide care, resulting in the rise of nursing services and related costs. The annual value of the provided care services and products for elderly in China is under 100 billion RMB, while the demand implies a massive potential, estimated at one trillion RMB. Moreover, the ratio of elderly dependency, meaning the number of elderly people out of every 100 working people, is expected to rise from 13.7 to 46.7 by 2050. Thus, the inability of young people to take care of the large aging population will create a huge demand for the nursing home industry and different senior care providers. According to Daxue Consulting's project manager Hu Yuwan, in earlier times, the aging society didn't even consider going to nursing homes, especially in China, but this kind of thinking is changing now, one reason is the transformation of many from poor to middle class in China.85 The Chinese government has made ageing a top priority for provinces facing fast-aging population, by establishing guidelines to accelerate the country's elderly care sectors6. In April 2019, the General Office of the State Council of China issued its opinions on advancing the development of elderly care services.
- In China's traditional system of palliative care, children's care for parents in their old age. Thus, another **important barrier to overcome for the development of elderly care system is to separate in the Chinese opinion the notion of elder care from the stigma of filial abandonment**. In addition, **Chinese have a low confidence in the senior care industry** as it is very recent. Fear of abuse, poor living conditions, or inadequate value for money is very high, as there have been scandals in the past. Thus, to create a confident eldercare system is also a big challenge for China. In this way, the government is making important efforts in building quality standards for caregivers so that trust and security can be ensured, with a view towards

⁸⁶ https://www.business-sweden.se/contentassets/9385356ddd88499badd69e23d80a09f0/elderly-care-in-china.pdf





⁸⁵ https://daxueconsulting.com/elderly-care-service-in-china/

long-term investment. Efforts in communication and marketing will also play an important role to secure the trust of the Chinese population.

• The Chinese government is promoting a three-tiered senior care system whereby 90 percent of elders are expected to stay at home, seven percent at community centres and three percent at institutional senior care centres. Thus, home elderly care services and technologies are enormous market potential, and digital health will play an increasing role.

In 2015, the "Guiding Opinions on Actively Promoting the "Internet +" Action" issued by the State Council clearly stated that it is **necessary to "promote the development of a smart, healthy and elderly care industry".** In 2017, the Ministry of Industry and Information Technology, the Ministry of Civil Affairs, and the Health and Family Planning Commission jointly issued the "Smart Health and Elderly Industry Development Action Plan (2017-2020)" and the "Notice on the Pilot and Demonstration of the Application of Smart Health and Elderly Applications" to announce China's senior care. **The industry has entered in the era of "smart pension".**

Smart pension industry refers to the use of new technologies and new products such as cloud computing, big data, Internet of Things, and smart hardware to provide better pension services and improve the quality of life of the elderly and their children.

- The rapid development and application of new technologies and products such as cloud computing, big data, Internet of Things, and intelligent hardware have provided prerequisites for the intelligent development of the smart pension industry. Fortunately, families will actively embrace new technologies and smart products, hoping to use smart technology and hardware to provide convenience to the lives of elderly people, escort life, and achieve a true "smart pension."
- "Smart pension" consists on relying on the social network and customer base of pension industry institutions, parks, and bases, and integrating pension service resources and modern information technologies such as "big things moving to the cloud". Building a digital platform for healthy pensions are conducive to accelerating the formation of a reasonable structure, complete categories, and management.
- The standardized modernized service system for the old-age industry realizes the full coverage of the old-age service and guarantees the health of China's strategic landing.
- At the same time, the "platform + industry + socialization" industry digitalization model is conducive to creating a new format of health services, stimulating new economic growth points in the pension industry, and promoting the overall prosperity of the large health industry.
- The acceptance of smart pensions by senior and elderly population is the ultimate goal. The development of the above technologies and the application of products need to be supported by technology, including computer science, medicine, electronic information technology, etc. Most of the old people's understanding and learning of new products and technologies come from their children or grandchildren. These technologies and products can not only guarantee the quality of life of the elderly, but also effectively reduce the burden of the children. With the popularization of smart elderly care concepts and products, the acceptance of smart pensions by the elderly will be likely to increase.





5.4 Relevant key programmes and funding agencies

The National Natural Science Foundation of China (NSFC)⁸⁷

The NSFC plays a significant role in boosting digital health on a national level. The foundation has a rigorous review process. By identifying funding categories, it can support truly innovative ideas and concepts which provide concrete solutions to meaningful scientific problems. Scientific research activities are divided into four categories according to the attributes of scientific issues: research of creative and timely ideas, research focusing on frontlines of science in unique ways, application-driven basic research, and transdisciplinary leading-edge research.

As a cross-disciplinary and emerging research field, digital health has been gradually becoming a popular research topic supported by the NSFC. For example, the NSFC's major research plan include the project "Big Data Integration and Sharing Platform Research and Demonstration Application for Population Health and Major Diseases". The launching meeting of this major research plan integration project was on March 23-24, 2019 in Xiang'an, Xiamen.

In recent years, digital health has been open to researchers as a separate section of the science foundation's application guidelines. However, as this field is recent, it is not possible to access sufficient information yet.

The Ministry of Science and Technology (MoST)⁸⁸

MoST is the state council department in charge of state science and technology. MoST implements the Communist Party of China central committee's policies and decisions on scientific and technological innovation and adheres to and strengthens the party's centralised and unified leadership over scientific and technological innovation in the course of performing its duties. It has many responsibilities: among the seventeen major duties, some have great facilitation towards national digital health.

MoST formulates and implements national basic research plans, policies and standards, and organises and coordinates major national projects on basic research and application-oriented basic research. MoST formulates and oversees the implementation of plans for major science, technology and innovation bases and infrastructure, leads the efforts to develop national laboratories, lays a sound groundwork for scientific research, and promotes the open access to and sharing of science and technology (S&T) resources. This helps to accelerate the digital health industry.

In addition, MoST creates plans for major national S&T projects and oversees their implementation, coordinates the R&D and innovation of key generic technologies, cutting-edge frontier technologies, modern engineering technologies and disruptive technologies, leads the efforts to tackle key technological problems, and promotes the demonstration and application of major R&D and innovation outcomes. The organisation coordinates the efforts to implement or participate in international mega-science programmes and projects. It takes the lead in formulating plans, policies and measures for the R&D and industrial application of high and new technologies and the promotion

⁸⁸ https://most.gov.pk/





⁸⁷ <u>http://www.nsfc.gov.cn/english/site 1/index.html</u>

of agricultural, rural and social development through S&T. It also analyses technological demands in priority areas, proposes major tasks and oversees their implementation. Moreover, MoST leads the efforts to develop the national technology transfer system, formulates and oversees the implementation of policies and measures for promoting the transfer and commercialisation of R&D outcomes and the collaboration among enterprises, universities and research institutes. MoST provides guidance for the development of S&T services, technology markets and S&T intermediaries. It also helps to coordinate the development of the regional innovation system, provides guidance for regional innovation-driven development, appropriate distribution of S&T resources and capacity building for collaborative innovation, and promotes the development of science parks. These major functions make it possible for digital health-related research and industries to incubate and develop in China. With great encouragement from the Chinese government, in the "Healthy China 2020 Strategy Research Report", the special construction of seven major medical systems has been proposed for the future. In terms of medical informatisation, the state will launch a national eHealth system project with a budget of 61.1 billion yuan, including the information system of large general hospitals, standardisation construction, the establishment of a national EHR and a regional medical information platform.

National Health Commission (NHC)⁸⁹

The Chinese government set up the NHC in order to promote the implementation of the Healthy China Strategy, establish the concept of great health, change the focus from solely curing diseases to focus on people's health, prevent and control major diseases, actively respond to the aging of the population, accelerate the development of undertakings and industries for the aged, and provide all-round, full-cycle health services for the people. As an important commission ensuring citizens' health, the NHC has several functions of which some are greatly relevant to national digital health.

The reformation of the medical and healthcare system has been deepened by the NHC providing suggestions on guidelines, policies and measures. The Commission also promotes comprehensive reform of public hospitals and the separation of public hospitals' supervision and operation, improves the modern hospital management system, formulates and implements policies and measures to promote the diversification of public health service providers, increases the ways of service provision, and gives advice for medical services and drug price policy. As well, the Commission organises and coordinates the formulation and implementation of policies and measures to cope with the aging population problem and is responsible for promoting the construction of the health service system and the integration of medical care and nursing for the elderly. It also organises the formulation of national drug policies and national essential medicine system, launches an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, gives suggestions on the pricing policy of national essential medicine, participates in compiling a pharmaceutical codex, organises food safety risk monitoring and assessment and formulates and publicises food safety standards in accordance with the law. The 61.1-billion-yuan national budget for the eHealth system project is prompted by these functions.

⁸⁹ http://en.nhc.gov.cn/





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In addition to the above mentioned, there are many other projects, including the National Key R&D Programme, the NHC's Special Project, provincial and local government funded projects as well as the National R&D Infrastructure and Facility Development Programme of China.

5.5 Most important players and networks in the field

Research actors

- The NSFC's major research plan integration project "Big Data Integration and Sharing Platform Research and Demonstration Applications for Population Health and Major Diseases" is led by the School of Public Health of Peking University, and Meinian Health is one of the main participating institutions. Other participating institutions include the Development Research Center of the State Council, Chinese Academy of Medical Sciences, Peking Union Medical College, Chinese Center for Disease Control and Prevention, Beijing Institute of Technology, Beijing Huasukang Data Technology Co., Ltd. and other important national scientific research institutes and research institutions.
- Regarding ICT security / safety, main actors are the Institute of Security of China Information and Communication Research Institute, the China Health Information and Health Medical Big Data Society Health Information Security and New Technology Application Professional Committee and the Data Protection Officer (DPO). In early 2020, they analysed the safety application of new technologies in the joint prevention and control of New Coronary Pneumonia. Typical cases of basic telecom operators were analysed such as China Telecom, China Mobile, China Unicom, and technology companies such as Ping An, Tencent, and Contempt to support the epidemic prevention and control work. New technologies such as artificial intelligence, big data, cloud computing, and blockchain are used to improve the efficiency of epidemic prevention and control, build situational awareness, support prevention and control resource scheduling, and promote work information disclosure. Safety application ideas in public health event prediction, prevention and control, diagnosis and treatment, recovery and other links.
- **Tsinghua University** is an important player in the advancement of digital health in China. Many institutions and teachers at Tsinghua University have made great achievements in the field of digital health.
 - o The Tsinghua University Data Science Research Institute, Tsinghua University Medical School and China Hospital Association Disease and Health Management Committee jointly hosted the "Tsinghua University Medical Health Big Data Frontier Forum" on January 17th, 2015⁹⁰. The conference aimed to promote positive communication between the academic community, internet data analysis and healthcare. Big data has become a popular subject because it is closely integrated with all walks of life and directly affects every aspect of life. At the same time, it hopes that the combination of big data and medical health can make a difference in the management of pollution and health, the difficulty of people's medical treatment, big data genetic testing and ageing care.

⁹⁰ http://www.stat.tsinghua.edu.cn/en/2018/04/15/medical-big-data-and-health-technology-assessment-forum/





- On 12th of July 2019, the Institute of Precision Medicine of Tsinghua University announced that it would launch six major medical research centres: Clinical Big Data Center, Digital Medical and Medical Robot Center, Artificial Cardiopulmonary Center, Smart Health Center, Medical Transformation Imaging Center, Wearable/Implantable Medical Device Center.
- **The Institute of Information Technology of Tsinghua University** is also involved in digital health thematic.
- There are 40 information workers (engineers founding medical data systems, analysists analysing medical health big data, etc.) at **Tsinghua Chang Gung Hospital**. The hospital is mainly self-developed. At present, the medical information system has been fully covered, and the information construction is also constantly being built and improved.

Local governments

- In September 2019, the demonstration platform for digital health insurance transactions jointly established by the Shanghai Insurance Exchange and the Ningbo Municipal Government was officially launched. It is reported that the platform construction has achieved initial results, completed the docking with the Ningbo Municipal Health and Health Commission National Health Information Platform, and reached cooperation with 16 insurance companies. Experts said that data is the core of the development of health insurance. The main bottleneck of data sharing is in public hospitals. If insurance companies and medical institutions can achieve information sharing, the ability of insurance companies in health insurance pricing and services will be improved. The benefit is insurance consumers.
- In October 2019, the Sixth World Internet Conference was held in Wuzhen, Zhejiang. More than 1,500 guests from more than 80 countries discussed the development trends of the Internet and digital industries. Government officials from Pingdingshan City, Henan Province, and Tai'an City, Shandong Province were invited to introduce their local experience in improving regional health through the construction of a "health community" "Community of disease and health" is the first to explore the application of digital technology in regional health management, chronic disease prevention and other aspects.

Networks

There are also other existing important networks in the field of digital health in China which work coherently as the mainstay of digital healthcare in China. They can be partly listed:

• The Active Health Alliance is a closed-loop crowd management of active population screening, prevention, care and effectiveness evaluation, driven by big data, providing residents with accurate personalized health services covering the entire life cycle with a people-oriented approach. The Alliance provides single-patient intelligent doctor services with "cognitive" capabilities and implements comprehensive quality supervision based on indicators such as service process, service quality effect and patient responsiveness. At the same time, it will build a medical big data operation platform and a medical cloud ecosystem based on the construction of medical information "high-speed rail", active health big data integration, and independent controllable security system.





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- Neusoft Medical's "Belt and Road" medical imaging diagnosis integrated service application practice;
- Hunan Provincial People's Hospital and Xikang "Internet + Nursing Service";
- Ningbo Municipal Health Commission and Xikang "Ningbo Cloud "Hospital Platform";
- Shengjing Hospital Affiliated to China Medical University and Neusoft Hanfeng "Shengjing Hospital 5G Smart Hospital";
- Zhongguancun Digital Health Industry Relies on **Zhongguancun Internet and Mobile Internet** Health Industry Chain Leading Enterprises to Realize Operation

5.6 Strengths and weaknesses in China

Strengths

- Widespread adoption of new technologies such as mobile devices, cloud computing, and big-data analytics
- Access to high speed internet, is increasingly
- Mature market on digital solutions everything from remote patient monitoring to drug purchasing
- Development of the EMRs and improvement of the hospital information systems
- Large amount of data that can be used to fully exploit the information that may be used for disease prediction and diagnosis
- Existence of important networks in the field of digital health in China which work coherently as the mainstay of digital health-care in China.

Opportunities

- Chinese government's continued effort to address long-standing inefficiencies and unmet needs within the healthcare system: effort that digital healthcare will help to advance
- Increasingly favourable regulatory environment to promote digital medicine
- Integration of Chinese and Western medicine can better promote the development of digital health including remote areas

Weaknesses

- Some inefficiencies in the Healthcare system: lack of resources for elderly, management of the utilisation of the facilities (over-utilisation of large hospitals and the underutilisation of smaller facilities) ...
- Compared with Western countries, the quality of healthcare in China is still lagging behind
- Unbalance between urban and rural areas: high-quality medical resources are mainly concentrated in large cities, including qualified doctors and medical equipment.

Threats

- Cultural barriers regarding the elderly care system
- Great challenges to the promotion of digital health in rural areas: medical standards are extremely underdeveloped, the medical system is very imperfect, residents' awareness of health management is weak, and active medical treatment is poor





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6 Digital health and AHA: Panorama and priorities in Japan

Japan is one of the most aged countries in the world. In 2018, 28% of Japan's total population (124.66 million) was 65 years and older⁹¹. The aging ratio of Japan is predicted to be continuously growing to 30.0% (2025), 35.3% (2040), and 38.1% (2060)⁹². As a result, all key questions about aging are more pressing in Japan.

Advancements in medicine, technology and social systems including the universal coverage of both health insurance and long-term care insurance for the elderlies have enabled Japanese people to live longer. Average life expectancy that was 81 for males and 87 for females (2017) is predicted to increase to 85 for males and 91 for females (2065). However, extension of life expectancy does not always mean extension of healthy life expectancy. Active and healthy aging always matters.

Along with the ageing population, another critical issue in Japan is the rapid declining of younger population due to the long-lasting declining of birthrate.⁹³.

The emergence of digital health in Japan seemed to be slower but has started to accelerate in the recent years, from the expectation that it will be a solution to compensate for the issues such as labor shortage due to the declining birthrate and ageing population. The government has begun to change regulations restricting activities like virtual care and telehealth, and ministries such as the Ministry of Economy, Trade & Industry (METI) as well as the Ministry of Health, Labor & Welfare (MHLW) are beginning to support investments in health tech start-ups.

6.1 Digital health R&I priorities

In terms of human and financial resources devoted to R&D, Japan is the third largest country in the world.⁹⁴ About 80% of the research expenses is spent by private companies, 11.5% by academics, 7.8% by governmental agencies, and 1.3% by non-profit organizations.

Especially within the health care field, Japan has a highly socialized system with a universal coverage both of health insurance and long-term-care insurance for the elderlies. Since both insurances are being funded mostly by the government (shared partially by the employers) with the total price control with fee schedule set by the national government, the industries of medical care and long-term care are highly regulated by the government.

Because of this situation, regarding the R&I in healthcare and senior care, all the players including the private sector tend to focus their R&D effort in line with the government's strategies and policies. In another words, it can be said that the influence of governmental leadership and/or policy is strong in Japan.

⁹⁴ <u>https://www.oecd.org/sti/inno/researchanddevelopmentstatisticsrds.htm</u>





⁹¹ <u>https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/kakutei19/dl/15_all.pdf</u>

⁹² https://www8.cao.go.jp/kourei/whitepaper/w-2019/html/zenbun/s1_1_1.html#:~:text

⁹³ https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/kakutei19/dl/15 all.pdf

The Prime Minister's Office has published the policy paper *"Health Care Strategy for 2020 - 2024"* on March 27, 2020^{95} .

According to the Health care strategy, the goal to be accomplished by 2024 is to extend the lifeexpectancy for both male- and female-Japanese by 3 years (and these three years must be active and healthy ones).

In order to realise this, the Japanese government will (1) establish the Promotion Headquarter on to set the comprehensive strategy for R&I in the medical field by inter-ministries unify and management of the related budgets of each ministry⁹⁶, and also will (2) make AMED (Japan Agency for Medical Research and Development) manage centrally all the R&D from the basic research to commercialization.

The 2020-2024 Priority Research Topics/fields for health care in Japan are:

- 1) drug discovery;
- 2) medical devise and healthcare;
- 3) regeneration/cell medicine, and gene therapy;
- 4) genome data infrastructure;
- 5) disease basic research;
- 6) seeds-development and research infrastructure.

R&D of digital technologies shall be included in all the topics.

More ambitious and longer-term research topics that seem to be difficult but are very impactful when accomplished are set as **"Moonshot" (Japan's research and development programme) projects**.

The biggest focus of the Moonshot projects are:

- (1) to develop the technologies that can guarantee/protect universal coverage to all Japanese
- (2) to develop the technologies that can control our body to improve our quality of life.

On the other hand, the field (2) will require more vast R&I, such as how to reduce the medical cost, how to close the medical gap between the urban area and rural area, how to eliminate labor-shortage in the future caused by declining the young population, and so on. It is needless to say that digital solutions are key.

In terms of policy for digital technologies in Japan, a new AI strategy 2019 was developed focusing on measures that Japanese government should immediately take concerted action on: AI for Everyone:





⁹⁵ https://www.kantei.go.jp/jp/singi/kenkouiryou/suisin/ketteisiryou/kakugi/r020327senryaku.pdf

⁹⁶ <u>https://www.kantei.go.jp/jp/singi/kenkouiryou/</u>

•>

People, Industries, Regions and Governments⁹⁷. The main principle behind is the "Social Principles of Human-Centric AI".

"Health, Medical Care, and Long-term care" was one of the 5 top priority areas. The medium and long-term goal is to achieve better health for the public, improved levels of medical and long-term care, and an improved working environment for health-related workers while simultaneously reducing the burden on taxpayers.

Specific objectives regarding the priority area "Health, Medical Care, and Long-term care" are:

- Provision of a data infrastructure for utilization of AI in the health, medical care and long-term care fields: smooth and fair use of anonymously processed medical information, accumulation of various data and establishment of an AI data infrastructure, creation of a system for collecting data (living laboratories)
- Promotion of AI technology development in medical fields in where Japan has strengths and reducing the burden on healthcare workers through AI utilization for medical treatment: medical devices and telemedicine services, early detection and diagnosis technology, drug discovery and development, toxicity evaluation....
- 3. <u>Promotion of the introduction of AO / IoT technology to the field of prevention and long-term care, and reducing the burden on care workers by using AI / IoT for long-term care: building a support system for AI start-up business in the prevention and long-term care field, examination of the provision of health maintenance / promotion services by the private sector...</u>
- 4. <u>Formation of the world's leading medical AI market and medical AI hub</u>: strengthening collaborative research such as AI development between companies and public institution, strengthening efforts for cooperation with overseas (in particular ASEAN members states and India through the Asia Health and Wellbeing Initiative) regarding data infrastructure, AI medical care...
- 5. <u>Education using AI in training facilities and training centers for medical professionals, and</u> <u>recurrent education for healthcare workers</u>.



A Japanese representative of a major AI lab and company specialised in digital health application who was consulted, suggested that the Japanese government believes that digital technology will reduce costs: "As you know, Japan has very attentive national healthcare and elderly care insurance system, and the cost of the system is increasing

very rapidly. Hence, I think that the Japanese government strongly expects digital healthcare technology to reduce the cost and make the system sustainable."

He also suggested that digital technology including AI can contribute in various aspects such as discovering new drugs, new personalized medical care methods, supporting doctor's diagnosis, detecting and preventing frailty in the elderly people, and recommendation of healthcare activities.

⁹⁷ <u>https://www8.cao.go.jp/cstp/english/humancentricai.pdf</u>





6.2 Main challenges related to digital health

Despite Japan being at the forefront of technology and innovation, and also having long successful history of nationalized senior care services along with the universal health care services, the emergence of digital health in Japan has been, overall, slower than in other countries (e.g. the US) but it has started to accelerate in recent years.

On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the three main challenges related to digital health are:

- 1. Lack of inter-sectorial collaboration
- 2. Regulation
- 3. Conservative attitude of the medical professionals

Major Challenges are (1) lack of inter-sectorial collaboration in R&I especially between the developers and or engineers of new technologies and the users (both health service providers and consumers of their services), (2) rigid governmental regulations from certification/approval process to application and pricing of new technologies, and (3) the conservative attitude of the medical professionals.

Lack of inter-sectorial collaboration

It is said, in general, that the reason for the delay of the digitalization on healthcare field is on the one hand that researchers and engineers do not understand the real needs and workflows of the careproviders and the patients as the end-user of the services, and on the other hand, the users do not understand which technologies are available and how they can get benefit by adopting them. This is true for Japan as well especially in the senior care sectors. Collaboration between the healthcare and IT sector is currently underway.

Another sectionalism exists among governmental agencies. The "digital health" is under the jurisdiction of the Ministry of Health, Labour and Welfare (MHLW), the Ministry of Economy, Trade and Industry (METI) and the Ministry of Internal Affairs and Communications (MIC). Since recent times, it is also under the jurisdiction of the Prime Minister's Office and the Cabinet Secretariat. Related to research, the Ministry of Education is another player. Since the basic roles of these Ministries are slightly different, the directions of policies are slightly (or in some cases critically) different to one another. The budget (and the governmental leadership along with the budget) is also separated ministry by ministry. Without having strong leadership and inter-sectorial collaboration, Japan cannot make real innovation to happen.

In the recent years, the awareness of such issues and problems has been deepened, and solutions have been sought through collaboration between ministries and agencies. One of them is the establishment of AMED (Japan Agency for Medical Research and Development) in 2015 aiming to promote integrated R&D from basic research to practical application with the fund collected from all the related





ministries⁹⁸. Furthermore, AIST (National Institute of Advanced Industrial Science and Technology), as part of METI, will help grantees make inter-industry collaboration with other sectors, especially closer to the commercialization⁹⁹. Another effort includes start-up support programs by MHLW and METI that will connect start-ups to the bigger corporations, health service providers (potential test-beds and service users) and VCs and so on¹⁰⁰.

Regulation

Japan used to be known for a complex and costly regulatory system. Registering products with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) was said to



"Providers have been mentally blocked by regulations" – Expert in Digital Health from Japan

be slow and a notorious stickler for details. Japan was criticized because it required more detailed data including raw data, lab records, and testing facility calibration records and so on and it took a few months more for the applicants to prepare. This long review and approval process for new technologies was often criticized as a high barrier for the development of new technologies and also as a hindrance to innovation.

In 2017, deregulation was enacted by MHLW to speed up part of the drug/medical devise review, and since then, the review process has been shortened for drugs/medical devises that meet certain conditions¹⁰¹. This deregulation has been benefiting not only domestic groups but also foreign groups.

Conservative attitude of the medical professionals

It might be perceived as contradictory, but in fact, the strong opposition to the promotion of digital health in Japan, so far, came from Japan Medical Association (JMA), one of the most powerful pressure groups to the policy makers. JMA has been opposing against



Administrative sectionalism, so called "vertical administrative wall of governmental offices" used to be the biggest problem in Japan – Governmental stakeholder from Japan

from the introduction of EHR in 1990s to the introduction of telehealth in 2000s. Even under COVID-19 pandemic, JMA was hesitant to introducing tele-consultation and stated that online treatment has to be limited to supplementing face-to-face medical care by doctors¹⁰². This very conservative attitude of the medical doctors is one of the biggest challenges for digital innovation in Japan.

¹⁰² <u>http://www.med.or.jp/nichiionline/article/009648.html</u>





⁹⁸ https://www.amed.go.jp/en/

⁹⁹ https://www.aist.go.jp/index_en.html

¹⁰⁰ MEDISO by MHLW: <u>https://mediso.mhlw.go.jp/en/</u> Healthcare Innovation Hub by METI: <u>https://healthcare-innohub.go.jp/?lang=en</u>

¹⁰¹ <u>https://www.mhlw.go.jp/content/11120000/000666236.pdf</u>

https://www.mhlw.go.jp/hourei/doc/tsuchi/T200901I0170.pdf

6.3 Specific challenges for the ageing population

Japan's aging has progressed rapidly. Aging speed is usually being compared by how many years it takes to get from aging ratio 7% to 14%. France took 115 years, Sweden 85 years, USA 72 years, UK 46 years, Germany 40 years and Japan took only 24 years (from 1970 to 1994). This speed itself has been the challenge for Japan, but Japan has been dealing with this unprecedently drastic change of the social demographics so far, so well.

On the other hand, what cannot be overlooked is, Japan's long-lasting declining birth rate that is accelerating Japan's rapid aging. It is estimated that the number of births will continue to decline and younger generation (0-14 years old) will fall to 89.8 million in 2065 that is about half of the present level. The working-age population that is estimated to be 45.29 million in 2060. It means that 1.3 working-age should support 1 senior (65 years and older)¹⁰³.

Japan faces a rapid increase in social security costs, and a decline in the workforce and shortage of healthcare and long-term care workers even though the Japanese government has been planning for this demographic change since the 1990s when it introduced the Golden Plan followed by a comprehensive long-term care insurance plan in the 2000s, which everyone above the age of 40 pays for ¹⁰⁴.

These challenges make Japan one of the most viable markets for new innovations for AHA-tech sectors. Japan, as the world's second largest healthcare market with almost a third of individuals in Japan being aged 65 or over and with 2.1 million being over 90, could be attractive to the innovators world-wide.

Four main challenges for ageing populations in Japan include:

- 1. Dementia care
- 2. Labour shortage of the healthcare and long-term care
- 3. Control of medical and long-term care expenditures
- 4. Isolation and poverty of the Japanese ageing population

Dementia care

Japan is the country in which population aging has advanced the most, thus dementia is a critical issue: according to simulated figures released by the Ministry of Health¹⁰⁵, in 2018 one in seven elderlies had dementia, and it is predicted that by 2025 one in five will have it in Japan. Concerning dementia care, one of the biggest challenges in Japan is not a medical one, but rather cultural. Today, many (not only a few) people in Japan still think that having dementia themselves or having someone with dementia in their family is embarrassing. This feeling creates a barrier and often refrains people from getting professional support. Japanese are eager to learn dementia care from EU and other countries.

¹⁰⁵ https://www.mhlw.go.jp/content/12300000/000519620.pdf





¹⁰³ <u>https://www8.cao.go.jp/kourei/whitepaper/w-2019/zenbun/01pdf_index.html</u>

¹⁰⁴ https://www.mhlw.go.jp/english/

Labour shortage of the healthcare and long-term care

With fewer young people and with little tradition of immigration into Japan, labor shortage is a significant issue, across the industries, but especially **for the hospital and nursing home industries**. As a solution, **robotics and other ways to automate daily care provision** is seen with huge interest, although this is still in an early phase. Care robotics to support/assist and/or substitute care givers is one of the areas that are starting to have investment. Al assisted sensor/monitor system is also widely inquired, expecting for reducing the burden of the caregivers. What cannot be forgotten is the platform that is the basis for realizing all these digital solutions, however, in Japan, the infrastructure development is pretty behind in health care industries comparing to the other, and far more behind in long-term care fields.

Control of medical and long-term care expenditures

Japanese health-care system provides universal coverage, with medical care and long-term care (both facility care and in-home care services) insurance systems. Despite the strict price control by the government, Japan's health expenditure is growing. Various factors are influencing the surge¹⁰⁶. One of Japan's ambition is home care and regional care instead of hospital care nor nursing homecare. The technologies considered to push this trend forward are: high-speed internet almost all around Japan with more/better WiFi access, and (AI assisted) sensors and tele-health services on it. Regarding reimbursement, telehealth has been deregulated (even still pretty much limited, though) to be financed by the insurance in 2019 and the sensors in nursing homes have been expected to be getting financed soon.





Isolation and poverty of the Japanese ageing population

In the 1960s over 87% of seniors lived with their children but now that number is below 50% and falling. The change is exacerbated by the low overall population growth and increase of number of "singles throughout life". Concerns about increases in loneliness, isolation, and the feeling of abandonment has become widespread. A 2017 New York Times article reported on the numerous

 ¹⁰⁷ https://www.bloomberg.com/news/articles/2018-12-13/health-care-paradox-threatens-to-add-to-japan-s-debt

 problems





This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

¹⁰⁶ <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5951584/</u>

Japanese elderly that die every year without anyone even noticing it, in a modern phenomenon known as kodoku-shi (孤独死, "solitary death")¹⁰⁸.

The charts show the number of isolated deaths (left) and the number of days passed before the death was discovered (right) in Tokyo in 2017. Vertical axis shows number of deaths and horizontal axis shows age (left) and days to be found (right) by sex (male=blue, female=red)¹⁰⁹. The community collapsed or at least, there was no community for these people to be a part of.



Figure 5: Number of isolated deaths (left) and days passed before the discovery (right)

These issues are also related to poverty among senior citizens. There is a "five-year gap" between the retirement age from the employment sector (60) to the beginning of pensions (65). Many of these "solitary deaths, especially of males, are observed among those in their early 60s. This indicates an urgent need to create co-working opportunities between the young and the elderly.

Both central and local governments of Japan have been working on measures, however the number is still growing.

The challenges referenced above provide a great opportunity for digital Health solutions and preventive technologies for the elderly populations. There is a critical need for technologies that are more personalized, promote senior engagement and inclusion, and technologies that focus on the unique needs of the senior. Technology provides an opportunity to support the elderly in the physical absence of their family and caregivers.

Traditionally, Japan is very good at "taking care" of the elderly, but comparatively weak in "supporting their independency" services for the elderlies. This attitude is reflected by the R&D of digital health: most of the



"How to support the independencies of the elderlies themselves is going to be the future issues and problems" – Expert in Digital Health from Japan

technologies and services developed for the elderly are to support the care givers of the elderlies, not

¹⁰⁹ <u>https://www.fukushihoken.metro.tokyo.lg.jp/smph/kansatsu/kodokushitoukei/kodokushitoukei29.html</u>





¹⁰⁸ <u>https://www.nytimes.com/2017/11/30/world/asia/japan-lonely-deaths-the-end.html</u>

to support the elderlies themselves. However, thinking in the context of "healthy and active aging", Japan should shift the focus more to the technologies and services to support elderlies themselves.

6.4 Relevant key programmes and funding agencies

There are various public players in the Japanese R&I domain that are actively working on helping the elderly through initiatives and projects aimed at supporting senior citizens in their day to day lives. There is no direct equivalent to the US NIH's National Institute on Aging, but similar functions and funding are spread across various ministries. Some noteworthy stakeholders are:

Ministry of Health, Labour and Welfare (MHLW)

Ministry of Health, Labour and Welfare (MHLW) sets both policy and fees for all medical care and long-term care in Japan, and also funds much of the basic medical research mostly through AMED but also independently by ministry-self. In 2017, it implemented significant deregulation to shorten the review process for drug and medical device approval¹¹⁰. In 2019, conditional reimbursement for virtual-visit by telehealth-system has begun and deregulation has been progressed in COVID-19 pandemic¹¹¹. MEDISO (Medical Innovation Support Office) established by MHLW in 2017 has been providing start-ups and entrepreneurs in healthcare field with "one-stop" service from whole MHLW and also outside-collaborators including potential service users, corporations, academia, and investors¹¹²

Ministry of Economy Trade and Industry (METI)

Ministry of Economy Trade and Industry (METI) succeeded the famed Ministry of International Trade and Industry (MITI) which was responsible for setting much of Japan's economic and industrial policies in the glory years of "Japan Inc" during the 1960s-1980s. While it does not have its predecessor's power, METI is creating programmes for start-ups including in the health sector as well as holding a promotional health technology business contest.¹¹³ It also organised the "Well Ageing Society Summit Asia-Japan (WASS)" in Tokyo in October 2018¹¹⁴, in collaboration with the Office of Healthcare Policy (Cabinet Secretariat), the MHLW, the Japan Agency for Medical Research and Development, the Life Science Innovation Network Japan and Aging Japan. The Summit has been being holded every year aiming at showcasing Japanese healthcare. METI also established "Helathcare Innovation Hub (inno-Hub)" to provide "one-stop" service to start-ups and entrepreneurs in 2018¹¹⁵.

Ministry of Internal Affairs and Communications (MIC)

Ministry of Internal Affairs and Communications (MIC) is regulatory ministry related to information and communication. It's not well known to the general public, it also has jurisdiction over the communication band used by digital devices¹¹⁶.

¹¹⁶ https://www.soumu.go.jp/menu_syokai/index.html





¹¹⁰https://www.mhlw.go.jp/file/05-Shingikai-11121000-Iyakushokuhinkyoku-Soumuka/0000123357.pdf

¹¹¹ <u>https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/rinsyo/index_00010.html</u>

¹¹² https://www.mhlw.go.jp/stf/newpage 07452.html

¹¹³ <u>https://www.meti.go.jp/english/press/2018/0118_002.html</u>

¹¹⁴ <u>https://was-summit.com/english/</u>

¹¹⁵ <u>https://www.meti.go.jp/policy/mono_info_service/healthcare/innohub.html</u>

Japan Agency for Medical Research and Development (AMED)

Japan Agency for Medical Research and Development (AMED) is a research funding agency introduced in 2015 and modelled after the NIH in the US. AMED functions as a redistribution agency for R&I budget collected from several ministries. Annual budget (FY2018) was JPY126.6 Billion¹¹⁷.

Pharmaceuticals and Medical Devices Agency (PMDA)

Pharmaceuticals and Medical Devices Agency (PMDA) is the Japanese regulatory agency responsible for the safety and quality of pharmaceuticals and medical devices.

6.5 Most important players and networks in the field

Japan has been trying hard to create an important industrial ecosystem active in the development of digital solutions for healthy ageing.

Most actors in the healthcare tech sector are big non-life science players¹¹⁸, mostly companies from the telecom industry, electronic industry, or promising start-ups. Each of the three major mobile communication companies in Japan (NTT Docomo, KDDI and SoftBank) has set up a subsidiary or business unit to offer services for health monitoring apps and wearables. Also, any of the major insurance companies have invested in new services focused on digital health. Among the insurance giants, the leader of digital transformation is Sompo Japan. it established "Sompo Digital Labs" in Tokyo, San Francisco, and Tel Aviv to identify the excellent seeds for them to invest, incubate and accelerate them¹¹⁹.

According to the research by Tracxn, in Japan, 164 health tech start-ups have been identified in December 2019¹²⁰. There are several Japanese start-ups which are expected to disrupt the market, such as Micin Inc., which operates the leading telehealth platform Curon, and Triple W Japan, award winner from METI, which has developed a wearable ultrasound device called DFree that can monitor and predict urinary excretions. Both have raised sizable investments from major Japanese corporates including Mitsubishi Corporation and Nissay.

Life Science Innovation Network Japan (LINK-J) is an association funded in 2016 to promote and support open innovation by creating networks and an ecosystem in the life science realm. It provides its members with acceleration program support, experts' counselling and various events¹²¹.

Research organizations specialized in gerontology include **the Tokyo Metropolitan Institute of Gerontology¹²²**, established in 1972 to promote interdisciplinary aging research, the **National Centre for Geriatrics and Gerontology¹²³**, founded in 2004, and the **Japan Gerontological Society**¹²⁴. University research centers and research projects specialized ageing issues have been more and more

¹²⁴ http://geront.jp/en/index.html





¹¹⁷ <u>https://www.amed.go.jp/en/</u>

¹¹⁸ <u>https://swissbiz.jp/wp-content/uploads/2018/01/sge_healthcaretech_japan_infographic.pdf</u>

¹¹⁹ https://sompo.io/en/

¹²⁰ https://tracxn.com/explore/HealthTech-Startups-in-Japan/

¹²¹ https://www.link-j.org/en/

¹²² https://www.tmig.or.jp/

¹²³ https://www.ncgg.go.jp/english/

active recently. Smart Ageing Reseach Center of Tohoku University has been focusing on dementia and has been actively working with EU groups for Horizon 2020 Project¹²⁵. The Institute of Gerontology of the University of Tokyo was established in 2009 under the President's office for the comprehensive and interdisciplinary R&I in the field¹²⁶.

Several of the larger regional governments and cities are also now promoting new technology initiatives. For example, **Köbe-city** has a programme to promote start-ups working with the American accelerator 500 start-ups¹²⁷. Kanagawa prefecture, under the leadership of the Governor Kuroiwa, has been promote "Me-Byo" (pursuing AHA with preventive services)¹²⁸. Kawasaki-city, as one of the "national strategic special zone", has been actively recruiting the medical/life-science companies to the zone, which is located close to Tokyo/Haneda International Airport, to create the center of cutting edge medical businesses¹²⁹.

6.6 Strengths and weaknesses in Japan

 Strengths Advanced digital technology market Governmental leadership Strategic investment in digital health research and development Universal Coverage for Medical and Long-Term Care Well-trained Professional Caregivers 	Weaknesses Healthcare labour shortage Regulation Conservative Medical Professionals
Opportunities Growing population of elderly Global commercialisation opportunities Well-educated Consumers Healthcare labour shortage world's second largest healthcare market technologically advanced population system 	Threats Increasing social isolation Frail population Dementia Sectorialism

¹²⁹ https://www.city.kawasaki.jp/590/page/0000063513.html





¹²⁵ http://www.idac.tohoku.ac.jp/saro_site/

¹²⁶ http://www.iog.u-tokyo.ac.jp/?page_id=22&lang=en

¹²⁷ http://jp.500kobe.com/

¹²⁸ https://www.pref.kanagawa.jp/docs/mv4/me-byo_style/index.html

7 Digital health and AHA: Panorama and priorities in South Korea

Korea is a super-aged society with 22.8% of all households being aged 65 or older in 2020, and about half (49.6 percent) of all households are expected to be elderly by 2047¹³⁰. According to the National Health Insurance Corporation, the causes of death for those aged 65 or older in 2019 are cancer (750.5), heart disease (335.7), pneumonia (283.1), cerebrovascular disease (232.0), and diabetes (87.1).¹³¹

The life expectancy of Koreans is foreseen to reach 90.8 years for women and 84.1 years for men by 2030. The average life expectancy of Koreans was 82.5 years between 2015 and 2020, 114.1% higher than the global average of 72.3 years.¹³²

Korea's super-aged society is expected to undergo the following changes in terms of social structure and lifestyle. First, in terms of production infrastructure, it can be assumed that the productive population and number of skilled workers will reduce, and that the working class will be diversified. In addition, in terms of social infrastructure, it is expected that residential infrastructure will age, urban density/farming villages will become more common, and increased infrastructure complexity and infrastructure digitalization will be achieved. In terms of social service infrastructure, demand for convenience of living environment, and demand for care services, such as health care services, safety services and lifelong education services are expected. It is also predicted that the expanding number of elderly people in need of care, such as the poor, those who live alone, and those with dementia, will increase the financial burden by causing an increase in support and welfare costs as well as causing a shortage in the labour force, undermining the nation's growth.

Therefore, digital healthcare service technologies, such as robots, bioengineering and Artificial Intelligence, should be utilized to replace the existing labour-based care for personalized senior care services. Also, it is crucial to establish policies to cope with the aged society and to enhance digital healthcare businesses. Indeed, considering the social gaps and the characteristics of generational diversity, it is necessary to establish R&D strategies to pursue in an ultra-aging society. Currently, more and more people intend to improve their quality of life, reduce social costs, and help to build social infrastructure through digital healthcare in Korea.

7.1 Digital health R&I priorities

The South Korean government announced its **policy on bio-health innovation in 2019** and stated that it will **increase government R&D investment to develop innovative new drugs and medical devices by more than 4 trillion won annually by 2025**¹³³, aiming to "resolve national health and medical

 ¹³¹ The Health Insurance Review and Assessment Service, 2019 <u>https://www.hira.or.kr</u>
 ¹³² National Health Insurance Statistical Yearbook, Statistics Korea, 2020
 <u>http://kostat.go.kr/portal/korea/kor_nw/1/1/index.board?bmode=read&aSeq=385322</u>
 ¹³³ KHIDI Brief, 2019. <u>www.khidi.or.kr</u>, <u>http://www.khiss.go.kr</u>1 Vol. 305





¹³⁰ 2020 Elderly Statistics. Statistics Korea, 2020 http://kostat.go.kr

problems by realizing people-centered innovative growth and strengthening public-interest R&D investment.".

On December 16th, 2020, the Ministry of Health and Welfare (MOHW) decided to provide a total of 527.8 billion won in R&D budget and finalized an integrated implementation plan. The MOHW's major R&D budget for 2021 is 527.8 billion won, up 13.0 percent or 60.9 billion won from the 2020 budget. The implementation plan targets 52 projects, including research and development of pan-ministerial electric medical devices, research and development of dementia eradication and treatment technologies, and plans to provide 149.5 billion won for new tasks and 378.3 billion won for continuing tasks.¹³⁴

South Korea, being one of the leading countries in the IT world, foresees its digital healthcare industry to also continuously grow. It is not easy to clearly understand the growth of South Korea's digital healthcare industry. Specifically, considering the trend of venture investment in medical and bio sectors, including smart healthcare as a proxy variable, the domestic digital health care industry can expect to cause an increase in tax. According to Venture Capital Market Brief of the Korea Venture Capital Association¹³⁵, many venture capitalists pointed to digital healthcare as a promising area for the future, and the trend of expanding investment is expected to continue. It seems that there will be a possibility of expanding investment in medical devices, bio and pharmaceutical sectors along with Internet of Things and software in the future.

There are **four major strategies (which can be considered as priorities)** and seven major directions as per the MOHW's implementation plan, as follows:

- 1. Innovating the bio-health industry
- 2. Strengthening public-interest R&D investment,
- **3.** Creating a hospital-based research ecosystem, and supporting localization of materials, parts and equipment
- 4. Supporting localization of materials, parts and equipment

Strategy 1. Innovating bio-health industry

- To foster the bio-health industry, the company will focus on supporting next-generation promising technologies such as innovative new drugs, medical devices, and regenerative medicine (KRW 59.2 billion out of a total of KRW 128.1 billion)
- It actively supports medical technologies based on the fourth industrial revolution, such as the establishment of 'National Bio Big Data', artificial intelligence, and precision medicine, which are worth 1 million people (about 5.1 billion won out of 58.8 billion won).

¹³⁵ http://www.kvca.or.kr/en/





¹³⁴ 2020 integrated implementation R&D plan <u>http://www.mohw.go.kr/eng/index.jsp</u>

Strategy 2. Strengthening public-interest R&D investment

- Developing diagnosis and treatment technologies and applying and expanding local communities to solve social problems such as new and mutated infectious diseases, dementia, and mental illness (KRW 23 billion out of KRW 104.1 billion)
- National health promotion R&D is carried out to reduce medical expenses and preventative health care, such as rehabilitation and care services for the medical vulnerable, chronic diseases, and development of service models for health care by life cycle (KRW 21.4 billion out of a total of KRW 102.2 billion).

Strategy 3. Creating a hospital-based research ecosystem

- The government will focus on fostering hospitals as a hub for innovation in the research ecosystem, including the establishment of a hospital-oriented joint research foundation (platform) that can be utilized by industries, universities, research institutes, and hospitals (out of a total of 67.4 billion won, 10 billion won for new tasks)
- Train key health and medical personnel who will drive innovative growth, including support for collaborative research between clinicians and researchers and companies in connection with leading research institutes abroad (KRW 1.7 billion out of a total of KRW 19.2 billion)

Strategy 4. Supporting localization of materials, parts and equipment

• Self-development of vaccines highly dependent on foreign countries, strengthening support for localization, including basic materials for imported-dependent cosmetics and assistive devices for the elderly and the disabled (KRW 29.1 billion out of a total of KRW 44.8 billion)

In addition, since the establishment of the Presidential Committee on the 4th Industrial Revolution (Nov. 2017), the Korean government has significantly expanded its support for DNA (Data, Network and AI), announcing various policies including: AI R&D Strategy (May 2018); Data Industry Activation Strategy (June 2018); System Semiconductor Strategy (April 2019); 5G+ Strategy (April 2019); and Manufacturing Renaissance Strategy (June 2019).

In particular, the Korean government adopted a **government-wide National Strategy for Artificial Intelligence** (this is the latest policy in the field up to 2020) under the vision of "Toward AI World Leader beyond IT" in an effort to give



"Data platforms and AI services that connect medical professionals and patients are also constantly increasing." – Expert in Digital Health from Korea

shape to the "Presidential Initiative for Artificial Intelligence (Oct. 2019)" announced by President Moon Jae-in. The strategy focused on maximizing the national strengths of the country such as the world's best ICT infrastructure and semiconductor and manufacturing technology (1st in market share in memory semiconductor), high education level (1st in higher education completion rate of young people in OECD countries), and high acceptance of new technology (1st in the world of smartphone penetration rate).

Bio and Medical is consider as a key sector of diffusion of the AI technology.







Figure 6:Expected effect of utilizing AI in each Sector

The main objectives are to establish the phased new drug development AI platform at each stage (~2021), supporting for medical data-oriented hospitals and field demonstration of medical AI services and products (2020~); and to establish sample data and professional review system for clinical verification of AI-based medical devices (~2021). Concretely:

- Dramatically reducing the new drug development period (15 years \rightarrow 7~8 years) through establishing the phased new drug development AI platform (~2021)
- Building a dataset and AI development ecosystem centered on medical institutions, such as medical data-oriented hospitals* and field demonstration of medical AI services and products (2020~)
 - Support by designating hospitals with medical research capabilities, establishing medical data production and utilization, and information systems (May 2020).
 - Support empirical research of various medical services such as emergency response, medical voice support, patient counselling.
- Improving the quality of AI medical devices and reducing time required for commercialization from three years to one year by establishing standard data for clinical verification and a professional review system (~2021)

Into the ambition "Building the Best-performing Digital Government", the healthcare system is also mentioned as Public Services. For example, welfare for the elderly is identified as key area for introducing AI technology, with innovative services aiming at care and nurse the elderly and dementia patients and supporting physical activities.¹³⁶



An expert from Korea suggested that Korea already has clear policy support and guidelines for personal information protection in response to changes in the digital environment. However, ethics remains an important issue in the field of digital healthcare. Korea is starting a national bio big data construction project and the

government's efforts to seek individual consent to share individual medical information are being strengthened, so digitalization is expected to proceed rapidly in the healthcare industry.

¹³⁶https://www.msit.go.kr/cms/english/pl/policies2/__icsFiles/afieldfile/2020/03/23/National%20Strategy%20for%20Artific ial%20Intelligence_200323.pdf




7.2 Main challenges related to Digital Health

The definition of digital healthcare in South Korea is the healthcare that applies and uses ICT technology for individual long-term care. Digital healthcare includes services and products for the prevention, treatment and cure of diseases, for healing and improvement of wellbeing, and further, pursuit of individual happiness.

In South Korea, it is difficult to industrialize innovative digital healthcare technologies due to complex and redundant certification procedures, hardware-oriented certification procedures, inflexible regulations, and a relatively small market in Korea. Therefore, innovative SMEs want to make inroads into overseas markets where they have relatively better chances to connect global business platforms and have less complications on conducting a new business.

On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the main challenges related to digital health relate to:

- 1. Certification procedures
- 2. Small market size
- 3. Research at the level of industrial linkage

Certification procedures

In the technology aspects, we should prepare future products & services using AI technology, **not only with engineering parts, but also with non-IT parts**. It is necessary to **build rules and standards for AI technology, considering human based needs and knowledge**. For example, in 2015, South Korea hosted Health 2.0 Conference in Seoul. The "Happiness IT Platform" concept was introduced, trying to verify human needs and to link to the right contents and services for enhancing people's individual wellbeing and happiness. As well, the idea that all need to share ideas and database related to elderly in order to develop physical/longevity age, wellness score, and other senior indexes as managing and caring standards for elderly's health and happiness have been discussed.

Small market size

It has been forecasted that 'age-friendly products' will contribute greatly to reducing social risks and improving quality of life in a super-aged society. However, for domestic markets, digital healthcare products are not fully utilized yet due to the nation's relatively



"The market in Korea is too small. I hope Korean SMEs with superior technologies cooperate with the world." – Expert in Digital Health from Korea

small market size, so that it is not possible to produce various pilot products for each individuals' needs. Indeed, there are insufficient empirical and standardized data for elderly, such as clothes and shoes sizes that considering senile physical features, and cognitive standards to manage their healthy conditions. Therefore, in order to develop innovative technologies to provide personalized services for the elderly, it is necessary to build up a 'senior index' by utilizing data in aged society. In fact, more





innovative R&D projects that will contribute to uncovering and reducing major risk factors in Korea's aging society are needed in the near future. The interconnection between risk factors and various environmental changes that add to the risk of an aged society should be considered as well. In this regard, it is necessary to address not only social care problems, such as poverty among senior citizens and the rising suicide rate, but also the enhancement of their mental health.

Research at the level of industrial linkage

Interviewees have cited several contributing factors on digital healthcare in Korea. There are regrets about existing science and technology policies and research at the level of industrial linkage. In terms of industrial links, expanding the research and development and policies, advancing and improving toward 'user-friendly interface' is insufficient.

7.3 Specific challenges for the ageing population

South Korea is expected to become a super-aged society with more than 20% of people aged 65 or older in 2026¹³⁷. The life expectancy of Koreans is foreseen to reach 90.8 years for women and 84.1 years for men by 2030. The average life expectancy of Koreans was 82.5 years between 2015 and 2020, 114.1% higher than the global average of 72.3 years.

An increasing number of elderly people suffer from **chronic and combined diseases** in Korea. According to the Health Insurance Policy Institute in 2018, medical expenses for the elderly population are expected to reach at least 229 trillion South Korean Won (KRW) and 337 trillion KRW at the most¹³⁸. The mortality rate from cancer, ischemic heart disease, and diabetes is changing in the direction of increasing chronic disease; mainly in their 50s and after 10 years becoming chronic diseases, 3 out of 10 people are transferred to one or more hypertension, diabetes, and neurological disease.

Furthermore, there is a growing number of Koreans suffering from **depression and cognitive dysfunction in terms of mental health**. The number of dementia patients in Korea is expected to increase to 10.4% by 2020 and 15.1% by 2050. South Korea with the world's fastest-growing number of dementia patients with an increase in social costs from 11.7 billion KRW in 2013 to 43.2 billion KRW in 2050, accounting for about 1.5% of the GDP¹³⁹.

Also, South Korea's **elderly poverty** rate is 43.4%, the highest among OECD countries compared to 23.1% in US, 9.5% in Germany, 11.3% in Sweden and 3.6% in France. The suicide rate of people aged 65 or older per 100,000 people due to economic poverty and loneliness was also far higher than the OECD average of 21.7% as of August 2020, according to the Social and Welfare Statistics, and the highest among OECD countries.

On the other hand, the number of **elderly people who are highly educated** is on the rise. Since the education level of the baby boomers is significantly higher than that of the previous generation, the proportion of highly educated people among the elderly is expected to increase significantly from

¹³⁹ National Science & Technology Commission, 2018. <u>www.nstc.go.kr</u>





¹³⁷ Ministry of Public Administration and Security, 2017. <u>https://www.mois.go.kr</u>

¹³⁸ <u>https://www.nhis.or.kr/static/html/wbd/g/a/wbdga0101.html</u>

2020¹⁴⁰. Such changes are likely to lead to an **increase in demand for personalized services and higher expectations for level of service**. Nevertheless, there is also a **widening social gap between urban and rural, high and low-income, and between highly educated and less educated people**. Also, there should be more social security enough for the fast-growing low-income bracket.

On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the main challenges related to the ageing population in Korea are:

- Dementia
- Social gap in technologies acceptance
- Alignment of technology policies in R&D sector

Dementia

About 10% of the Korean population aged 65 or older are estimated to become dementia patients in Korea. Therefore, personal and social burdens are increasing as we enter an aged society.

After the age of 65, the prevalence of dementia tends to double every five years, with about 30% of those aged 85 or older reporting to suffer from dementia in advanced countries. Korea is expected to have the world's fastest-growing rate of dementia



"The mental, emotional, and social problems of the elderly is a big challenge. The number of single-person households in Korea is increasing markedly." – Expert in Health from Korea

patients: this number was 6,552,528 in 2015, and is expected to rise to 17,252,027 by 2030 and 22,362,538 by 2050. The social cost of dementia will also increase from 11.7 billion KRW (2013) to 43.2 billion KRW (2050, 1.5% of the GDP)¹⁴¹. Three out of four dementia patients aged 65 or older suffer from Alzheimer's-type dementia. As of 2015, the dementia prevalence rate for people aged 65 and older was tallied at 9.54%, or about 625,259, with the number of dementia patients expected to exceed 1 million in 2025.

About 60% to 70% of dementia patients are suffering from Alzheimer's disease, so there is a great need for solutions to prevent dementia. Indeed, there is a high demand for effective digital healthcare devices and contents to prevent and cure the disease as well.¹⁴²

¹⁴⁰ Social Welfare Statistics, OECD, 2020. <u>http://www.oecd.org/social/</u>

¹⁴¹ National Institution of Dementia <u>https://www.nid.or.kr/</u>,

(2018, 2025) https://www.nid.or.kr/info/ub_2019.aspx?no=47995

142AnnualReport2019NationalInstituteofDementia(2019):https://www.nid.or.kr/notification/activityview.aspx?boardseq=1983&page&searchfield&searchword(2019):





Types of Dementia (Aged 60+)



Figure 7: Types of Dementia (Aged 60+) in Korea

As the burden of social and economic costs of Alzheimer's increases, the development of a drug that can fundamentally inhibit the progression of the disease is becoming more important. Above all, before the treatment is developed, it is necessary to reduce dementia-related costs through preventive measures, such as a system for preventing and managing personal dementia using digital healthcare technology.

The Ministry of Health and Welfare assessed the achievements of the "Dementia National Responsibility System (DNRS)" announced in September 2017. It said that it will invest 200 billion KRW for nine years from 2020 to 2028. As a result, the Korean government plans to discover and promote various new tasks that focus on preventing dementia and strengthening care services for mild dementia patients living alone or with their families at home. The "Dementia National Responsibility System" has been working to reduce the burden on dementia patients and their families by providing customized case management, medical assistance, and extended long-term care services.

"Dementia National Responsibility System"

- Two years of implementation of Dementia State Liability System
- Two years to implement DNRS has establishment of dementia relief centers in 256 public health centres nationwide
- Continue to expand dedicated facilities for dementia; Total 130 new construction stages in five years since 2018
- The cost of neurocognitive tests (dementia tests) is lowered to less than half (300,000 KRW → 150,000 KRW)
- Invested 200 billion KRW in dementia research for nine years from 2020 (preliminary feasibility study passed)

Social gap in technologies' acceptance

The need for digital health care utilizing telemedicine and ICT to reduce costs and support personalized services is growing. However, both senior citizens and ICT service providers should foster ICT convergence for the efficient operation of digital health services. Fortunately, **the number of elderly people who use smartphones are increasing. In South Korea, the ratio of smartphone owners in their**





60s and older stood at 80.3% in 2019, up 14.8% from 2017¹⁴³. At the same time, smartphone users in their 50s and older prefer to watch YouTube using any other apps. Their activities as youtubers (one making the video) engaged in sharing political thought, exercise and healthy cooking, and beautiful sight-seeing video are also on the rise. Considering the average viewing time per person is also significant. Users in their 50s and older watched YouTube for 1,045 minutes a month. They share their experiences as "Prosumers" through YouTube. They also upload and share professional knowledge from their own experience through YouTube content, including exercise, healing, and cooking for their happy and healthy life.

However, the gaps between cities and rural areas, different income levels and between different regions are widening, and digital healthcare is not easily accessible for the low income and rural residents. Therefore, to prepare for the 2026 super-aged society, the government needs to establish strategies to support the elderly through the industrialization of welfare as well as the improvement of the quality of life for the vulnerable.

Alignment of technology policies in R&D sector

Despite the continued population growth and changes in the characteristics of senior citizens, there are problems with existing technology policies in South Korea's R&D sector. Firstly, **existing research on ageing is centred on the treatment of senile diseases. It is necessary to focus on preventing the disease, not just treatment, not only for physical illness but also mental illness.** More importantly, there is a **lack of research on mental and emotional health issues in old age**, such as senile depression and suicide. Indeed, there are challenges for lack of a holistic healthcare service system which includes not only medical fields but also Wellness (Wellbeing+Happiness) issues, such as sexual, spiritual, environmental, cultural, and social issues. It is necessary to verify knowledge about the multi-faceted abilities of the elderly, such as cognitive, academic, physical, workability, and communication skills in terms of active, happy and healthy ageing. Furthermore, R&D is being carried out on cell unit research for cell and tissue regeneration technologies, but it does not cover 'ageing' comprehensively.

7.4 Relevant key programmes and funding agencies

South Korea's overall R&D budget is 20.5 trillion won, of which the **health sector budget is 1.6 trillion won in 2019**¹⁴⁴. This This is 8.5% of the GDP in Korea.

There are **three major ministries for policy making and funding of digital healthcare** in the age of the 4th Industrial Revolution in South Korea.

- Firstly, the Ministry of Science and ICT have spent 684.4 billion won on innovative basic science and research on digital healthcare related projects in 2017¹⁴⁵.
- Secondly, the Ministry of Trade, Industry and Energy designated the bio and health industries as the top five new industries, such as big data/ new medicine and medical devices based on artificial intelligence and smart healthcare, and expanded the R&D budgeting to 205.3 billion

¹⁴⁵ <u>https://english.msit.go.kr/english/main/main.do</u>





^{143.} Broadcasting Media Behavior Survey, 2018: <u>www.kcc.go.kr</u>.

¹⁴⁴ https://www.ntis.go.kr/en/GpIndex.do

won in R&D in 2017. In addition, building public big data and easing regulations in the health care industry can be critical for companies to maintain and grow smart healthcare industries.

• Thirdly, the Ministry of Health and Welfare spent 451.6 billion won in 2017.¹⁴⁶

The Health and Welfare Ministry's major R&D budget for 2019 was a total of 466.9 billion won for 44 projects, and it increased to a total of 527.8 billion won in 2020.

The 2019 budget was mainly dedicated to fostering innovative growth engines, solving high-cost health and medical problems and addressing health threats. The budget included aiming to nurture human resources, such as bio-medical global professions and areas related to the fourth industrial revolution, such as building platforms for developing artificial intelligence for new drugs. Also, the budget increased by 14.4 billion won for fine dust diseases.

The Ministry of Health and Welfare's major R&D budget is distributed between the following five agencies:

- 1. Korea Health Industry Promotion Agency: 33 projects including patient-centred medical technology optimization research by 347.8 billion won
- Centres for Disease Control and Prevention (National Institute of Health): Seven projects including research on the development of infectious disease management technologies (74.9 billion won)
- 3. National Cancer Center: Major projects of the Cancer Institute and the National Cancer Management Business Headquarters (33.4 billion won)
- 1. High-Speed Medical Complex: High-Speed Medical Complex Building and Two Projects (5.5 billion won)
- 4. National Rehabilitation Center: Rehabilitation R&D Service Project (5.4 billion won)

In addition, the MOHW plans to carry out new long-term and large-scale flagship projects for the following items:

<u>Advanced Medical Technology</u>: Promoting precise medical and rehabilitation-related projects that can create jobs in new industries based on the 4th Industrial Revolution.

- Building Genetic Big Data to realise 'Personalised Healthcare' based on health data, Promoting 'Development of Precision Medical Data Platform';
- Expanding R&D of stem cells and regenerative medicine centered on rare and incurable diseases to lead the related industry through the enactment of the Advanced Regenerative Medical Act.

<u>High value-added industry</u>: Expanding the business related to innovative new drugs and advanced medical devices so that technology export performance will lead to full-fledged industrial growth.

• To streamline the development of innovative new drugs, the government is pushing ahead with a project to support the transfer of candidate materials, non-clinical and clinical tests, and consulting for commercialisation.

¹⁴⁶ http://www.mohw.go.kr/eng/index.jsp





 A project to develop advanced medical devices that can be customised for prevention and management by converging biotechnology with leading technology in the 4th Industrial Revolution.

<u>Reducing social burdens</u>: Expanding the project to solve the health and medical problems of large social and economic losses and suffering of the people.

- Investing in areas with high public health burden such as dementia, diabetes and cancer, and strengthening public health crisis response capabilities such as towards new infections and antibiotic resistant bacteria.
- Development of technology for localisation of ancillary equipment, such as wheelchairs, and support for the development of community smart healthcare service models and empirical research using ICT convergence technology.

7.5 Most important players and networks in the field

The digital healthcare ecosystem consists of government institutions, regulatory bodies, industry associations, medical centres, large corporations, blockchain-based healthcare service providers and a few notable start-ups and scale-ups. Key players in digital healthcare include¹⁴⁷:

- The leading local hospitals such as Seoul National University Hospital and Asan Medical Centre
- Large Korean conglomerates like Samsung Electronics and LG Electronics
- Telecommunications providers, such as SK Telecom and KT
- Systems integrators, such as LG CNS and SK CNC
- as well as start-up and scale-ups, such as H3Systems, Lunit, etc.



Figure 8: Digital Health Ecosystem in Korea

¹⁴⁷ Source: Digital Healthcare Ecosystem - Digital Health South Korea Market Intelligence Report. June, 2019: https://www.intralinkgroup.com/getmedia/3153c79b-463d-47c7-84e6-56848c98aab7/Intralink-Report Life-Sciences June





Hospitals have been exceptionally active through internal efforts in digitizing information, building internal Big Data systems, and introducing AI solutions through their own initiatives. The 'Big 5' have become leaders in the digitization of Korea's healthcare system, largely driven by the need to meet better care standards as a responsibility for servicing around 5% of all patients in the country. These hospitals are recognized as the essential cornerstones of Korea's healthcare system and benefit from government funding and designations as government research hospitals.

There are many government agencies that plan R&D projects and provide government funds for selected R&D. Most of R&D, especially health and medical related one is for Korean companies that conduct within the nation. Also, there are non-for-profits associations assigned by ministries, however, multi-functional agents and associations are very rare.

The Global SMEs Business Council (GSBC) is assigned by the Ministry of SMEs and Start-ups, and it helps innovative SMEs to go global. Usually, GSBC is directly participating in planning testbeds or pilot studies and/or studying human needs funded by domestic/international government agencies, as a project base, in order to support innovative SMEs to be participated as a global alliance member. It also may help SMEs for soft-landing abroad. GSBC has its own know-how with patents (Business Models) on how to make alliances as a team, how to evaluate function added services, and how to link to customers for their own benefits. Since it is essential that health and wellness services are to be offered as a holistic care, making rules and standards for analysing data and strategies for convergence, and planning testbeds are necessary.

Focus on the National Insurance system

- The National Health Insurance Service (NHIS) in Korea is mandatory and all citizens Koreans pay insurance premiums out of their wages¹⁴⁸. The NHIS, operated by the social insurance system, aims to solve the medical cost problem based on social solidarity, so the insurance premium is levied according to the income level and the ability to pay the premium. However, regardless of the level of insurance burden, insurance benefits are evenly distributed under the relevant laws.
- In 2017, **the 'Moon Jae-in care' policy** appeared to reduce the cost of healthcare for all citizens in Korea. The move aimed to reduce the burden on citizens for almost all diseases, including serious cancer, excluding cosmetic, beauty and health check-ups. In fact, the insurance fees in Korea are lower than the OECD average, and there is also controversy over more taxpayers' money being spent to realize the policy.
- Furthermore, the government introduced a national responsibility system for dementia patients. It covers medical expenses for senior citizens, such as precision neuro-awareness tests and imaging tests needed to diagnose dementia. Indeed, it covers medical care expenses for severely ill dementia patients, and they only need to pay 10% of the medical expenses, while the national health insurance covered 20% to 60% of the medical expenses for general public. The national insurance is being implemented for senior citizens, with the ratio of dentistry implants to aged 65 or older also lowered from the current 50% to 30%.

¹⁴⁸ https://www.nhis.or.kr/static/html/wbd/g/a/wbdga0101.html





- There is also another social insurance system that provides long-term care benefit to the elderly who have difficulty in taking care of themselves for more than six months due to old age or geriatric disease. It supports their physical activities or housework based on the principle of social solidarity. The long-term care insurance benefits include assistance with bathing, eating, cooking, nursing, treatment or recuperation counselling. The national health insurance manages the services provided by hospitals (clinic) and pharmacies including diagnosis of disease (such as Alzheimer's disease, stroke, etc.), hospitalization, outpatient treatment, and rehabilitation. However, the Long-Term Care Insurance provides services that support physical or housework activities for the elderly who have difficulty in taking care of themselves due to Alzheimer's disease, stroke, or other geriatric diseases.
- Private insurance is guaranteed differently for individual depending on the insurance level and contract details, and depending on the extent of the guarantee, the degree of disease risk, and the contents of the contract, the insurance can be subscribed at additional cost.

7.6 Strengths and weaknesses in South Korea

On the basis of desk research and expert views gathered through qualitative interviews, a SWOT overview could be established as follows:

Strengths	Weaknesses
 Familiarity with digital technologies Eagerness for leadership in the digital healthcare market compared to the same generation in other countries Growth of the South Korean government's R&D investments related to digital health projects 	 Difficulties in commercialisation of technology: small market Personalised management The social security system is vulnerable There is a large gap in income, education, and health status, and a great diversity of life patterns among the elderly.
Opportunities	Threats





8 Digital health and AHA: Panorama and priorities in the USA

In the US, the number of Americans aged 65 and older is projected to nearly double from 52 million today to over 95 million by 2060 - older Americans will account for nearly a quarter of the total population.¹⁴⁹ This unprecedented demographic shift presents various challenges, as the geriatric population is heavily dependent on Social Security as well as federal health insurance programmes such as Medicare and Medicaid. Currently, combined Social Security and Medicare expenditures account for 8.7% of the GDP and are projected to increase to 11.8% by 2050.¹⁵⁰

Advances in medicine, technology, and social systems have enabled Americans to live longer with an average life expectancy of 78.6 years.¹⁵¹ While the increase in life expectancy is a celebratory achievement, it is accompanied by age-related diseases such as chronic and neurodegenerative diseases. According to the US Centers for Disease Control and Prevention, nearly 80% of older Americans have one chronic condition and 60% have at least two chronic conditions.¹⁵² In addition, six million Americans currently live with Alzheimer's disease and by 2050, it is estimated that 13.8 million will be diagnosed with the illness.¹⁵³ Such high prevalence of disease has raised concerns on the nation's ability to provide sustainable and quality healthcare services for elderly Americans

8.1 Digital health R&I priorities

The ageing society has prompted lawmakers, government agencies, and healthcare organisations to begin exploring innovative care delivery and payment models that reduce the prevalence of disease, promote health and wellness, and support those with age-related diseases. The **National Institute on Aging (NIA)**, a division of the **National Institutes of Health (NIH)**, has led research efforts **that prioritise the following:**

- 1. Comprehending the underlying forces of the aging process, which includes: the biology of aging to better assess its impact on preventing and addressing disease and disability; the impacts and mechanisms of personal, interpersonal, and societal factors on aging
- 2. Bettering the health, well-being, and independence of adults as they age, which includes: developing effective interventions for age-related diseases, disorders, and disabilities; making progress in the research on and treatments for Alzheimer's and dementia; gaining further insight into health disparities relevant to aging and the implications of an aging society on intervention and policy decisions

¹⁵³ https://www.healthsystemtracker.org/chart-collection/u-s-life-expectancy-compare-countries/





¹⁴⁹ https://www.prb.org/aging-unitedstates-fact-sheet/

¹⁵⁰ https://www.ssa.gov/oact/TRSUM/tr18summary.pdf

¹⁵¹ <u>https://www.healthsystemtracker.org/chart-collection/u-s-life-expectancy-compare-countries/</u>

¹⁵² <u>https://www.nia.nih.gov/health/supporting-older-patients-chronic-conditions</u>

3. Facilitating and backing the research enterprise by: supporting the infrastructure and resources needed to promote robust research, effective outreach and communication, and allocation of public resources¹⁵⁴¹⁵⁵

Furthermore, the NIA at the NIH devotes resources specifically to the study of **Global Aging**, bridging the research in the United States with that in countries around the world. The research here is done within the Division of Behavioral and Social Research, who are "committed to improving health and aging-related outcomes both nationally and internationally".¹⁵⁶

"Research on chronic diseases and the health of older adults is important in order to understand the growing global burden due to these conditions, as well as understanding better the specific challenges of aging in the United States." – Global Aging Homepage, Division of Behavioural and Social Research in the NIA at NIH

The Digital Health R&I priorities in the USA are:

- Research to understand the biological, interpersonal, and societal factors of aging
 - The aim is to create effective interventions for the treatment and prevention of age-related diseases, disorders, and disabilities, and to address Alzheimer's and dementia, as well as aging-related health disparities.
- Digital tools for health promotion and disease prevention
 - Health technologies are increasingly being explored as a viable avenue to improve access to care, reduce costs, and improve health outcomes for not just the elderly, but for the general population overall.
- Independence at home through telehealth services
 - Telehealth services will continue to be implemented in the USA. They will benefit seniors with multiple chronic conditions to receive care from primary care teams in their homes to reduce hospital readmissions.
- Favourable conditions for health technologies development
 - Digital therapeutics, the IoT, AI, blockchain, and other technologies are expected to play a pivotal role in health care. The Government aims to promote health information sharing, encourage an open app economy via standards-based application interface programming, etc.

In 2019, the WHO launched a toolkit aimed at improving care for older adults, which included the WHO ICOPE Handbook App, a digital health application that enables caregivers and health providers to better care for and treat the elderly.¹⁵⁷ At the forefront of the priorities in creating these resources are the ideas from the 2030 Agenda and the Sustainable Development Goals from the United Nations, which places importance on improving health, healthy environments, and reducing inequalities, all of which can be achieved in part through creating resources such as digital health tools to advance

¹⁵⁷ https://www.who.int/news/item/30-09-2019-who-launches-digital-app-to-improve-care-for-older-people.





¹⁵⁴ <u>https://www.nia.nih.gov/about/aging-well-21st-century-strategic-directions-research-aging</u>

¹⁵⁵ https://www.nia.nih.gov/about/aging-strategic-directions-research

¹⁵⁶ https://www.nia.nih.gov/research/dbsr/global-aging

AHA.¹⁵⁸ Health technologies are increasingly being explored as a viable avenue to improve access to care, reduce costs, and improve health outcomes for not just the elderly, but for the general population overall.

With the success of telehealth, which has been proven to be a cost-effective model that improved outcomes for patients diagnosed with stroke,¹⁵⁹ neurological conditions,¹⁶⁰ and chronic diseases,¹⁶¹ **US** health officials are increasingly embracing digital health. The NIH Wide Strategic Plan for 2016-2020 does not have a specific section on digital health. However, it lists EHRs and mhealth as tools for health promotion and disease prevention.¹⁶² While this plan has not been updated yet, especially as COVID-19 has required reallotment of resources in order to more directly combat the virus, it is worth noting that the prior NIH strategic planning process took place from 1991-1992, so it may be assumed that the ideas outlined in the current version are intended to last beyond 2020.¹⁶³

The US Congress passed the "Creating High-Quality Results and Outcomes Necessary to Improve the Chronic Care Act (CHRONIC Care Act)" in 2016, that **expands telehealth services offered through different healthcare providers that will benefit seniors in rural areas and increase access to primary care services and telestroke**.¹⁶⁴ This Act became law in 2018 and has been more fully implemented in 2020 in the United States.¹⁶⁵ The act also aimed to extend the "Independence at Home" (IAH) model that allows seniors with multiple chronic conditions to receive care from primary care teams in their homes to reduce hospital readmissions.¹⁶⁶ The IAH model is powered by various health technologies including mobile EHRs, remote patient monitoring devices and sensors, telehealth, and care coordination/ management tools.

Digital therapeutics, the IoT, AI, blockchain, and other technologies are expected to play a pivotal role in creating a passive and continuous care environment that allow Americans to age in place. The US Federal government recognizes this opportunity and has been committed to advancing health technologies. The 2016 21st Century Cures Act included components that aimed to promote health information sharing, encourage an open app economy via standards-based application interface programming, and accelerate the development and clearance of low-risk medical devices. ¹⁶⁷ A regulatory framework introduced in late 2020 will mandate this data-sharing be implemented by provider organizations in 2021-2¹⁶⁸. These recent legislative efforts are reflective of Americans' growing desire for health technologies that enable AHA outside of traditional medical settings.

¹⁶⁶ https://innovation.cms.gov/files/fact-sheet/iah-fs.pdf

¹⁶⁸ HHS Extends Compliance Dates for Information Blocking and Health IT Certification Requirements in 21st Century Cures Act Final Rule <u>https://www.hhs.gov/about/news/2020/10/29/hhs-extends-compliance-dates-information-blocking-health-</u> <u>it-certification-requirements-21st-century-cures-act-final-rule.html</u>





¹⁵⁸ <u>https://sustainabledevelopment.un.org/</u>.

¹⁵⁹ https://n.neurology.org/content/77/17/1590.short

¹⁶⁰ <u>https://www.ncbi.nlm.nih.gov/pubmed/29652625</u>

¹⁶¹ <u>https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0216</u>

¹⁶² <u>https://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf</u>

¹⁶³ <u>https://www.nih.gov/about-nih/nih-wide-strategic-plan</u> Webpage last updated on 10 April 2020.

¹⁶⁴ <u>https://www.finance.senate.gov/imo/media/doc/CHRONIC%20Care%20Act%20of%202017%20One-Pager%204.6.17.pdf</u>

¹⁶⁵ Jane Sung and Claire Noel-Miller, AARP Public Policy Institute, *Supplemental Benefits in Medicare Advantage: Recent Public Policy Changes and What They Mean for Consumers*, July 2019.

¹⁶⁷ https://docs.house.gov/billsthisweek/20161128/CPRT-114-HPRT-RU00-SAHR34.pdf



An expert from the US suggested that as digital health becomes an integral part of care delivery for the elderly, the NIH/ NIA has been funding start-ups and small businesses in the US to foster innovation and create technologies that may offer global health care solutions/ participate in international projects.

8.2 Main challenges related to digital health

From an innovation standpoint, America provides unparalleled opportunities and incentives for entrepreneurship. According to Rock Health's 2020 Midyear Digital Health Funding Report, \$5.4 billion was invested in the US across 214 deals in the first half of 2020, with the average deal size of \$30.2 million surpassing the prior record of \$21.5 million in 2018. and it is projected that 2020 digital health investments will surpass the previous years, reaching an estimated \$12 billion.^{169 170}



Figure 9: Digital Health Funding and deal size

The US is a global leader in this arena and American investors are typically the first to spot "unicorns" companies valued at over \$1 billion. Unicorns such as Livongo (which went public in July 2019 and was acquired by Teladoc in August 2020), GoodRx, and One Medical (both of which went public in 2020) have made significant impacts in delivering digital medicine and consumer-focused care delivery to larger numbers of patients.



"Most of the biotech pharma companies have also launched venture funds to invest directly into digital health solutions, digital therapeutics. So, there is just a mass amount of capital that is on the sidelines right now waiting to be deployed and to help fund the further evolution of solutions. Most other countries around the world just don't have the access to that" – US Expert (Innovation Portfolio Lead)

¹⁷⁰ https://rockhealth.com/reports/q3-2020-digital-health-funding-already-sets-a-new-annual-record/





¹⁶⁹ https://rockhealth.com/reports/2020-midyear-digital-health-market-update-unprecedented-funding-in-anunprecedented-time/

Though the potential of digital health is recognised, a plethora of barriers limits the adoption of such technologies.

On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the main challenges related to digital health in the USA relate to:

- 1. Lack of interoperability
- 2. Reimbursement models
- 3. Operational chasm and acceptance by end-user

Lack of interoperability

Lack of interoperability is a major challenge facing the adoption of digital health in the US.

In a 2018 report to Congress, the Office of the National Coordinator for Health Information Technology (ONC) detailed the country's progress toward interoperability.¹⁷¹ It noted that health information is not always accessible across different systems or accessible by all users. For example, health care providers often lack access to patient data at point of care and patients often lack access to their own health information.

The report also listed the following as barriers to progress for interoperability: 1) technical barriers such as lack of standards, 2) financial barriers such as costs related to development, and 3) trust barriers such as a reluctance to share data.



"The health care market is still very difficult to penetrate due to regulatory principles, the complexity of medicine, data interoperability" - US stakeholder in Health Information Technology.

Reimbursement models

While the public-private healthcare system is great for the market, it has created misaligned incentives that can drive stakeholders away from patient-centred care. Hence, research as well as policy reform is greatly needed to create a common goal that mutually benefits all stakeholders. Reimbursements for digital health technologies are not standardised in the US. For HCOs that contract with private health insurers, reimbursements for virtual services are at the insurer's discretion.

The federal programme for the over-65 population, Medicare, is now reimbursing for telehealth for certain services, providers, patient populations, and service areas (e.g. rural). In 2019, Medicare expanded reimbursement to include virtual and digital services such as a virtual check-in, remote

¹⁷¹ https://www.healthit.gov/sites/default/files/page/2018-12/2018-HITECH-report-to-congress.pdf





evaluation of recorded video/or images, and remote patient monitoring.¹⁷² These were extended under emergency provisions during the COVID-19 epidemic in 2020.¹⁷³ Though the upward trend for digital health reimbursement is promising, it is currently still limited. Unless there are concrete financial incentives and reimbursement models and/or a legal mandate to adopt, health care organisations (HCOs) do not have the urgency to change.

Operational chasm and acceptance by end users

Implementation of novel tech requires significant resource and labour investments that many HCOs are hesitant to commit to without adequate evidence for the return on investment (ROI).

HCOs are struggling to evaluate the ROI for many emerging technologies. The evidence base for digital health tools is lacking and often relies on pilots or small-scale studies for validation. However, health technologies often experience an operational chasm,¹⁷⁴ in which innovators successfully pilot and/ or commercialise but fail to penetrate the market.

Interviewees have cited several contributing factors to "death by pilot": 1) lack of user-focused design, 2) lack of objective metrics to prove the tool's efficacy, and 3) failure to test atscale.



"One of the most prominent challenges in digital health in the US is the lack of useroriented design: innovators often fail to include users in the design process or misidentify appropriate users" – a Professor of Public Health from the USA

Technologies need to be co-designed with the end users in order to fully address the actual need and pain-points the solution aims to address. In addition, pilots need to be implemented with metrics and targets that align with the host organisation's objectives. Lastly, the innovations must demonstrate scalability, which is often not considered during the initial pilot. As one interviewed expert noted, the health tech community has glorified pilots and small studies that yield interesting results as opposed to technologies that have been implemented at scale. Technologies that are tested at scale allows HCOs to truly understand the technology's impact beyond a subset of their patient population and decide whether or not the product can be implemented.

8.3 Specific challenges for ageing populations

According to AARP, adults 50 and older account for almost \$2 trillion in healthcare spending and \$7.6 trillion total in consumer spending, nearly 70% of the nation's GDP.¹⁷⁵ With this in mind, there has been a drastic increase in start-ups that either target the elder population or address health issues that disproportionately affect seniors. Over 400 start-ups focus on the elderly care market while thousands of companies are targeting chronic care, mobility, and care coordination platforms.

 ¹⁷⁴M. Hostetter, S. Klein, and D. McCarthy, The Digital Health Revolution, The Commonwealth Fund, February 2015
 ¹⁷⁵ Accius, Jean, and Joo Yeoun Suh. *The Longevity Economy Outlook: How People Ages 50 and Older Are Fueling Economic Growth, Stimulating Jobs, and Creating Opportunities for All.* Washington, DC: AARP Thought Leadership, December 2019. https://doi.org/10.26419/int.00042.001





¹⁷² <u>https://avalere.com/insights/medicare-reimbursement-of-virtual-care-delivery-and-remote-monitoring</u>

¹⁷³https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

On the basis of desk research and expert views gathered through qualitative interviews, it can be concluded that the main specific challenges for aging populations in the USA are:

- 1. Maintaining the ageing population at home despite chronic illnesses
- 2. Prevent social isolation and loneliness
- 3. Overcome financial barriers to access care system

Chronic illness

According to the American Association of Retired Persons (AARP), three out of four Americans age 50 and older want to stay in their home and community as they age.¹⁷⁶ However, the ability to do so diminishes among older adults that have chronic illness(es) and are experiencing physical and/or cognitive decline. Approximately 34% of all older adults report some type of disability (e.g. hearing loss, vision loss, cognitive, etc.) that affects their ability to live independently. In addition, older patients require significantly more health care services and more than 20% of seniors visit their doctor 10+ times per year.¹⁷⁷ Hence, it is difficult for seniors to remain at home and receive appropriate care as opposed to those who live in nursing homes and other long-term care institutions.

Social isolation

Ageing in place is even more difficult as American families often live apart from their family members. It is reported that 13.8 million older adults (28%) live alone. Those who live alone and are physically frail are also more susceptible to feeling socially isolated and lonely.¹⁷⁸ The NIA has flagged this as a priority issue as social isolation and loneliness is correlated to increased risk in physical and mental conditions such as heart disease, obesity, cognitive decline, Alzheimer's, and even death.¹⁷⁹



"In our population, loneliness is the single biggest predictor of dissatisfaction in healthcare. Yes, there has been data about correlation with health risk effects of half a pack of cigarettes a day, correlation with higher risk for mortality than obesity, and in our population, there is about a 43% loneliness in the 65-and-older Medicare supplemental plan population, about 19% we call severe, and their health care costs are 34% higher than those who are not lonely, and the moderately lonely have a 27% higher costs." – Medical Director from the USA

Financial barriers

In 2017, the Commonwealth Fund reported that older Americans were sicker and faced more financial barriers than those in Australia, Canada, the United Kingdom, France, Germany, and five other countries. The report found nearly 25% of older adults did not visit a doctor when they were sick,

¹⁷⁹ <u>https://www.nia.nih.gov/news/social-isolation-loneliness-older-people-pose-health-risks</u>





¹⁷⁶ https://www.aarp.org/research/topics/community/info-2018/2018-home-community-preference.html

 ¹⁷⁷ https://acl.gov/sites/default/files/Aging%20and%20Disability%20in%20America/2019ProfileOlderAmericans508.pdf
 ¹⁷⁸ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4985072/

skipped a recommended treatment or procedure, or skipped medication due to cost. ¹⁸⁰ Although the Center for Medicaid and Medicare Services (CMS) provides nearly universal coverage (93%) for American seniors, the federal health insurance programme is fragmented with inconsistent funding streams for healthcare services. Medicare is split into four parts as outlined in **Erreur ! Source du renvoi introuvable.**.

The cost of Part A is generally covered by the Federal government, but Part B requires a monthly premium contribution as well as a deductible and co-pays for services. The original Medicare program (which was just Part A and B) covers some home healthcare, but does not cover longterm care, dental, vision, and certain prescription drugs, although Medicare Part D introduced in 2004 has mostly covered the gap on drugs. Given the limitations, one in three Medicare enrolees (20.4 million) opted for Medicare Advantage (MA)



plans that are offered by CMS-approved private health insurers and tend to provide more comprehensive coverage.¹⁸¹

In 2018, those 65 and older spent \$6,802 ,out of pocket on healthcare expenses, which accounts for 11.9% of their total spending. Of those expenses, 70% were attributed to insurance premiums, copays, and deductibles while 15% was spent on medical services that were not covered and 11% on prescription medications.¹⁸² When factoring in those ages 55 to 64 as well, people age 55 and over accounted for over half of the total healthcare spending in 2016.¹⁸³ American seniors are particularly vulnerable to rising healthcare costs and there is a dire need to help them access quality, yet low-cost, care.

¹⁸³ https://www.healthsystemtracker.org/chart-collection/health-expenditures-vary-across-population/#item-people-age-55-and-over-account-for-over-half-of-total-health-spending_2016





¹⁸⁰ https://www.commonwealthfund.org/publications/journal-article/2017/nov/older-americans-were-sicker-and-facedmore-financial-barriers

¹⁸¹ <u>https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage/</u>

¹⁸² https://acl.gov/sites/default/files/Aging%20and%20Disability%20in%20America/2019ProfileOlderAmericans508.pdf



The challenges above provide a great opportunity for digital solutions, which may assist in health promotion, enhance care management, promote social engagement, facilitate cost comparisons, and more. However, the experts interviewed worry that digital literacy will impede older adults' use and reception of innovative technologies.

Although the Pew Research Center reported that 67% of Americans of the age 65+ use the internet and 42% now own a smartphone, it was found that nearly 35% of older internet users have little to no confidence in their ability to use electronic devices to perform online tasks.¹⁸⁴ In addition, 48% of seniors need someone to help set up their device or show them how to use it.¹⁸⁵ In another study, researchers found that many seniors needed guidance_to understand technical jargon (e.g. "sync with Bluetooth") and help to modify app features such as changing physical activity goals.¹⁸⁶ In order for the ageing population to maximise the benefit of digital health technologies, more effort needs to go toward digital health literacy, user-centred design, and other support for seniors and their caregivers.

In addition, while there is increased interest in the elderly care market, much digital health innovation still focuses on the young and healthy as opposed to those who need it most. Interviewees suggested



"We have been testing animatronic pets, and bottom line is we have found for people who are lonely in our population, it reduced loneliness, increased their mental health, quality of life, and the state of New York is actually testing these Joy for All Pets as companion pets, as one of their programs for elder affairs" – Medical Director from the USA

that the elderly, disabled, and vulnerable populations are often neglected in product design—creating tools that fail to truly engage with those in need. While this issue may be universal, the US can benefit from learnings from other countries who have exemplified user-centred design and product development.

8.4 Relevant key programmes and funding agencies

The **Department of Health and Human Services (HHS)** is the cabinet-level health department of the US Federal Government and encompasses major federal agencies such as **the Centers for Medicare and Medicaid Services (CMS)**, **the Food and Drug Administration (FDA)**, the Office of the **National Coordinator for Health Information Technology (ONC)**, the **National Institutes of Health (NIH)**, and many more.

The HHS serves as the key funding agency for healthcare services and research, and has developed several programmes, initiatives, and funding opportunities to support the digital health ecosystem. These include:

¹⁸⁶ <u>https://www.iproc.org/2018/2/e11803/</u>





¹⁸⁴ <u>https://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/</u>

¹⁸⁵ https://www.ncbi.nlm.nih.gov/pubmed/29652625



- **Open Innovation**, also known as the IDEA Lab fosters innovation through challenges, hackathons, and accelerators. Since 2011, it has administered over 170 challenges and distributed \$35 million in cash prizes to over 9,000 innovators.¹⁸⁷
- Secretary's Venture Fund, which offers growth-stage funding and support to HHS employees with innovative ideas for how to dramatically improve the Department's ability to carry out its mission.¹⁸⁸
- Entrepreneurs-in-Residence Program, where HHS recruits private-sector innovators to assist in specific challenges in the health and delivery of human services. Through this programme, the innovator gains access to the highest level of HHS leadership, a network internal and external of innovators, and a suite of tools for app development and testing.¹⁸⁹

CMS is the largest public health insurer in the US and Medicare is projected to insure nearly 80 million elderly beneficiaries by 2030.¹⁹⁰ The large volume of enrolees is expected to strain CMS, prompting the agency to explore both innovative payment models as well as new technologies that enhance the delivery of care.

In a first attempt at modernising their approach, CMS launched *eMedicare and the "What's Covered"* app to help Medicare enrolees, caregivers, and others to quickly assess which medical item or services are covered. CMS also announced that it would allow MA plans to offer additional telehealth benefits starting in 2020. In the meantime, CMS has made ongoing efforts to experiment different care delivery models for ageing populations:

- The Independence at Home (IAH) Demonstration was started to test service delivery and payment incentives models that use home-based primary care teams to improve health outcomes and reduce expenditures.¹⁹¹
- The Program for All-Inclusive Care for the Elderly (PACE) features a comprehensive medical and social service delivery system using an interdisciplinary team approach in an adult day health centre. PACE integrates and coordinates primary care services, social services, personal care, nutrition counselling, meals, and mental health services. The programme is currently in 31 states with 263 PACE centres and has 50,000 enrolees.¹⁹²

Although neither of the two programmes was specific to health technology, they demonstrate CMS' strong desire to promote independence and inclusive care, areas in which digital health tools can be leveraged and be especially impactful.

Another agency under HHS is the ONC, which has been instrumental in the adoption of health information technology and the promotion of nationwide health information exchange (HIE).¹⁹³ Through the HITECH Act 2009 (part of the wider American Recovery and Reinvestment Act), nearly \$30 billion in funding was issued to establish a national health IT infrastructure and promote the adoption

¹⁹³ <u>https://www.healthit.gov/</u>





¹⁸⁷ <u>https://www.hhs.gov/cto/initiatives/open-innovation/about/index.html</u>

¹⁸⁸ <u>https://www.hhs.gov/cto/initiatives/secretarys-ventures-fund/index.html</u>

¹⁸⁹ https://www.hhs.gov/cto/initiatives/entrepreneurs-in-residence/index.html

¹⁹⁰ <u>https://www.cms.gov/blog/empowering-patients-and-unleashing-innovation-emedicare-today-and-future-generations</u>

¹⁹¹ <u>https://innovation.cms.gov/initiatives/independence-at-home/</u>

¹⁹² https://www.cms.gov/Medicare/Health-Plans/pace/downloads/PACEFactSheet.pdf

of EHRs in hospitals and physician offices. ONC led those efforts and now, 97% of large hospitals possess certified health IT and 96% of non-federal acute care hospital have adopted EHR's.¹⁹⁴

ONC's current focus is on data interoperability and standards development in alignment with the 21st Century Cures Act. To support nationwide interoperability, ONC will enforce penalties and fines on information blocking, "a practice by a healthcare provider, health information technology (IT) developer, health information exchange, or health information network that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI)."¹⁹⁵ As data interoperability is still a major issue in the US healthcare system, ONC has also announced various funding opportunities such as the Integrating the Healthcare Enterprise Cooperative Agreement Program and Leading Edge Accelerator Program.¹⁹⁶ The programmes offer \$500,000 to \$1,000,000 awards to support advancements in technical standards to achieve interoperability. While ONC does not have specific initiatives for AHA, their efforts in establishing health IT infrastructure and interoperability, benefit the elderly patients via the efficient and timely exchange of crucial health information.

The FDA which regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices, is **becoming increasingly involved in digital health**. In early 2019, the FDA has launched its Software Pre-certification Program (Pre-Cert) and released its Digital Health Innovation Action Plan.¹⁹⁷ The Pre-Cert programme is a voluntary programme to provide more streamlined regulatory oversight over software-based medical devices (SaMD) for eligible manufacturers. Upon completion of the programme, qualified innovators may be able to market their lower-risk medical devices without additional FDA review. Currently, the SaMD programme finished undergoing a piloting phase with nine companies that were admitted, and recent findings and learnings have been released to inform the future status of the program.¹⁹⁸

As outlined in their Digital Health Action Plan, the FDA is committed to providing access to high quality, safe, and effective digital health tools. Their efforts will be supported by nearly \$500 million in funding over nine years from the 21st Century Cures Act.¹⁹⁹ This should make technology-based platforms for chronic care management, remote monitoring, and care navigation become more readily available.

The National Institute on Aging (NIA) is the part of NIH which focuses on policy and research for the

elderly. The division has been a driving force in the investigation of aging and health outcomes in the international arena, sponsoring



"We have just launched a new funding opportunity at the NIH called the Commercial Readiness Program. That program is specifically designed to enable scale up and to fund scale up activities that may not be in their own way innovative, but the innovation really lies in the technology once commercialized." – Stakeholder working in Small Business Research from the USA

¹⁹⁹ https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act





¹⁹⁴ https://dashboard.healthit.gov/quickstats/quickstats.php

¹⁹⁵ <u>https://www.healthit.gov/topic/information-blocking</u>

¹⁹⁶ <u>https://www.healthit.gov/topic/onc-funding-opportunities/funding-announcements</u>

¹⁹⁷ <u>https://www.fda.gov/media/119722/download</u>

¹⁹⁸ https://www.fda.gov/media/142107/download

collaborative international projects, and disseminating findings in aging-related conditions and concerns affecting people worldwide. The NIA offers various grants and research opportunities so that the new innovations can rapidly come to market. Under the NIA Small Business Innovation Research and Small Business Technology Transfer programmes, \$100 million in funding is granted for small business innovation in healthy aging and Alzheimer's disease.²⁰⁰ Furthermore, the NIA has also funded pragmatic clinical trials that investigate a variety of interventions, including digital health, to address age-related diseases.²⁰¹ The goal of the trials is to test the interventions at-scale and appropriately evaluate the effectiveness of the tools.

8.5 Most important players and networks in the field

While public agencies play a pivotal role in the American healthcare system, the private sector is of equal importance. For older adults, private insurers that offer MA plans such as Aetna, Cigna, Kaiser Permanente, Blue Cross Blue Shield, Humana, UnitedHealthcare, and many others, provide more comprehensive health plans that facilitate ageing in place.

As MA plans are paid a capitated amount per beneficiary, these insurers are incentivised to keep their patients as healthy as possible through various care delivery models and tools. For example, UnitedHealthcare offer virtual visits to its members and will be collaborating with Dexcom, Inc., to launch individualised glucose management programmes driven by wearable technology.²⁰² To maximise cost savings and promote health outcomes, these insurers have increasingly leveraged digital health. UnitedHealthcare invests \$3.2 billion annually in data, technology, and innovation and is one of the leading organisations moving towards a digital health entrepreneurship. Cigna launched Cigna Ventures²⁰³ with \$250 million in capital to invest in early and growth stage start-ups while Kaiser Permanente Ventures invests \$170 million in capital for companies in all stages. Kaiser Ventures has invested in digital health start-ups such as Omada Health, Vidyo, and Health Catalyst.²⁰⁴ These insurers are critical in the health innovation space and are some of the largest proponents for digital health in chronic care management, health promotion, and AHA.

Another major player for older Americans is the **AARP**, an organisation that helps seniors with healthcare, employment and more.²⁰⁵ AARP prides itself as one of the leading organisations that recognise the potential of the "longevity economy," which is the economic opportunity that elderly Americans present. Throughout its history, the organisation has consistently researched the 50+ consumer market and explored opportunities to engage with various sectors in an effort to improve the quality of life for older adults.

AARP focuses on adults 50 and older and has been instrumental in reimagining the term "ageing." The organisation is dedicated to helping their members thrive and steer away from assumptions on the elderly population. In recent years, AARP has focused on assisting elders with developing a sense of

²⁰⁵ https://www.aarp.org/





²⁰⁰ https://www.nia.nih.gov/research/osbr/about-nia-small-business-funding

²⁰¹ https://grants.nih.gov/grants/guide/pa-files/PAR-18-585.html

²⁰² <u>https://newsroom.uhc.com/news-releases/new-digital-health-resources-for-2018.html</u>

²⁰³ <u>https://www.cignaventures.com/</u>

²⁰⁴ https://www.kpventures.com/portfolio/

purpose, painting a positive view of aging, and addressing social engagement and social isolation issues. The association conducts and sponsors research in various areas related to AHA and has been an advocate for leveraging social media and digital health tools. AARP has launched several initiatives to support their mission:

AARP Disrupt Aging aims to change the conversation on aging via social media and partners with companies and communities to create new solutions that enable active ageing.²⁰⁶

AARP Innovation Labs created the "Hatchery," to bring together top-tier entrepreneurs to share ideas for keeping people 50 and older healthy and designing new products and services to this purpose. The Hatchery uses design challenges, pitch competitions, and other start-up accelerators to co-create products and services.²⁰⁷

Partnering with JP Morgan Asset Management, AARP provides \$40 million in capital to innovative companies. Known as the "AARP Innovation Fund," the fund is focused on digital solutions for ageing at home, convenient and access to healthcare and preventative health.

Academic medical centres (AMCs) also play a crucial role in the digital health ecosystem. Our interviewed experts have emphasised that AMCs power research efforts that help validate and commercialise technologies. Although AMCs traditionally focused on biomedical research, many universities have now developed centres for digital health and/or health innovation.

For example, the University of California San Francisco established the Center for Digital Health Innovation (CDHI) to support the discovery, innovation, and implementation of digital health technologies by providing developmental resources and leveraging external partnerships.²⁰⁸ CDHI has partnered with Samsung to create a digital health innovation lab to provide a test-bed where entrepreneurs can validate their products and accelerate the adoption of preventive health solutions.

Another noteworthy research effort is the University of California Center for Information Technology Research in the Interested of Society (CITRIS), which leads several global research efforts including telehealth, as well studying whether AI can detect and prevent falls.²⁰⁹ CITRIS partnered with global researchers from Denmark as well as several members of the EU to create the "Transatlantic Telehealth Research Network" and has published literature outlining the global research agenda for telehealth.²¹⁰ In comparison to the various players in the healthcare system, AMCs and universities are most likely to participate in global research projects and explore international frameworks for digital health implementation.

²¹⁰ https://citris-uc.org/telehealth/project/transatlantic-telehealth-research-network/





²⁰⁶ <u>https://www.aarp.org/disrupt-aging/</u>

²⁰⁷ <u>https://www.aarp.org/about-aarp/innovation/aarp-innovation-labs/</u>

²⁰⁸ <u>https://www.centerfordigitalhealthinnovation.org/</u>

²⁰⁹ <u>https://citris-uc.org/health/</u>

8.6 Strengths and weaknesses in the USA

The US healthcare system's public-private nature has created strengths as well as weaknesses in the nation's ability to promote AHA. These obviously go along with social and market opportunities, but have to face threats as well.

Strengths	Weaknesses
 Vibrant entrepreneurial environment Largest digital health hubs and research centers established in US 	 Misaligned incentives that can drive stakeholders away from patient-centred care Non-standardised and incomplete reimbursement models for digital health Unclear ROI to HCO Digital health innovation focused on the young and healthy
 Opportunities Expanding digital health solutions for the elderly Attractive market 	Threats Increasing elderly population Chronic conditions and social isolation





9 International S&I collaborations in digital Health between EU & strategic partners



"International cooperation is needed as challenges regarding innovation are universal." – Expert in Digital Health from the EU

The importance of a coordinated approach in eHealth-related areas such as ICT standardisation, semantic interoperability, common indicators to facilitate eHealth benchmarking, IT skills of medical workforce and evidence collection have been emphasised by the EC, the United States (US) of America, the WHO, the Organisation for Economic Co-operation and Development (OECD) and international standardisation organisations. This is where bilateral and multilateral S&I agreements come into play. At the same time, such agreements can be a means of overcoming perceived barriers, such as data regulations, which are at the moment very much fragmented according to the markets (countries/ geographic regions).



Experts from Europe, Japan and China, who participated in a Webinar organised by IDIH in collaboration with the SENET EU project on the 4th of December 2020 on "Artificial Intelligence (AI) applications in Health Research and Innovation", were consulted on their views on international collaboration. The experts agreed that a major barrier to collaboration on international level is related to data regulations.

Indeed, they suggested that there is a trade-off for data sharing which would support AI applications in health whilst patients' data needs of course to be handled with particular care. It seems there is even data fragmentation within countries, e.g. the Japanese expert indicated data was collected in individual hospitals and it was difficult to have an overall view of data in the country that would however be necessary to apply machine learning in health research. He said however that there was the possibility to share algorithms rather than data which could be a way of overcoming such barrier (at least partly).

In its **European Data Strategy**²¹¹, the EC aims at giving a response to this challenge, which will obviously impact also the Digital Health field and the collaboration on international level. Also, very recently, the EC has specified its actions in response to a global challenge, the coronavirus pandemic, using digital technologies. ²¹²

On a global level, the **World Health Organization** has "acknowledged that institutionalisation of digital health in the national health system requires a decision and commitment by countries" and "digital health initiatives require an integrated strategy". This is why in its **Global Strategy on Digital Health 2020-2025**, the WHO has set four strategic objectives which are "intended to provide guidance and coordination on global digital health transformation and to strengthen synergies between initiatives

 $^{^{212}\} https://ec.europa.eu/digital-single-market/en/content/digital-technologies-actions-response-coronavirus-pandemic$





²¹¹ https://ec.europa.eu/commission/presscorner/detail/en/fs_20_283

and stakeholders to improve health outcomes and mitigate associated risks at all levels". The four objectives are:

- Promote global collaboration and advance the transfer of knowledge on digital health
- Advance the implementation of national digital health strategies
- Strengthen governance for digital health at global, regional and national levels
- Advocate people-centred health systems that are enabled by digital health²¹³

It has also initiated, together with numerous other countries and territories, the Global Digital Health Partnership (GDHP)²¹⁴ in 2018 (now 31 members). Participants include digital health officials from several EU Member States such as Austria, Estonia, Italy, The Netherlands, Poland, Portugal and Sweden, as well as international countries such as Brazil, Canada, Chile, Hong Kong, India, Japan, New Zealand, Singapore, South Korea, the US, and many more. The goal of the GDHP is to support governments and health system reformers to improve the health and well-being of their citizens through the best use of evidence-based digital technologies. The partnership identified five work streams focused on cybersecurity, interoperability, evidence and evaluation, policy environments, as well as clinical and consumer engagement. In its initial year, the GDHP has published a white paper for each of the work streams outlining each participating countries' status as well as the way forward.²¹⁵

9.1 Major bilateral and multilateral S&I Agreements

A number of bilateral and multilateral S&I agreements have been formed between the EU and the Strategic Partner Countries with relevance to digital health. It should be noted that the EU has signed agreements with some of the countries specifically for eHealth cooperation, whereas collaboration in this field with other countries comes under a more generic Science & Technology Agreement. Also, it may be part of agreements related to the Health sector or digital technologies (details in the chapters below). Whilst the political agreements provide a good framework, it is obvious that they need to evolve over time and policy dialogue is necessary to ensure the agreements' content remains up to date in a world where technological developments are evolving extremely fast.

The following chapters provide an overview of existing agreements and their evolutions over time.

9.1.1 Canada

Canada is one of the EU's oldest and closest partners and the Science, Technology, and Innovation (STI) collaboration between EU and Canada started in 1959 with the signing of the Agreement for Cooperation in the Peaceful Uses of Atomic Energy. The **Agreement for Scientific and Technological Cooperation** between Canada and the European Union has been in place since 1996 and is not limited in time ²¹⁶. Under this agreement, Canada and the EU have established priority areas for STI cooperation, which include aerospace, agriculture and agri-food, Arctic and marine (under the Galway

²¹⁶ <u>https://ec.europa.eu/info/research-and-innovation/strategy/international-cooperation/canada_en;</u> Amendment signed in 1999. *This is the most up to date Agreement*.





²¹³ WHO Global Strategy on Digital Health 2020-2025, https://www.who.int/docs/defaultsource/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf?sfvrsn=f112ede5_42

²¹⁴ <u>https://www.gdhp.org/</u>

²¹⁵ <u>https://www.gdhp.org/media-hub/news_feed/gdhp-reports</u>

Statement on Atlantic Ocean Cooperation), **information communication technologies**, **health**, researcher mobility and research infrastructure.

An Implementing Arrangement between the European Commission and the Canadian Tri-Agency Institutional Programs Secretariat was signed in 2016 which aims at supporting research collaboration with "health sciences" specifically mentioned.²¹⁷

The responsibility for the S&T cooperation dialogue lies with the EU–Canada Joint Science and Technology Cooperation Committee (JSTCC). The JSTCC meets on a regular basis to review progress and provides new directions for cooperation in the fields of science and technology. At the 14th meeting of the EU–Canada JSTCC on 20 March 2018 both sides agreed that their key areas for co-operation are: Marine, **Health**, Aeronautics and the sustainable management of the fragile Arctic environment, and how to balance this with economic interests.

Regarding Health, main areas of collaboration concerned Rare Diseases, Chronic diseases, Epigenomic, Traumatic Brain Injury, Neurodegenerative Diseases and Anti-Microbial Resistance. **A new area of cooperation regarding technologies for Global Health Care was agreed in 2018.** "Along with the US, Europe, Japan and Canada have mature, large-scale healthcare markets and are part of the main global regulatory domains in healthcare. The promotion of regulatory harmonisation and global cooperation between them will not only enhance trust in European healthcare product regulations, but also promote the adoption of common reference and technical standards world-wide and at the same time maintain and enhance access to worldwide markets. As new regulations on medical devices and in vitro diagnostic medical devices will affect imports/exports from and to the EU, EU-Canada cooperation in the area of regulatory science for medical technology products is strongly encouraged"²¹⁸. Regarding ICT, **cyber-security** is considered as a hot topic for cooperation.

Previously at the Canada-EU Summit which took place in Brussels 27 October 2016 the leaders adopted a Joint Declaration committing to renew the strategic partnership between both sides. The leaders **recognised the importance of increasing cooperation on scientific research and signed an Implementing Arrangement to facilitate cooperation of Canadian researchers in the Horizon 2020 programme**. They also committed to continue developing common principles and enhancing framework conditions for researchers from Canada and the European Union through programme level activities and alignment of respective funding streams.

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https://ec.europa.eu/info/sites/info/files/research_and_innovation/strategy_on_research_and_innovation/documents/agr eement-ec-tips.pdf

²¹⁸ <u>https://ec.europa.eu/research/iscp/pdf/policy/ca_roadmap_2018.pdf#view=fit&pagemode=none</u>





Until 2018, there was no federal matching fund in Canada concerning Horizon 2020. The Canadian federal budget 2018 established a new tri-council fund to support research that is international, interdisciplinary, fast-breaking and higher-risk with a funding of CAD \$ 275 million over five years. This fund was set up to help support Canadian cooperation with Horizon 2020. In addition, there seemed to be a growing interest in the provinces to use provincial funding programmes to support Canadian participants in Horizon 2020 projects.

Canada is also involved in the EUREKA network: EUREKA is an international network for market-driven industrial R&D that includes 45 economies from the EU and across the globe. Through Canada's associate The Canadian Institute of Health Research (CIHR) participates in the H2020 Active Assisted Living Program Programme (AAL): the supports projects in publicprivate partnership in the field of information and communication technology (ICT) for active and healthy aging. AAL's goal is to deliver concrete ICT solutions for older adults to live independently. In this project, Canada is represented by CIHR Institute of Aging, CIHR Institute of Health Services and Policy Research, and AGE-WELL Networks of Centres of Excellence.

membership in EUREKA, Canadian innovators have a new advantage in accessing technology, expertise, and markets in Europe and beyond. The National Research Council Canada (NRC) is the national contact point for EUREKA. The network has been operating successfully since 1985 supporting market-oriented R&D and innovation projects in all technology sectors. Initially a European intergovernmental network, EUREKA has expanded beyond Europe to include Israel, Turkey, South Korea, South Africa, Chile, Argentina and Canada.²¹⁹

The GoGlobal Canada programme of EIT Health provides 13 top European SMEs with a unique gateway to three recognised Canadian innovation hubs, which can act as major stepping stones into the North American market. Reciprocal relationships have a key added value of the programme, with long-term involvement of strong local partners developed at recognised international events

9.1.2 China

The EU-China scientific cooperation is governed by a **Science & Technology Cooperation Agreement** signed in December 1998 and renewed for the third time in December 2014. The China-EU S&T cooperation relationship has gradually shifted to an equal partnership. In May 2009, China and the EU signed the China-EU Science and Technology Partnership Program.

The importance of China as a key partner country has been confirmed by the Commission's decision to set up a dedicated **High Level Innovation Cooperation Dialogue** (ICD) in 2012: China and the EU signed the "Sino-European Joint Statement on Innovation Cooperation Dialogue". ICD offers a forum for discussing innovation policies and systems, addresses framework conditions and launches new joint research and innovation (R&I) initiatives.

²¹⁹ https://www.eithealth.eu/goglobal-canada





This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

During the 16th China-EU Summit in 2013, China and the EU jointly adopted the **China-EU 2020 Strategic Agenda for Cooperation**²²⁰, where both sides committed to continue promoting cooperation on the environmental flagship initiatives developed respectively by China and the EU, maximising the mutual synergies between China's sociological civilisation and the EU's resource efficiency agenda.

The two sides strengthened communication and consultation on a series of issues such as optimising and adjusting the innovation governance system, promoting effective innovation support measures, and providing a better innovation environment²²¹. China and the EU established the Joint Research and Innovation Funding Mechanism (CFM) in 2015, which is one of the results of the annual China-EU Innovation Cooperation Dialogue. Starting from 2016, MoST provided financial support for Chinese institutions to participate in the R&I projects of H2020 and the exchange of scientific research personnel.

At the 3rd EU-China Innovation Cooperation Dialogue (ICD-3) in 2017, the two sides declared they would jointly implement the 2018-2020 Flagship Initiatives and explore a roadmap for further cooperation in areas such as basic research, frontier science and key societal challenges, building on the Co-Funding Mechanism. **11 topics** were agreed and covered the areas of food agriculture and bioeconomy (FAB); environment, climate and sustainable urbanization; surface transport; safer and greener aviation; biotechnology and biomaterials; Energy (non-nuclear); Space research and GEO: Research infrastructure; **ICT** and **human health**²²².

The most recent EU-China Innovation Cooperation Dialogue held in 2019 launched the development of a joint roadmap for future EU-China collaboration in science, technology and innovation.²²³

Health research is an area where the EU and China have a lot to gain from closer cooperation. There has been a strong tradition of cooperation in Health, with major cooperation taking place in the areas of **rare diseases** (within the International Rare Diseases Research Consortium), of **chronic diseases** (in the frame of the Global Alliance for Chronic Diseases) and **of cancer** (as part of the International Cancer Genome Consortium), **prevention and treatment of infectious diseases** (in the context of initiatives such as the Global Tuberculosis Vaccine Partnership) and **traumatic brain injuries** (with the joint participation in the International Initiative for Traumatic Brain Injury). New areas of coordination are explored since 2018, which can be seen as specifically important to active and health ageing: **personalised medicine, brain research, Alzheimer's disease, diabetes and respiratory diseases.**²²⁴

https://ec.europa.eu/research/iscp/pdf/policy/ec_rtd_joint_communique_icd4_2019.pdf
 https://shareapp.cvol.com/cmsfile/News/202002/19/333797.html





²²⁰ <u>https://eeas.europa.eu/sites/eeas/files/20131123.pdf</u>

²²¹ https://ec.europa.eu/research/iscp/pdf/policy/icd-2_joint_statement-29jun2015.pdf

²²² http://ec.europa.eu/research/iscp/pdf/policy/cn_roadmap_2018.pdf#view=fit&pagemode=none_

The EU and China both **consider the ICT sector and the digital economy as strategic priorities**. Achieving a Connected DSM for the EU is one of the top political priorities. Similarly, China's central government has underlined the strategic importance of the ICT sector and the digital economy not just in their own right but also to positively transform traditional sectors of the economy in its "Made in China 2025 strategy plan". Under the existing EU-China ICT Dialogue, the

In 2020, COVID-19 spread to the world. Chinese ambassadors to the EU conducted in-depth exchanges with high-level officials such as the European Commission health committee and crisis management committee. Chinese and European health experts also maintain close communication through video conferences, and promptly report and analyse the latest epidemic situation. **The two sides are cooperating in depth on diagnosis and treatment of epidemics, scientific information sharing, and medical clinical experiments**.¹⁹⁶

Commission continues to cooperate with the Ministry of Industry and Information Technology (MIIT) on a number of policy issues under their responsibility: closer cooperation between the EU and China in this key sector that is considered mutually beneficial for both sides, **ensuring reciprocal access to markets, standard-setting bodies and R&I programmes**. **5G and IoT** are key topics of the EU-China collaboration, with a strong presence of Huawaï in H2020 projects. The EC signed a Joint Declaration on strategic cooperation in 5G mobile networks with China's Ministry of Industry and Information Technology.²²⁵ A White Paper presented the IoT developments in EU and China and the envisaged future cooperation avenues in 2016.²²⁶ The **digital health domain is one of the topics targeted by these agreements**.

The international cooperation programmes of the Tsinghua University Data Science Institute cover many fields. Such as international students' interaction, the International Electrocardiogram (ECG) Intelligence Competition as well as various academic forums. There is a paediatric arrhythmia programme within Yishun Han's medical support programme, and the applicant is a tenured professor at York University, Canada. He hopes to achieve accurate positioning of the radiofrequency ablation of the heart through statistical models. He therefore requires a lot of ECG data from the hospital for machine training. In this project, professor Han and his colleague learned about international advanced technology and they demonstrated to foreign experts the exquisite skills of Chinese clinicians as well as the incredible amount of available data, which is difficult for any country outside China to obtain. **Through the cooperation of this project, relevant hospitals were supported to establish a complete set of safe EMR databases, which is of great significance for future scientific research.**

The increasing importance of Digital Health is also reflected in the wider bilateral relations between the EU and China with the topic regularly being addressed at the EU-China Summit as well as the High Level Economic and Trade Dialogue. The "China-Europe Collaborative Innovation Network" covers the interconnected cooperation of key industries such as biopharmaceuticals, medical devices,

²²⁶ https://ec.europa.eu/digital-single-market/sites/digital-agenda/files/newsroom/eu-china white paper 13756.jpg





²²⁵ https://ec.europa.eu/digital-single-market/en/5G-international-cooperation

therapeutic vaccines, **and digital health**, and can provide comprehensive support and services for Chinese companies in R&D, innovation, skill development, and business development.²²⁷

9.1.3 Japan

Cooperation between the EU and Japan in R&I is governed by the Agreement on S&T Cooperation (2011). The EU-Japan Joint S&T Committee established under this Agreement aims to "exchange information and views on S&T policy issues; identify and decide cooperative activities; review accomplishments; provide advice on the implementation of the agreement; review the reciprocal access to Research and Innovation (R&I) programmes and projects and arrangements for visiting researchers; and to examine measures to improve that access and to ensure the principle on reciprocity".²²⁸

The 23rd EU-Japan Summit in 2015 agreed about a new EU-Japan Strategic Partnership in Research and Innovation, which involves: "thematic cooperation in strategic areas (ICT, aeronautics and materials, and new cooperation possibilities in health, energy, environment and high energy physics); adding framework conditions to facilitate cooperation (for the joint funding of projects, and measures to enhance researchers' mobility); regular consultation and cooperation in R&I policy areas (such as Open Science); deepening strategic cooperation by frequent consultation at multiple levels (Summit, Joint S&T Committee meetings, Senior Officials meetings, Task Force meetings, thematic dialogues); and support activities and public engagement (National Contact Points in Japan and outreach activities)".

At the centre of the EU-Japan cooperation agenda nowadays are the Economic Partnership Agreement (free trade agreement) and a wider **Strategic Partnership Agreement (SPA)**. The latter is covering political dialogue, cooperation in addressing regional and global challenges, and sectoral cooperation, including Science and Technology (S&T). These two agreements were signed at the EU-Japan Summit on 17 July 2018, and they are aimed at "strengthening the strategic partnership between the EU and Japan and boost cooperation prospects in Science, Technology and Innovation (STI) and related issues of norms and standardisation, with strengthened IPR protection." In this context and with specific relevance to digital Health, the conclusion of EU-Japan talks on 16 July 2018 on a **reciprocal recognition of the adequate level of data protection** is also important. This mutual adequacy arrangement is expected to "create the world's largest area of safe transfers of data based on a high level of protection for personal data". Outcomes are still to prove widespread recognition.



A Japanese representative of a major AI lab and company specialised in digital health application who was consulted, suggested that data fragmentation is one of the most serious problems, and this is the main barrier to international collaboration.

On the basis of the **EU-Japan Joint S&T Committee** (JSTC) meeting in November 2017 three areas are considered to be priority areas for future cooperation with Japan out of which ICT which has long been

²²⁸ <u>http://ec.europa.eu/research/iscp/pdf/policy/jp_roadmap_2018.pdf</u>





²²⁷ http://www.mofcom.gov.cn/article/i/jshz/zn/201807/20180702764036.shtml

one of the most active areas of EU-Japan S&T cooperation, both at policy and project level (focus on 5G, Internet of Things, Cloud and Big Data). Whilst e-Health is not specifically mentioned, these digital technologies can obviously play a major role in Health applications. Also, the EU and Japan cooperate in multilateral initiatives aimed at addressing global health challenges. Of **specific relevance to active and healthy ageing** can be seen that it is mentioned that there is potential to exploit collaborations in "neurodegenerative diseases (...), in particular Alzheimer's disease and dementia, brain research, starting with areas such as traumatic brain injury and epilepsy".²²⁹ As a start, in 2016, a coordinated call for research projects was launched between the EU and two Japanese agencies in H2020 in the field of ICT robotics for AHA and two projects have been funded.²³⁰

As shown, S&T Cooperation with Japan has a long history and evolves steadily over time. Indeed, very recently, a <u>Letter of Intent</u>²³¹ was signed by both sides in May 2020 to strengthen cooperation in **Science, Technology and Innovation**, and to enhance the synergies between the next EU research and innovation programme Horizon Europe, and Moonshot, Japan's research and development programme. It is expected to enable researchers and innovators to be able to cooperate more easily on global challenges, including health. Specific emphasis is given to fighting the coronavirus pandemic, including through open access to research data and results.²³²

9.1.4 South Korea

In October 2018, at the latest bilateral summit between the EU and South Korea in Brussels, leaders reaffirmed their strong ties and their commitment to strengthen their strategic partnership. The summit was also an occasion to welcome the substantial progress made in the EU-South Korea cooperation in research and innovation and to agree to continue close cooperation.

Since 2010, the EU and South Korea have upgraded their relationship to a Strategic Partnership: South Korea is the EU's first partner to have signed agreements in the three key areas of political (the EU-South Korea Framework Agreement -FA, signed in 2010), trade (the EU-South Korea Free Trade Agreement -FTA, applied since 2011) and security cooperation in EU-led crisis management operations (the Framework Participation Agreement -FPA, signed in 2014).

Cooperation between the EU and South Korea on research and innovation is governed by the Agreement for Scientific and Technological Cooperation which came into force in 2007 and is still in place²³³. Every two years, a Joint Science & Technology Cooperation Committee (JSTCC) takes place to review current joint activities and to seek future cooperative areas. South Korea has one of the lowest rates of business R&D funded by firms or institutions from abroad. In addition, direct funding received from the government is also very low, and R&D in South Korea is almost entirely performed and funded by the business sector (more than 75%). Nearly two-thirds of all R&D is directly targeted at developing specific new or improved applications, whereas basic research represents about 20% of total R&D

https://ec.europa.eu/info/sites/info/files/research and innovation/strategy on research and innovation/documents/ec rtd_eu-korea_roadmap.pdf. Most recent information as of Dec 2020





²²⁹ <u>http://ec.europa.eu/research/iscp/pdf/policy/jp_roadmap_2018.pdf</u>

²³⁰ <u>https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-pm-14-2016</u>

²³¹ <u>https://ec.europa.eu/research/iscp/pdf/policy/ec_rtd_ec-japan-letter-of-intent.pdf</u>

²³² <u>https://ec.europa.eu/info/research-and-innovation/strategy/international-cooperation/japan_en</u>

²³³

spending. This is unfortunately disproportionate to the relatively high rate of tertiary graduates from South Korea studying natural sciences and engineering.

In spite of the government-level agreement setting positive framework conditions, **some practical issues in R&I cooperation are still to be improved**. These are illustrated by the low real access for South Korean-based European entities to South Korean research and innovation programmes, and the lack of penetration to public procurement of R&D services and innovative solutions. Today, only very few European companies undertake R&D activities in South Korea, whereas there are growing opportunities for cooperation, both in research and in innovation. To support the participation of entities established in South Korea in Horizon 2020 projects, the South Korean government regularly co-funds such participation. The mechanism covers all thematic areas of Horizon 2020.

FP7 had 67 South Korean participants who took part in 54 projects with a total budget of €284 million. Up to October 2018, under Horizon 2020, there are 42 South Korean participations in collaborative actions, 20 participations in Marie Sklodowska-Curie Actions (MSCA) and 1 participation in a European Research Council (ERC) grant. **Horizon 2020 participation so far is mainly in the areas of ICT, health,** energy, climate action, and satellite navigation.

For example, there are two South Korean participants in the €25 million TBVAC2020 project that aims to innovate and diversify the current tuberculosis vaccine and biomarker pipeline while at the same time applying portfolio management using gating and priority setting criteria to select as early as possible the most promising tuberculosis vaccine candidates, and accelerate their development.

During the sixth EU-South Korea Joint Scientific and Technological Cooperation Committee meeting held on 20 September 2017 in Brussels, both the EU and Korea emphasised the **need to deepen, scale up and open opportunities for cooperation in selected technological areas** such as **ICT (5G, IoT, AI, and Cloud)**, nanosafety, nanoelectronics, **health/bio (infectious diseases, rare diseases and antimicrobial resistance)**, energy, satellite navigation, transport including automated vehicles, climate, polar research, disaster-resilience etc. Besides the joint research in specific fields, researchers' mobility through the European Research Council (ERC) programme and Marie Skłodowska-Curie Actions (MSCA) were also encouraged.²³⁴ Thus, digital health is not explicitly quoted as main priority for cooperation but could be approached through ICT and health/bio technological sector areas.²³⁵

For example, under the EIT Health community, specific accelerator programmes have been set-up. The Accelerator programme "GoGlobal", BioM developed the training project Start.Smart.Global especially for start-ups and SMEs, whose goal it is to enter **the Japanese and Korean life-science markets**. European life science SMEs offer innovative and globally competitive technologies, products and services. For most of them, it is a big challenge to set up their business on their own in unknown, often time-consuming and complex markets outside Europe, and to identify the right business partners and contacts.

²³⁵ <u>https://www.bio-m.org/ueber-biom/projekte/startsmartglobal.html</u>





²³⁴ <u>https://ec.europa.eu/research/iscp/pdf/policy/ko_roadmap_2018.pdf</u>

9.1.5 USA

The European Union and the United States joined forces to enhance health-related information and communication technology, called eHealth in Europe and health IT in the US respectively (for easier reading we use digital Health or eHealth as a common terminology here). EU-US S&I collaboration with relevance to digital Health has been formalised for more than a decade by several agreements.²³⁶

In 2010, an **EU-US collaboration was formally instituted between the US HHS and EU's Directorate-General for Communications Networks, Content and Technology of the EC** (DG Connect) for **transatlantic cooperation for eHealth and Health IT**.²³⁷ Indeed, the collaboration with the US on eHealth was part of the actions described in the EU eHealth Action Plan 2012-2020.²³⁸

In spring 2013, DG CONNECT and HHS outlined an **18-month roadmap of MoU actions**, focusing on two priority areas: 1) the establishment and maintenance of **standards** across the bodies, with a focus on **interoperability** across communication and information platforms and 2) the need for a capable and **highly skilled eHealth and Digital Health workforce**. For the latter objective, the collaboration aimed to develop shared vocabulary, competencies, and a coordinated curriculum for development.

In 2014, EU and US leaders underlined the commitment "to expand cooperation in research, innovation and new emerging technologies, and protection of intellectual property rights as strong drivers for increased trade and future economic growth"; e-Health was among the cited priorities of the Transatlantic Economic Council.²³⁹

At the end of 2015, the MoU put in place between DG CONNECT and HHS has been revised to add a third work stream regarding **transatlantic eHealth/Health IT Innovation Ecosystems.** A public consultation was set up between December 2015 and March 2016 for the purpose of gathering stakeholder opinions which resulted in the final revised Roadmap. The new work-stream aimed at **encouraging innovation** in the eHealth/health IT industry and ensuring linkages to the other two roadmap work-streams. One of its key elements was to identify the key US and EU stakeholders that can incite collaboration between companies and ecosystems in each jurisdiction.²⁴⁰ The foreseen activities for this additional work-stream are outlined in the annex to the roadmap; the activities started in 2016.²⁴¹

By 2018, the partnership successfully delivered a revised roadmap and identified the gaps regarding Health IT interoperability and the competencies and knowledge deficiencies among the eHealth workforce. Through this joint effort, the US and the EU made major progress in supporting the transatlantic eHealth/ Health IT innovation ecosystems.

Over the time, several projects have been co-funded by the EC to support the EU-US eHealth roadmap putting into practice. Also, an EU-US Health agreement is in place which fosters collaborations that can for some include digital components; for example, this **bilateral arrangement between the US**

²⁴¹ <u>https://ec.europa.eu/digital-single-market/en/news/eu-and-us-strengthen-their-collaboration-ehealth-it</u>





²³⁶ <u>https://ec.europa.eu/digital-single-market/en/transatlantic-ehealth-cooperation</u>

²³⁷ <u>https://ec.europa.eu/digital-single-market/en/news/eu-and-us-strengthen-their-collaboration-ehealth-it</u>

²³⁸ <u>https://ec.europa.eu/digital-single-market/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century</u>

²³⁹ <u>https://ec.europa.eu/info/research-and-innovation/strategy/international-cooperation/united-states_en</u>

²⁴⁰ http://ec.europa.eu/information_society/newsroom/image/document/2016-30/eu_us_roadmap_16674.pdf

National Institutes of Health (NIH) and the European Commission allows for co-funding opportunities in the US programme for participants from the EU and vice versa.

On the policy side, no more recent agreement was put into place, even though the recent US elections (November 2020) and the resulting change of government might give the relations a new impulse. It is yet to be seen what the results will be with regards to EU-US digital Health collaboration.

9.2 Good practices and outlook for further international collaboration

As shown, digital Health and its application to support an active and healthy ageing is a global challenge and aim that is shared between the EU and the strategic partner countries. Even though some priorities and employed strategies may differ, a number of initiatives have been set up in each region / country over the years that may be a basis for collaboration on international level. The following chapters provide a non-exhaustive list of examples stemming from desk research and exchange with experts in particular and give thus an outlook into potential pathways for future collaboration.

9.2.1 Canada

The following two case studies are key examples of research projects in the area of digital health for active and healthy aging that were developed in Canada and have been implemented successfully into healthcare delivery settings in various regions throughout the country. The first case study highlights the use of a home health telemonitoring system that was developed in a Canadian province but has since garnered international partnerships through one of EUREKA's international programs and is expected to be implemented and evaluated in several European countries. The second case study showcases one of Canada's innovations that improves access and reduces long waiting times for specialist care through an online platform that connects primary care providers to specialists. This innovation is a prime example of a Canadian-born solution that can be replicated in any country around the world.

Case study 1.

Dr. Kendall Ho, a practicing emergency medicine specialist, is one of Canada's leading eHealth researchers and the founding Director of the University of British Columbia's eHealth Strategy Office. In 2015, Dr. Ho was funded to lead one of CIHR's eHealth Innovations Partnership Program teams, TEC4Home. Partnering with British Columbia's Ministry of Health and TELUS Health, the programme will implement and evaluate a home health telemonitoring system designed to support transitions from hospital to home for heart failure patients. Patients are discharged from the hospital with a kit that includes a tablet, weight scale, blood pressure cuff, and pulse oximeter to collect and send biometric measurements daily for 60 days post-discharge. A clinician monitors the data remotely and can follow up with patients if they detect any early deterioration as a means to avoid emergency department readmissions, a 59% reduction in hospitalizations and a 44% decrease in health costs per patient. The TEC4Home technology has spread across 19 communities in the province





of British Columbia. In addition, Dr. Ho has taken this technology internationally, partnering with two international consortia which applied respectively to the EU's Active and Assisted Living Programme and the industry-led EUREKA ITEA3 cluster instrument funded in Canada by NRC IRAP.

Case Study 2.

Primary care physician, Dr. Clare Liddy, was frustrated with the poor access and long waits times to receive specialist care and advice in Canada. In order to combat this dilemma, Dr. Liddy developed The Champlain BASE™ (Building Access to Specialists through eConsultation) eConsult service, a secure online platform connecting primary care providers and specialists. Primary care physicians can submit a question via the web-based portal and an eConsult Specialist assigns the case to an available specialist, who receives an email notification prompting them to access the case through a secure site. The average response time is two days and the specialist is able to answer the question, request more information, or recommend a referral. This platform offers patients more efficient, integrated, coordinated care. It has reduced wait times for accessing specialist care for non-urgent cases from months to days and 40% of cases resulted in avoidance of an unnecessary face-to-face referral. Furthermore, a recent cost analysis estimates an average savings of \$254.30 each time a patient living in rural area uses the platform and avoids an in-person visit to a specialist in terms of lost wages and associated travel costs. The Champlain BASE™ eConsult is now spreading to various regions across Canada and is available in over 110 different specialty services, including cardiology, pharmacy, and geriatric medicine.

A new area of cooperation regarding technologies for Global Health Care was agreed in 2018. "Along with the US, Europe and Japan, Canada has mature, large-scale healthcare markets that are part of the main global regulatory domains in healthcare. The promotion of **regulatory harmonisation** and global cooperation between them will not only enhance trust in European healthcare product regulations, but also promote the **adoption of common reference and technical standards** world-wide and at the same time maintain and enhance access to worldwide markets. "



In addition, the experts interviewed expressed their interests in learning from Europe about **how digital health is implemented into health and social systems** in the different European countries, and particularly within the countries similar to Canada and with similar challenges. The **impact of digital health on the health system and on health policy** is of interest for future collaboration.

9.2.2 China

International Collaboration may be one response to fulfil expectations set into digital health which are to improve patients' awareness of diseases and access to high-quality medical resources through digitalisation, to innovate digital diagnosis and treatment of the entire course of disease, and to drive long-term disease management through digital drive.







In an interview, an academic stakeholder specialized in Digital Health from China, expressed that in the past projects, their cooperation with the EU have been considered as very good. In order to solve a problem together, they had a very clear division of labour and close communication. They have been regularly conducting academic visits and sharing work results. He suggested that he hopes that in the future the cooperation would continue, and that this can be innovative for University students – working with other cultures would be beneficial for students' education.

At the same time, China will practice digital innovation in the fields of drug research and development, disease management, medication services, and innovative payment. Current hot topics are Artificial intelligence, Internet of Things and other technologies to create a new patient-centric digital medical and health service model to improve access to high-quality health resources, serving the majority of doctors and patients.²⁴²

Medical imaging and medical robotics are the two priority fields for Sino-EU collaborations. EU has a very solid technical and industrial foundation in these two fields. Meanwhile, AI medicine and intelligent manufacturing are rapidly growing in China. The collaborations in these fields are expected to bring new innovations to advance clinical diagnosis, therapy and medical research.

9.2.3 Japan

Healthcare challenges are very similar around the globe. Japan may emerge as the leading learning laboratory for digital health innovation, providing the world with technology and policy lessons learned.243

Japanese policy towards digital health and healthy aging continues to focus on automation and productivity improvements, while creating a more robust safer environment for healthy European countries aging. are considered by experts with a long history of advanced senior care. This



"The knowledge and wisdom based on their rich experiences have been reflected to the designs of their care-providing systems and policies, care services, and also the design of digital devises and *service applications" – Digital Health* Expert from Japan

long experience is considered as an interesting opportunity for Japan, which could learn to think and design Japanese future innovation on digital services and applications. For example, on telemedicine or on patient-centred homebased care.

Dementia care with digital technologies is also considered as a hot topic for further collaboration with Europe.

²⁴³ https://www.healthcareitnews.com/news/john-halamka-japan-emerge-leading-learning-lab-digital-health-innovation







²⁴² https://www2.deloitte.com/content/dam/Deloitte/cn/Documents/life-sciences-health-care/deloitte-cn-lshcpredictions-2022-zh-180326.pdf
More in general, it will be important to work on the **more general collaborative environment**: how to create mutually equal collaborations among all the players such as private tech-companies, academia, and professional care givers like us and care-taker, patients and families?

9.2.4 South Korea

In efforts to address infectious diseases, rare diseases and antimicrobial resistance, the EU and ROK began the Initiative for Global Research Collaboration for Infectious Disease Preparedness. Both sides cited good progress and expressed the need to continue their endeavour.

When addressing global challenges, the relationship between trading and S&I is an important factor. Technology is constantly changing, so in order to keep up with new technology one must participate in global commerce. This is the most efficient way to develop technology. Ignoring trade causes limitations in technology and halts the progress of innovation. This in turn slows down economic growth. If technology is to be used to address global challenges, then both Korea's and the EU's trade policies must support technology.

In conclusion, there is a demand for the **development and global commercialisation of holistic care services with innovative technologies and cooperation.** Therefore, Korea is a relevant place to conduct pilot projects for **AHA related technologies** as the elderly population is large and the governmental support is high.

Interviewees confirmed that there is a great need for and commitment to cooperating with Korea's innovative SMEs and global partners as much as possible. They notice the importance of building, analysing, and exchanging data for the **holistic care service** globally. An **'AHA platform'** shall be built all together to solve social problems caused by a super-ageing society soon. Furthermore, along with concerns over rising welfare costs, all countries should find out how to transform the welfare in the direction of industrialisation for the future generations.

Experts also mentioned the importance to develop and commercialise new technologies together with various pilot projects. In particular, they consider crucial to develop **digital solutions for the prevention and management of dementia** since there is no medicine to cure it and the dementia-related costs are estimated at 240 trillion won in 2020 worldwide.

Finally, mental, psychological and wellness related R&D are considered to be interesting topics for collaboration, since EU is advanced in these topics.

9.2.5 USA

As previous international collaborations have demonstrated, global partnerships yield significant findings that help healthcare systems discover best practices for universal challenges. With the global ageing society, many nations share common priorities in regard to the management of chronically ill seniors, rising healthcare costs, and the unmet desire for individuals to age in place. The US, which has consistently been criticised for the fragmented and costly healthcare system, is actively working to achieve the triple aim of high-quality care, improved population health, and low per capita healthcare costs. Digital health has been deemed as one of the key elements towards this vision. The potential





displayed by telehealth, digital therapeutics, AI, IoT and blockchain have prompted people to envision and demand a passive, preventative, and continuous model of care that allows people to age well.

While the American market has provided a supportive environment for health technology developers to create and pilot, challenges regarding the adoption and implementation of digital health remains. Hence, the experts we interviewed would like to turn to international partners for **research on how to seamlessly implement digital health technology and maximise its potential for the AHA movement**.





This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826092.

10 Conclusion

Worldwide the ageing population is growing while the economic old age dependency ratio (inactive 65+ year olds vs. employed aged 20-64) is projected to rise significantly in the coming decades. Living longer does unfortunately not necessarily mean living a healthier, more active and independent life. This results in public spending on health and long-term care that is steadily rising and is expected to continue to do so.

Digital technologies including wearables, sensors and telehealth tools that allow patients to engage in their own health and benefit from different care delivery models are an important means of reducing the societal economic burden whilst bringing evident improvement to the ageing population in their daily lives. Indeed, to tackle the rising challenges, the global trend is shifting from centralised and institutional health care models to more individual and personalised AHA solutions.

Active and healthy aging is a global challenge where international collaboration can make a real difference: as digital health equipment and processes have the potential to contribute to higher quality therapeutic decision-making and treatment as well as to increase the process and performance quality of health services, the central importance of digitalisation in the healthcare sector is internationally recognised. The aim must be to enable healthcare systems to provide preventative, integrated, connected, and inclusive care and to support mutual learning.

The country-specific chapters of this report have provided an overview of the R&I landscape in the EU and each of the strategic international countries (Canada, China, Japan, South Korea, the USA). They have also illustrated each region's/country's priorities and challenges. Each nation (geographical region) has its own approach towards care delivery and the use of health technology. Numerous players and stakeholders are building networks on a national and international level with the aim to address the demands of AHA and eHealth and to promote collaboration and support at multiple levels. Relevant key programmes and funding agencies are supporting collaboration on a national and international level facilitated e.g. by the MFF (Multiannual Financial Framework) and other financial frameworks.

Still, the access of new technologies to the market is difficult due to policy regulations and market penetration. Therefore, international collaboration is necessary not only to trigger excellence in research but also to enhance the understanding on how health technology can be promoted and made acceptable for users, thus find a market and bring benefit to the ageing population in particular.

Chapter 9 has specified the existing policy framework for international collaboration but also pointed to some open aspects that can be perceived as barriers. As a main example can be cited the data regulations. Indeed, it has been highlighted that without cross-border secure access to data sets, shared computing and storage capacity and an appropriate regulatory framework that allows for secure access to datasets across borders, it remains difficult for healthcare organisations to optimise their services and for researchers to reach the scientific achievements that are needed to support early disease diagnosis, coordinate response to epidemics and accelerate therapy development. In order to come to important achievements with relevance for active and healthy ageing, many sources point to the necessity of a continued and enhanced strong policy dialogue.





Even though good practices and success stories have been identified in each target country in form of funded and ongoing or successful terminated projects and collaborative initiatives, further international demand for cross border projects especially between EU R&I actors with Asia and North America seems to be evident. Whilst R&I funding programmes provide a framework and important players in each country/ geographic region engage in them and collaborate on research and innovation related to digital Health, political arrangements are needed to facilitate the access to programmes and trigger results for the benefit of patients and the ageing population in particular on a global scale.

In conclusion, active and healthy aging is a global challenge and the improvements of the conditions of the aging population should be a common goal. This requires a common set of priorities, among others in the field of digital Health. Whilst this Panorama Report in its descriptive nature had for purpose to provide an overview of the current landscape in each country / geographic region and to describe the state of the international collaboration frame, another IDIH report will develop a matrix on commonalities: the Report "Recommended areas to consider for international cooperation in digital health' research and innovation, including priority matrix", will illustrate where shared priorities between the EU and the international partner countries could foster collaborations. It will be the basis of further consultative work with expert groups from research, user groups and policy and for the final development of a joint Roadmap in order to implement the IDIH project's vision:

To develop a Roadmap to design international collaboration of the digital transformation in active and healthy ageing.





11 Annex – Interview Guidelines

11.1 Guidelines for the EU interviews

IDIH - Interview Guidelines for Panorama of digital health landscape in the EU

General information

Interviewing IDIH partner	
Interview No.	(No names please!)

1 - What are the main research and innovation priorities in digital health (and specifically active and healthy aging) in the EU? What are the main trends?

Summary of the interview	Notes

2 - Which of these priorities are already funded in an international cooperation context?

Summary of the interview	Notes

3 - Which of the priorities could you envisage to be selected for international collaboration, and why?

Summary of the interview	Notes

4 - What do you consider to be the main challenges related to digital health and active and healthy aging in the EU?

Summary of the interview	Notes

5 - Which do you consider to be the main relevant key programmes and funding opportunities in the EU?

Summary of the interview	Notes

6 - Who do you consider to be the most important players and networks in digital health in the EU (including the most active in FP7 and H2020 participants)?





Summary of the interview	Notes

7 - What are the strengths and the weaknesses related to digital health in the EU?

Summary of the interview	Notes

8 - Could you comment on your experience of cooperation between the EU and other countries / major bilateral and multilateral S&I agreements?

Summary of the interview	Notes

9 - Could you share some best practices/success stories and added value for international cooperation?

Summary of the interview	Notes

10 - If you would like to learn from other countries' experiences, what would be the most interesting and useful for you?

Summary of the interview	Notes

11 - In your opinion, what are the research topics that are the most suitable for inter-country collaboration?

Summary of the interview	Notes

12 - How important do you consider engaging in international cooperation?

Summary of the interview	Notes







11.2 Guidelines for the interviews in the Strategic Partner Countries

IDIH – Interview Guidelines for Panorama of digital health landscape in the Strategic Partner Countries

General information		
Interviewing IDIH partner		
Interview No.	(No names please!)	

1 - Which of your national priority fields are already funded in an international cooperation context?

Summary of the interview	Notes

2 - Which of the priorities could you envisage to be selected for international collaboration with the EU, and why?

Summary of the interview	Notes

3 - What do you consider to be the main challenges related to digital health and active and healthy aging in your country?

Summary of the interview	Notes

4 - Which do you consider to be the main relevant key programmes and funding opportunities in your country?

Summary of the interview	Notes

5 - What are the main digital health trends in your country?

Summary of the interview	Notes

6 - Who do you consider to be the most important players and networks in the field in your country/region?

Summary of the interview	Notes





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7 - What are the strengths and what are the weaknesses related to digital health in your country/region?

Summary of the interview	Notes

8 - Could you comment on your experience of cooperation with the EU / the bilateral and multilateral S&I agreements?

Summary of the interview	Notes

9 - Could you share some best practices/success stories and added value for international cooperation?

Summary of the interview	Notes

10 - If you would like to learn from EU's experience, what would be the most interesting and useful for you?

Summary of the interview	Notes

11 - In your opinion, what are the research topics that are the most suitable for inter-country collaboration?

Summary of the interview	Notes

12 - How important do you consider to engage in international cooperation?

Summary of the interview	Notes





