Co-funded by the Horizon 2020
Framework Programme of the European Union

Deliverable 8.4
Market Analysis, Targeting and Positioning

Work Package 8: Impact, Outreach and Collaboration

affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project

Grant Agreement ID: 875325

Start date: 1 November 2019

End date: 31 October 2022

Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019

Topic: SC1-DTH-11-2019 Large Scale pilots of personalised & outcome based integrated care

Funding Scheme: IA - Innovation action

Disclaimer

The TeNDER consortium consists of the following Partners.

Table 1: Consortium Partners List

No	Name	Short name	Country
1	UNIVERSIDAD POLITECNICA DE MADRID	UPM	Spain
2	MAGGIOLI SPA	MAG	Italy
3	DATAWIZARD SRL	DW	Italy
4	UBIWHERE LDA	UBI	Portugal
5	ELGOLINE DOO	ELGO	Slovenia
6	ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	CERTH	Greece
7	VRIJE UNIVERSITEIT BRUSSEL	VUB	Belgium
8	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	HOPE	Belgium
9	SERVICIO MADRILENO DE SALUD	SERMAS	Spain
10	SCHON KLINIK BAD AIBLING SE & CO KG	SKBA	Germany
11	UNIVERSITA DEGLI STUDI DI ROMA TOR VERGATA	UNITOV	Italy
12	SLOVENSKO ZDRUZENJE ZA POMOC PRI DEMENCI - SPOMINCICA ALZHEIMER SLOVENIJA	SPO	Slovenia
13	ASOCIACION PARKINSON MADRID	APM	Spain

Document Information

Project short name and Grant Agreement ID	TeNDER (875325)
Work package	WP8
Deliverable number	D8.4
Deliverable title	Market Analysis, Targeting and Positioning
Responsible beneficiary	UBI
Involved beneficiaries	DW
Type[1]	R
Dissemination level[2]	PU
Contractual date of delivery	M15
Last update	27/01/2021

[1] **R:** Document, report; **DEM:** Demonstrator, pilot, prototype; **DEC:** Websites, patent fillings, videos, etc.; **OTHER**; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot.

[2] **PU:** Public; **CO:** Confidential, only for members of the consortium (including the Commission Services).

Document History

Version	Date	Status	Authors, Reviewers	Description
v 0.1	10/11/2020	Draft	Beatriz Barateiro (Ubi)	Table of Contents
v 0.2	18/01/2021	Draft	Beatriz Barateiro (Ubi)	Added content
v 0.3	18/01/2021	Draft	Paride Criscio (DW)	
v 0.4	20/01/2021	Draft	Tomaz Kompara (ELG)	Added content
v 0.5	21/01/2021	Draft	Beatriz Barateiro (Ubi)	Added content (according to feedback from meeting)
v 0.6	22/01/2021	Draft	Beatriz Barateiro (Ubi), Sofia (HOPE)	Added content (according to feedback from meeting)
v 0.7	25/01/2021	Version for peer review	Beatriz Barateiro (Ubi)	Added content (according to feedback from meeting)
V0.8	26/01/2021	Peer review	Paride Criscio (DW)	General review and added contents
V0.9	27/01/2021	Peer review	Armend Duzha (MAG)	General review

Acronyms and Abbreviations

Acronym/Abbreviation	Description
AD	Alzheimer's Disease
PD	Parkinson's Disease
CVD	Cardiovascular Diseases
EU	European Union
ICT	Information and Communication Technology
TeNDER	affecTive basEd iNtegrateD carE for betteR Quality of Life
mHealth	Mobile health
WHO	World Health Organization
QoL	Quality of life
DALYs	Disability-adjusted life years
GDP	Gross domestic product
IoMT	Internet of medical things
CAGR	Compound annual growth rate
SHI	Statutory health insurance
GHG	Greenhouse gases
DiGA	Digital health applications
IT	Information technologies
NHS	National health system
AI	Artificial Intelligence
GP	General practitioner
LTC	Long term care

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Executive Summary

This deliverable provides a detailed analysis of the state of the art in the healthcare sector, covering tendencies and expectations about demographic and health issues, but also about the market evolution in Europe. An extensive analysis of four strategic countries – Germany, Spain, Slovenia, and Italy – is presented, which was performed using the PESTEL methodology and some potential competitors are identified. The target groups and positioning that TeNDER should adopt are also described ate the end of the document.

1. Introduction

1.1. Purpose and scope

TeNDER, which stands for affecTive basEd iNtegrateD carE for betteR Quality of Life, is a project funded by Horizon 2020 that aims to develop an integrated care solution by using affect based micro tools. The solution in development consists of an extensive set of products and services that aims to support in the provision of healthcare manly to the elderly who reveal chronic conditions, particularly Alzheimer's disease (AD), Parkinson's disease (PD) and comorbidity with Cardiovascular Diseases (CVD). With its mission in mind, TenDER will perform 5 pilots involving more than 1,500 people in total, from patients, to healthcare professionals, social workers, caregivers, and others. Each pilot will fit into a different scenario ranging from home, day-care centre, rehabilitation centre, and hospital.

This deliverable is the output of Task 8.4: Market Analysis, Targeting and Positioning part of Work Package 8: Impact, Outreach, and Collaboration. Its main objective is to present an overview of the markets associated with the TeNDER ecosystem, by completing a thorough market analysis across EU countries, starting from the partners' countries of origin. This document will serve as a basis for future decisions on diversified topics concerning TeNDER' market entry.

1.2. Contribution to other deliverables

This deliverable covers important matters that will feed into the deliverable 8.5: business model, since it covers relevant topics to define a sustainable business plan to integrate TeNDER solutions in the market. Particularly, it analyses opportunities and challenges for ICT technologies operating in the healthcare sector that will be useful for completing a SWOT analysis that must be included in the business model.

1.3. Structure of the document

This deliverable is structured in eight sections, after Introduction. At first, we focus on a general analysis, from demographic to health tendencies. Next, we present a more detailed analysis about the healthcare sector, particularly covering technology access and the scenario of AD, PD, and CVD in Europe. Following this, we cover future trends of the e-/m-Health industry, both at global and European level. The next two sections contain the opportunities and challenges identified for businesses operating in this industry. The sixth section extensively describes the external environment of the selected markets for analysis, namely

Germany, Spain, Slovenia, and Italy, which consist of the countries where the pilots will be held in the duration of the project. The following comprises the study on potential competitors, and is divided in two subsections, one that focuses on other projects funded by the Horizon 2020 programme and another that is concentrated on the bigger market players. To finalize, the last section suggests our target market and positioning near our potential customers.

2. Industry Overview

2.1. Population and Health

Over the past years we have been facing changes in the population dimension. We are going through an unprecedented population growth era; life expectancy keeps rising both in developed and in-development countries, leading to an ageing population scenario., We are facing environmental changes with unknown consequences, due to changes in our lifestyles. These are just some examples. We must take into consideration that these changes are impacted by healthcare or have an impact on it. The population growth and increase in life expectancy can be explained by the great improvements in health systems worldwide, but these will increase the pressure on the system.

The increase in life expectancy in Europe, which was 78,2 years for male and 83,7 for female, in 2018, has placed the population aged over 65 years representing 19,7% of Europe's population, whilst young population, aged between 0 and 14 years old, only accounts for 15,6%. In this scenario, Italy and Greece are the countries with the higher elderly population percentage, being 22,6% and 21.8% respectively (1).

Although they are representing a higher percentage of the population and healthcare evolution, people aged over 65 are not necessarily living with better quality of life. At 65, European citizens are expected to live 19,9 more years, but only 9,9 of those will be healthy, without any limitation (2). In fact, more than 50% reveal at least one chronic disease, mainly non communicable. These are commonly known diseases such as cancer, diabetes, cardiovascular disease, chronic respiratory diseases, Alzheimer, and other forms of dementias. NDC's deaths represent around 70% of all deaths globally, but this number raises to 80% when considering only developed countries (3).

In 2016, diseases of the circulatory system caused the death of almost 1.7 million people just in the European Union. Cancer was the second major death cause, representing 1,3 million deaths. In the same year, mental and behavioural diseases and diseases of the nervous system together were responsible for the death of almost 440.000 people (4). In 2018, approximately 9,1 million people aged over 60 are living with dementia in EU member states.

This scenario of an increasing number of citizens with chronic diseases and disabilities has brought up the need to supply citizens with long-term healthcare. This type of care consists of delivering personal, medical, and social services that help monitoring and manage the health status of individuals with disabilities, illness, or other sources of dependency. The main goal of long-term healthcare is to allow these patients to live a normal life as much as possible (5).

2.2. Healthcare State of the Art

The increase of healthcare needs associated with the population growth has been a stimulus for innovation and technological development in the health sector. The ageing population also pressures the current health system to become more integrated and people-centred and focused on well-being. Some EU countries have already begun this transformation, but efforts still need to be made to achieve the desired patient engagement and empowerment.

Now, more than ever, citizens no longer want to play a passive role on their health, but rather a proactive one, characterized by transparency and personalized care. Consumers want a trust relationship with the system, therefore being available to share information on their health and other necessary domains, but at the expense of having access to health records and being involved. Consumers want to use the available tools to increase their health and well-being. These tendencies are taking hospital leaders to invest in virtual care technologies and telemedicine, rather than expanding physically. Quite the same has been happening around Europe, with some countries reducing hospital capacity and average length of stay and strengthening community care.

Moved by societal changes, healthcare is being dominated by various technological innovations. Namely, the 5G technology, designed to support the movement towards a complete digital environment and the massive transference of data in the healthcare industry associated with it. Also, the integration of Artificial Intelligence (AI) to improve diagnostic and treatment efficiency and inclusion of robotics that assist in complex procedures by improving flexibility and precision and augmented reality. AI and process automation are helpful in data

management as well, facilitating cooperation and delivering information to support in the decision-making process. In addition, Natural Language Processing (NLP) systems are being used for medical notes and (virtual) assistance based on spoken conversations. Sensors and wearables are also being used in healthcare, mostly to monitor patient health through vital signs and/or other indicators. The Internet of Medical Things (IoMT) has also assumed a relevant part in the progress of healthcare, namely by connecting medical devices to software applications, allowing to integrate patients, caregivers, data, and processes aiming for more efficient outcomes.

Concrete situations of the utilization of these innovations, and those more common amongst several healthcare systems, are live videoconferencing for virtual medical appointments, platforms for patient's medical records storage and sharing, electronic prescriptions and remote patient monitoring.

These are just a few examples of disruptive technologies invading the system to improve life conditions at last. A specific example is Japan's healthcare system that is evolving towards home-based care, given the rates of prevalence of dementia. New technologies are being implemented to understand disease progression and enhance communication between patients, families, doctors, and other caregivers. The ReMiND[3] project in India is another example of usage of new technologies to give access to healthcare. This platform supports caregivers in client assessment, counselling, and early identification and rapid treatment of pregnancy, postpartum and new-born complications. Additionally, AccuHealth[4] is a platform for patient remote monitoring that integrates a monitoring device for vital signs and responses to abnormal readings through a 24/7 medical team acting as an extension of the platform. Likewise, ElliQ[5] is a robot developed for an Israelite start-up, to address social isolation. The robot is interactive and equipped with a microphone, a detachable tablet, and a camera, which together allow to study the environment, identify the user's activity, interact with them, make contact with other devices, and other features. Samsung also created a robot - Bot Care - that resorts to AI and sensors to measure vital signs, control medication schedules and offer exercise suggestions. Furthermore, devices that detect falls and call for help are also being developed, for example Walabot[6] Home and Abeye[7].

[3] https://www.crs.org/our-work-overseas/research-publications/remind-project
[4] https://www.accuhealth.tech/home
[5] https://elliq.com/
[6] https://walabot.com/
[7] https://www.abeye.tech/

2.2.1. Alzheimer's disease

Alzheimer's disease (AD) is the most common form of dementia. It is a neurodegenerative disease that slowly and progressively destroys brain cells that affects memory and cognitive function of 60 to 80% of people with dementia, leading to confusion and mood swings. It also impacts basic activities such as eating and bathing. It is most diagnosed in 65-year-olds or more, who eventually will become dependent and in need of support from others in daily activities, and it is terminal (6).

In 2018, 9.780.678 people aged between 30 and 90+ reported some sort of dementia. 320.917 of them are aged between 30 and 59 years old. This means that around 224.000 people of this age range in Europe live with AD (7). 1 in 20 65-year-olds or more and 1 in 5 people over 85 years old have AD (8).

Alzheimer's patients are mostly in homecare (50% to 80%). Therefore, the number of people affected doubles, once it also impacts the carer's life, who may need to give up employment, leisure activities and his/her own daily life to assume the informal carer tasks. From an inquiry performed to more than a thousand caregivers, half of them reported to be caring for an AD patient for more than 10 hours a day, half reported they had insufficient information about the disease and most reported that behavioural symptoms and practical difficulties are the most problematic. This accounts for a significant financial impact for the patient and families due to the costs of healthcare and possible reduction of income (8).

The Global Action Plan on the public health response to dementia 2017-2025 from the World Health Organisation (WHO) aims to guide the strategy definition by Member States to improve the lives of people with dementia and caregivers while diminishing the impact on the economy.

Currently, AD represents a considerably high percentage of the expenses in healthcare in Europe. The overall costs, in 2015, reached an amount of € 232 billion (9). If the treatment method and strategy for dementia does not change, the predicted cost will reach € 421 billion in 2030 and € 633 billion in 2050. According to another study that analysed the economic burden of Alzheimer's patients in Germany, France, the United Kingdom and Czech Republic, the annual cost per patient was € 51, € 37, € 21, and € 10 thousand, respectively (10).

In response to the economic burden of this disease and the need to act on an increasing population suffering from Alzheimer's, aligned with the global action against

dementia, some countries have already started to implement national dementia plans. Germany announced a national dementia strategy that has started in September 2020, and it is the 32nd country to do so. On the other hand, France was the first country adopting this strategy to react on the increase of the prevalence of the disease, in 2001, and it has been updating it since, every 5 years. The UK followed the tendency and started a national dementia strategy with a publication called "Living Well with Dementia" in 2009, that established 17 objectives. Although the goals were not accomplished yet, significant progress has been made, and the dementia strategy is still ongoing. Lastly, Czech Republic also launched a national action plan for AD and similar disease for the period of 2016-2019 that assembled 14 aims and 28 objectives (6).

Supported by all national plans on dementia, to increase the quality of life of Alzheimer's and other dementia's patients and their families, there is an effort to empower patients to live in the community, to give them tools that ensure some level of independence, and to give access to an integrated, centred, and long-term care. To provide these, a variety of technologies are already being used, including digital devices, intelligent applications, sensor and sound devices, wearables, and others. Other tools, of a simpler nature, are also being used by Alzheimer's patients, like reminders in the form of recorded messages that play at the scheduled time or messages that play according to some activity or lack of it, sleep monitors, and also medication management technologies. Some devices are also integrated with GPS location and tracking software that alert in case of irregular movements. More complex instruments, some still in development, consist of smart devices that control the use of electronics in the house that give an alert if something was left on, monitoring solutions like mobility sensors and video cameras, and personal assistive robots. These and other solutions can be categorized in groups of ambient assisted living, according to its nature or the needs they fulfil, that consist of daily task facilitation, mobility assistance, healthcare and rehabilitation and social inclusion and communication (11).

2.2.2. Parkinson's disease

Parkinson's disease (PD) is the most frequent neurodegenerative condition characterized by affecting the cells that control movement (12). Around 10 million people suffer from PD, most of them are 60 years old or more but 1 out of 10 are under 50. This condition reveals motor and non-motor symptoms, being the most common ones: tremor, slowness of movement, muscle rigidity, pain, anxiety, depression, sleeping disorders and dementia. Although PD is not life threatening, it can have a great impact on quality of life and each individual's

independence (13). Among other neurological conditions, PD has the most increasing prevalence and death rates. In Europe there are around 1,2 million people living with Parkinson's and this number is expected to double by 2030 (14).

Parkinson's is a progressive disease with great impact on the quality of life, that does not affect life expectancy, so people can live up to 20 years with PD. This suggests that the financial burden will escalate, not only since it increases as the symptoms get more severe but also due to the increase of the number of individuals aged over 60 reporting to have this condition. In 2004, the annual spend on PD in Europe was € 10,7 billion, which is almost 13% of the total expenses in neurological diseases. In 2010 that value raised to € 13.9 billion, which represents a 30% increase (14).

A study performed in five European countries - Austria, Czech Republic, Italy, Portugal and Russia - concluded that the average cost per patient fluctuated between € 2620 in Russia and € 9820 in Austria. Direct costs represented about 60-70% and the major expenditures were allocated to inpatient and outpatient care, medication and formal and informal care (15).

The scenario of an increasing prevalence of Parkinson's, calls for raising awareness about technologies that are already being used by patients and caregivers, that allow for a certain increase of the Quality of Life (QoL) and the need to continue research and investment in this field. Optimizing expert care for PD will help caregivers and release some burden of health systems. This will also be beneficial for the patients, once it may increase access to skilled and specialized care, lowering the risk of complications. In this sense, many excellence centres have been appearing across Europe, for example Fresco Network in Italy, Philipps University in Germany, 2 others in the UK and more, totalizing 47 centres worldwide (16).

In Europe it is noticeable that there are some gaps when it comes to dealing with PD, namely the need for a personalised approach that considers personal needs, the lack of access to specialized healthcare professionals, both for the diagnosis and for monitor progression. Coordination and communication must also be improved as well as monitoring methods (17).

Guided by these needs, a variety of technologies have been developed and implemented with the objective of significantly improving diagnostic, monitoring and integrated care for PD patients, such as sensors, cloud computing, IoMT, mobile communications, among others. The use of these technology-based innovations for remotely analysing behaviours in everyday life can be helpful in optimizing treatment, for example. Most technological devices target physical aspects, like movements, tremor frequency, gait and balance changes. There is an

urgent need for the development of some system that targets non-motor symptoms, or both motor and non-motor. In this way, it will be possible for the patients to have access to expert home-based care, improving their quality of life, saving time, money and effort, both to the patient and patient's family and caregivers.

2.2.3. Cardiovascular Disease

Cardiovascular diseases (CVDs) consist of a group of conditions affecting the heart and circulatory system, including coronary heart disease and cerebrovascular disease, among others. Heart attacks and strokes are the most common acute events that CVD's patients experience.

CVDs are the lead cause of death globally. In 2016, CVDs killed almost 18 million people at a world scale, being a considerable share (75%) in low- and middle-income countries and one third premature deaths (deaths of people under 70 years old) (18). In Europe, these conditions account for approximately 3,9 million deaths, which represents 45% of total deaths. In 2015, there were more than 85 million people living with CVDs, and although disability-adjusted life years (DALYs) has been falling, CVDs is still responsible for the loss of more than 64 million DALYs in Europe (19).

The incidence of CVDs in the European Union costs its economy an estimated value of € 210 billion each year, segmented in healthcare costs (in and outpatient care, medication, primary care), productivity losses and informal care at a scale of 53%, 26% and 21% respectively. Ischaemic heart disease is estimated to cost € 59 billion and stroke € 45. The healthcare costs with CVDs alone are equivalent to 8% of total expenditure in healthcare across the European Union, varying from 3% in Denmark, Ireland, and Sweden to 19% in Hungary, which amounts to a mean value of € 218 per capita annually, ranging from € 48 in Bulgaria to € 365 in Finland. In absolute values, Germany was the country with major total health costs which were equivalent to more than 25% of all EU costs. Besides the expenditure directly in healthcare, the financial burden arising from mortality and morbidity is also significant, with losses in productivity evaluated in more than €31 billion due to disability of those still in working ages. Informal care costs are also relevant since they reached an amount of €45 billion (19).

In light of the tendencies noticed over the past years, there is a WHO programme for the development of global strategies to reduce prevalence and mortality of CVDs, however there is still a gap between countries acknowledging the best practices and their execution (20).

Emerging technologies are being implemented to assist mainly in health monitoring with the goal of reducing rates of mortality and rehospitalization and, consequently, healthcare costs. Blood pressure device, weight scale, glucometer, pulse oximeter, continuous positive airway pressure machine, and haematology machine are some of the devices which patients are familiar with. Most recognize the relevance of being in constant contact with doctors and sharing real time information that could provide early detection of worsening conditions (21). Patient empowerment and autonomy can have a positive impact both on the life of the patient and his family and carers (22). However, some patients alone cannot assume the responsibility for monitoring this risk factor, therefore arising the need for user friendliness of all devices or even the automation of some processes.

Besides devices that measure risk factors of the patients, mobile health (mHealth) tools also show benefits and can contribute to improved lifestyle behaviours and disease management. Examples of mHealth instruments are interactive voice response (allows patients to interact with recorded messages and answer inquiries that will give doctors automated access to how the patient is feeling), short message service (communication through reminders in the form of text messages with the goal of improving lifestyle behaviours) and smartphones (these allow for a more interactive communication and access to information via Internet) (23). Movement and biosensors are also in the highlight and digital health means, such as mHealth apps.

These digital devices and intelligent applications assisting CVDs patients allow remote monitoring, for a more integrated and personalised care, and faster response from medical teams. With the spread of the use of technologies, wearables like skin patches, accessories and smart clothing will also be of effective use in the remote monitoring process, over the next few years.

2.3. Future Trends

Some of the future trends have been slightly disclosed above. Namely the population growth that is projected to reach 8,5 billion in 2030 and 9,7 billion in 2050, with 60% and 70% living in urban areas in respective years. Likewise, an aging population is a predictable phenomenon, with people aged over 60 years accounting for 1,4 billion in 2030, which means more old people than children aged between 0 and 9, and in 2050 people of that age group will outnumber the younger generation aged between 10 and 24, reaching 2,1 billion. In relative terms, the elderly population (>60 years) will represent 22% of the world population and Europe will be the most aged region. Those aged over 80 years old will reach 202 million

in 2030 and more than double from then to 2050, overtaking 430 million. Among the causes that justify this, are fertility declining rates and improved longevity, since the first one will be at 1,84 (without considering Africa) in 2050 while life expectancy will reach or surpass 80 years everywhere but in Africa (24).

Ageing populations mean higher pressure on the healthcare systems, since chronic, non-communicable diseases and disabilities are common amongst most 60 or more-year old's, many of which require regular doctor visitations or treatments and daily medication. National policies need to focus on the capacity and sustainability of healthcare systems, both financially and at infrastructure and human resources levels. The integration of technology needs to be at the centre of the decision-making process, as a driver for better public health and a more resilient system, once these will allow for early detection of chronic conditions, avoid hospital admissions, diminish length of stay, among other benefits, thus lightening the stress on the system.

Retailed clinics, virtual care and home-based care will be some of the options for patients in need of a more flexible offer from healthcare providers. Nanotechnology, biotechnology, 3D printing, artificial intelligence, neurotech, digitalization and many other fields, will likewise become commonly used in delivering care models. Disruptive technologies will take over the healthcare industry, focusing on its various dimensions, from preventive medicine, to diagnosis, to treatment, monitoring, long-term care, and even just well-being.

Besides hospital care, the experience inside the hospital will also change. There will be smart-hospitals, equipped with a lot more artificial-intelligence interactions, automated, allowing a more immediate care, giving directions to patients leading them to the right place at the exact time, ending waiting rooms. In ten years, we will be able to accurately measure vital signs with a smartphone, and it will take the temperature and analyse blood pressure as well. In a few years it will be likely unusual to operate with human hands instead of robotics, since it will be much more precise and less invasive. Virtual reality will be present to bring patients and families together, improving the experience and diminishing the negative impact of being ill and/or in the hospital, also contributing to a reduced hospital stay (25).

However, the tendency to become less dependent on hospitals, associated with an aging population and increase in the prevalence of chronic and non-communicable diseases, relies on the development of mobile health solutions and tools that assist in providing distant care. Smartphones capabilities in this field are continuously improving, but more recent

innovations impacting mHealth consist of personal voice assistants and interactive social robots.

The global wearable sensors market is rocket speed growing, and it is predicted to value $139 billion in 2026 (26), with Fitbit, Apple, Samsung, Philips Healthcare, and others leading the way. There are already diversified sensors, for example skin patches, ear plugs, watches, clothing and so on. The adoption of this technology will be driven by healthcare awareness and favourable regulatory policies, which are already starting to be visible in some societies.

In 2018, the European Union Aging Economy was worth $4 trillion, according to Oxford Economics, and it is expected to grow given the demographic trends already stated above. With the digitalization also growing across different sectors, it can be projected that the global ageing economy reaches $27 trillion in 2025 (27). When it comes to routinely adopting these ageing relatable technologies, Japan will most likely lead the way, since it has a rapidly ageing population, strong technological infrastructure, and also social and cultural fit. In Europe, The Netherlands, Denmark, Norway, Sweden, and UK, all reveal strong interest in this field, both from governments and private corporations. Overall, the rest of Europe is well positioned to follow the trend.

2.4. Opportunities

Many tendencies that are leading the shifts in the healthcare systems consist of opportunities to platforms like TeNDER.

Starting with demographic and health facts, the number of citizens that report having dementia is of great relevance, since it is expected to reach 82 million by 2030 and 152 million by 2050. In this sense, countries must be prepared to give the necessary care to its citizens and account for the pressure that this increasing number will put on the economy and people at working ages.

Ageing population has also been raising questions about whether a longer period of life will mean more productive years, living with a reasonable quality of life and in social engagement, or will those extra years consist of periods of illness and dependency. The first hypothesis is clearly the society's goal. Therefore, there is an incentive to platforms that may ease the burden on formal and informal caregivers and institutions, by giving back patients as much dependency as possible.

The need for technologies to make this possible and home-based care also arises from globalization and the population movement towards urban areas, once that contributes to a scenario in which fewer older people have family members to monitor and assist them during those years with a higher level of dependency and disabilities.

Also, today, there are less people getting married and having kids. These societal changes increase the urgency to acquire better knowledge and information and tools that will give access to care to the older generations, as support from families and informal caregivers will be rarer each year.

All the above-mentioned link to another tendency, observed across Europe, that consists of increase in healthcare investment, mainly in a more sustainable health system and technologies. Healthcare spending accounted for 9,9% of the GDP in Europe, in the year of 2017 (28). This value is expected to increase, with spending in long-term care raising faster than in other domains of the health system. ICT solutions for chronic and long-term care needs that promote people centred care, developed to empower the aging population to remain active and independent for longer, will be one of the main investments and spending areas. Healthcare spending must be faced as growth-friendly expenditure since citizens' health and well-being influences their productivity and their public spending. This is important, not only from the patient's perspective, but also families and informal caregivers. This willingness of engagement of the population, both patients and families and attention paid from public and private stakeholders funding health care systems to disruptive technologies in this field, consist of opportunities for TeNDER.

The goal is not only to improve patients experience, but to increase effectiveness and reduce costs associated with healthcare. Here, effectiveness of the system plays a major role as it could reduce premature mortality ("more than 1,2 million deaths could have been avoided in EU countries in 2015 through better public health policies or more effective and timely health care") (2). A platform like TeNDER may have an enormous impact on the response to abnormalities revealed by its users, by reducing the time until action and therefore reducing the number of premature deaths.

Finally, another factor that showed the importance of distant healthcare services was the COVID-19 pandemic. The need for social distancing and lockdowns and the overload of healthcare facilities brought to public and private decision-makers attention the benefits and advantages of long-distance care and also the potential of new technologies to improve the work and decision making of health professionals. This health crisis scenario is accelerating

several tendencies in the healthcare sector, like telemedicine and robotics. And it is also an opportunity for ICT and IoMT to flourish in the market. Throughout this crisis, both health administration systems and professionals had to accept and expand the methods to provide care at distance, but the major accomplishment was the acceptance of this modality by consumers. Another aspect that came to light during the pandemic was the scarce of human resources in some countries, which also consists of an opportunity for platforms like TeNDER.

From the tendencies already stated previously it is clear that the eHealth market and particularly the telehealth market are getting more dynamic and will be growing faster for the next few years. In the beginning of 2020, the size of the European eHealth market was evaluated at $3.393 million and it is predicted that it will reach $7.107 million in 2025 (29). Inside this market we can consider the evolution of patient monitoring market, telemedicine market and wearable medical devices market. All of them are expected to grow rapidly in the future, with a 7,10% (30), 14,1% (31) and 18,80% (32) CARGs respectively[8].

2.5. Challenges

All telehealth, digital health and mHealth solutions have shown effectiveness in monitoring patients with various chronic diseases and facilitating patient self-management. However, its popularity has been increasing over the years, and its worldwide implementation is expected, these technologies still face several challenges, of different natures, namely technical issues, patient-related obstacles, and healthcare barriers.

For instance, although some studies are starting to be published, there is still lack of clinical evidence that proves the positive impact of the use of technologies in the health of the patient. The uncertainty around this subject leads to little confidence in the technological capabilities and system efficiency and reliability. The healthcare community, both doctors or other health professionals and formal caregivers, are concerned about the increase of workload and also the need to integrate the already existing systems with the new technologies, revealing doubts about the interoperability, data integrity and quality that can be offered by these sorts of solutions. Besides, clinicians are also worried about the lack of knowledge and training that would give them the skills and capabilities to correctly use the new digital tools.

[8] The CAGR (compound annual growth rate) of patient monitoring market refers to the period of 2019-2024, all others consider 2020-2025.

Systems interoperability can be considered a barrier, mainly due to its complexity, in the case where various digital technologies are being integrated without compromising individual efficiency of each platform. The goal of interoperability is to allow a comprehensive vision about the patients, regardless of the technology or system used to create the information, however this can be compromised when systems are integrated leading to gaps in the communications between them (33). Interoperability will also be a challenge as of the moment for integrating the platform system with public healthcare information systems, on account of the need for market validation and lack of regulation (34).

One challenge that may be faced when integrating TeNDER in the market, is the need to understand social and cultural aspects, namely about acceptability of technological devices, particularly those related with healthcare. This is important from a perspective of the patient, that most times will be of an older age, reveal little personal motivation, low digital literacy, and possibly low economic capacities, but as well as from the perspective of the family or informal caregivers, that may not feel comfortable about depending on digital technology or a gadget they do not understand nor trust, especially due to the substitution of personal face-to-face contact. Low digital literacy is probably the main barrier of this nature, since older patients have less cognitive capacities to understand the usability of different tools, consequently being overwhelmed by technological innovation they cannot keep up with.

Furthermore, long term adherence to telemonitoring or home-based care represents a challenge, particularly if results and improvements are not visible from the beginning. Recent studies showed a decrease in the use of technologies over time, ranging from 90% adherence when the study started to 55% in half a year (21).

In addition, there is a need to be cost-effective, contribute to the reduction of healthcare expenses and be sustainably financed (35).

Finally, the absence of data security regulations and standards and the issues around privacy and security, consist of a technical obstacle to implementing mHealth platforms and tele-health. The process involves transfer physiological data, from external or internal sensors to a centralised platform, encompassing the use of wireless communication networks, processing units, software, and algorithms for data capture and processing. This complex transfer of data and information about the patients is of major concern to the competent authorities and the patients themselves.

3. External analysis

To analyse and monitor the external factors that have influence in TeNDER external macro-environment, a PESTEL analysis will be conducted, to assist in the choice of the country where TeNDER should first enter the market. This analysis allows the consideration of various variables of distinct natures, leading to a wide study of external contingents namely political, economic, social, technological, environmental, and legal.

3.1. PESTEL Analysis

3.1.1. Germany

The Federal Republic of Germany is a federal parliamentary democracy with a tripartite authority into the executive power, legislative power, and judiciary power. The Federal President, Frank-Walter Steinmeier, is the Head of State and the Federal Chancellor, Angela Merkel the Head of Government. The President of the Bundestag, Wolfgang Schäuble, and The President of the Federal Constitutional Court, Prof. Dr. Stephan Harbarth are likewise two of the country's high representatives (36).

The Federal Republic of Germany is formed by 16 states, from which 3 are city-states: Berlin, Bremen, and Hamburg. Most of the states are governed by a cabinet under the administration of a Minister-President.

In 2017 the Christian Democratic Union/Christian Social Union (CDU/CSU), won the highest percentage of the vote (33%), leaving Angela Merkel as Chancellor for the fourth time, the Social Democratic Party (SPD) achieved its worst result since the Second World War (21%) an Alternative for Germany (AfD), unrepresented until this year, became the third party in the Bundestag (13%). Later, in 2018 the CDU/CSU formed a coalition with the SPD, after unsuccessful attempts with FDP and Alliance90/The Greens. Of the 709 Members of Parliament, the coalition partners account for 399 seats. One of the main challenges for this Grand Coalition is the rise of the right wing, anti-immigrant party.

The Grand Coalition between the left-centre social democrats and the right centre conservatives lifted some issues regarding healthcare policies, particularly about health insurance, that the SPD believed should be available for all and not exist in private, contrarily to CDU/CSU ideals. The healthcare system adopted since 2009 defines a **statutory health insurance (SHI)** and **private health insurance (PHI)** mandatory and requires that employees contribute SHI according to income value and to PHI dependent on a person's health, age,

individual risk, and type of coverage. Therefore, health insurance is financed by contributors, on the principle of solidarity, in the sense that all contributors bear the costs and all of them are entitled to medical care. This complex system is self-coordinated, which means that the state defines the framework for medical care and decrees the regulations, but decision on what medical treatments, operations, therapies, and medicines are financed by the health insurance funds and those that are not are decided within the healthcare system, by representatives of doctors, hospitals, health insurance funds and the insured. At last, the supreme decision-making body is the **Federal Joint Committee (G-BA)**.

In March 2018, the CDU /CSU member Jens Spahn was appointed Federal Minister of Health. This Ministry is responsible for different policy areas that can be divided into three main scopes – health, prevention, and long-term care. Responsibility for statutory health insurance is a federal matter. The state's power on healthcare consists of implementing federal legislation, planning, and financing inpatient care as well as supervising municipal public health services. The first new bill of the 2018 Ministry of Health was to reduce mandatory contributions to SHI. Additionally, this administration issued a decree on minimum staffing requirements for nurses in hospitals. Moreover, efforts to improve integrated care have been implemented, following the work of the Innovation Fund that has been promoting new forms of cross-sectoral and integrated care (also for vulnerable groups) with an annual funding of €300 million. Since 2015, electronic medical chip cards have been used nationwide by all the SHI-insured. Recently, there were three **Long-Term Care Strengthening Acts** and an increase in the contributions rate for insurance, with the goal of creating a long-term care precaution fund to support the system from 2035. In the end of 2019, a new **Digital Care Act** was approved in parliament to promote digitalisation in the healthcare sector, through the development of measures to allow innovative and emerging technologies to access this typically conservative market.

Germany remains the most political and economic influencer in the European Union, as its biggest economic power and fourth largest economy of the world, after the US, China, and Japan. In 2019 Germany's GDP amounted to €3,4 trillion and the economic growth rate was 0,6% (in 2018 and 2017 was 1,5% and 2,5% respectively). 2009 was the worst economic year for Germany, but the country recovered extremely quickly reaching a GDP growth of 4,2% already in the next year. It expected that the German economy would decrease 7% in 2020 but again, it probably will recover shortly, with the already approved **German Stability Programme.** In terms of international trade, Germany is the main European exporter, with focus on other European markets but also China and the US. When it comes to

unemployment, rates have fallen considerably, reaching 3,8% in 2017, however these have increased again in 2020, reaching 6,9% in October.

When looking at health spending, Germany has one of the **most expensive health systems**, therefore it represents one of the highest spending in healthcare in Europe, equivalent to approximately **11% of the GDP**. In 2019, the health care expenses amounted to more than **€400 billion**, which represents an **8,5% increase from 2018**, when **healthcare spending per capita reached €4.712**. The biggest share of health expenditure usually comes from the SHI (€230 billion in 2018), that insures almost **90% of the population**. **Hospitals represented more than 24% of those expenses and medicines 13%. Outpatient care amounted to more than €21 million, which is 5% and investments accounted for €7 million**. Recently, the legalization of digital health is driving the **extension of a €200 million investment per year**, for innovation, **until 2024**. Another reform of this administration was the establishment of a health innovation hub, a neutral platform that assists and advises the ministry of health about digitalization opportunities. The digital health driving measures are leading Germany to be the country with **the most favourable business conditions for innovative solutions** in this field. Particularly, **the German eHealth market revenue per habitant is the 4th highest in Europe, evaluated in €4,69 and in 2018 total revenues amounted €554 million**.

The number of people living with dementia has been increasing in Germany, which already represents a significant economic and social burden for the society. **The total cost of people living with dementia** (from the payer's perspective) **was €34 billion in 2016**. For the payer, **people with dementia living at home had lower costs compared to those who are institutionalized**, however this option has **higher total societal cost** due to the increased need for informal care time, **reaching a total cost of €73 billion in 2016**. **In 2015, the cost of CVD was €46 billion**, which represents 14% of total cost of illness, being the most expensive type of illness. **Germany is the European country with higher costs from CVDs**.

The spending in these diseases and the total healthcare expenditure is expected to increase in the next few years, mostly in consequence of demographic tendencies and social behaviours. In December 2020, German population was almost 84 million, being the 17th most populous country in the world with life expectancy reaching 82 years. The distribution between rural and urban areas is like European tendencies, once 76% people living in urban regions and the most populous cities being Berlin, Hamburg, and Munich. In 2019, people with less than 20 years represented 18% of the population, while people aged over 65 accounted for 22%. The old-age dependency ratio is already 31% and expected to be 49 in

2050, a year when the population aged 60 and over will represent more than one third of the population. The scalability of the aging population is clear when comparing the 1,8% increase in German total population between 1990 and 2014, with the number of people in Germany aged 65 and over that rose by 43% during the same period.

Even though health problems increase in old age, **most senior citizens in Germany aged 65 and over report to have good health**. Less than 25% say their health is impaired to such an extent that they are unable to pursue their normal routines, however only 6% of people in this age range are still in employment. **Overweight is the most common health issue in Germany, affecting 70% of men and 60% women aged 65+.** Contrarily to this tendency, **smoking is not very usual for older population** as only 9% report to have smoking habits.

The increase in life expectancy leads to more hospital stays, with people aged 65+ representing 43% of hospital treatments in 2014. **The most frequent diagnosis are CVDs followed by cancer and there is a tendency for multimorbidity**. **The need for long-term care rises sharply beyond the age of 75, representing 1 in 10 persons aged between 75 and 79, while in the 80 to 85 age group the number rises to approximately one in every five**. In the 90 and over age group, the proportion increases to roughly two thirds. **71% of those requiring long-term care (1.9 million in 2013) are being cared for in a care home**. **The number of people in need for long term care will likely rise to 3.4 million in 2030.**

The German health system is one of the most equipped of Europe, therefore considerably prepared for this aging scenario. In 2018 there were almost 2.000 hospitals in Germany, stocked with almost 500.000 beds, 34 per 100.000 of them in intensive care units and 8 per 1.000 inhabitants in total, and with 5,7 million health professionals, **of which 645.000 were in care for the elderly**. In 2017, the number of doctors was 4,3 and 12 nurses per 1000 population, which was higher than the EU averages.

Internet activities are becoming more common among older people being mostly used to write emails, search for information, and read news, with **more than 80% people aged between 60 and 69 using it**, as well as **more than 50% people aged more than 70 years**. In 2017, **91% of households had computer and internet access**, one of the causes that led Germany to be in the 12th place of the ICT Development Index.

Focusing on technology use in the healthcare sector, since the new Digital Care Act was approved **in 2019 many digital solutions for patients and physicians have been implemented**, like online video consultation, access to a secure healthcare data network,

doctors will be able to prescribe **digital health applications (DiGA)** and this **will be reimbursed by insurance companies**. The goal is to connect hospitals, pharmacies and patients, with health insurance guaranteeing that people have access to the innovative technologies and have the necessary skills to use it.

AI is already being used by German doctors, to simulate surgeries and connect with specialized doctors in remote locations. Furthermore, there are already dozens of telemedicine projects active in Germany, like **tele-stroke** units.

Improved QoL is linked to better health and these two are directly connected with environmental conditions, since air quality, for example, can impact respiratory diseases. **In Germany there is much pressure on the environment**, due to the high industrialization level and population density, and the main challenges in this country are improving air quality, addressing water pollution and finishing the designation process for Special Areas of Conservation. On the other hand, **Germany excels at recycling rate**, implementing Green Infrastructure and working to achieve sustainable development goals, **being the European Union leader in waste management**.

In the country there is a diversified range of projects and programmes to achieve better environment conditions, namely the **ProgRess II resource efficiency programme**, which covers sustainable building and urban development, and the resource efficiency of ICT products and the **national programme for sustainable consumption** operating in six different categories. The German government also implemented EU programs, like the **Directive 2015/720** that decreased plastic bags consumption by a third and theEuropean Commission's **Eco-Management and Audit Scheme (EMAS)**, that soon started to lead as the country with the highest number of registrations. Finally, looking at the Eco-innovation index, Germany already scores 4th place while it is still working on the Eco-innovation action plan.

Particularly looking for climate action, we can see **a decrease in total greenhouse gases emissions**, **guided by the Paris Agreement and a national action plan that intends to reduce emissions by 38% in 2030 (compared to 2005)** and provides guiding principles for each sector to reach the stipulated targets and transformations. The sector with higher GHG emissions is energy, in line with the other EU member states, followed by transports, manufacturing industries and other energy use. In this matter, traffic management also arises as a priority, therefore innovative approaches and multimodal transport are being developed and tested in many cities and the Federal Government is making funding of € 1 billion available for municipalities to electrify and retrofit public transport and taxi fleets.

Looking at air quality strategies, the EU has developed a comprehensive body of air quality, which establishes health-based standards and objectives for a number of air pollutants, that has led **emissions of several air pollutants to decrease significantly in Germany** and was the driver for the creation of **the new National Emissions Ceilings Directive for 2020-2029**. Although emissions are being reduced, Germany is still behind in many targets and needs to accelerate reductions in NOx emissions and NO2 concentrations and in other pollutants like ammonia (NH3) and volatile organic compounds.

Additionally, noise is a major concern for the EU and Germany, since excessive noise from aircraft, railways and roads is among the main causes of health problems in the EU and caused approximately 2.200 premature deaths and 13.200 hospital admissions per year in Germany (2017).

In the same way, several new regulations are arising for environmental management; healthcare is a central issue for all countries, mainly due to the demographic changes. In this sense, the most recent and relevant reforms in the German healthcare system are **the Digital Care Act**, approved in 2019, and **the Hospital Future Act**, that passed the Bundestag in September 2020. These are aligned with the above mentioned emerging innovative technologies like software as medical devices (SaMD), apps, wearables and long-distance medical treatment. The German competent authorities are currently working on the definition of a telematics infrastructure for this matter, in line with European laws on the same topic. Some of the regulatory bodies, authorized to regulate by means of guidelines and secondary regulations are the Federal and State Associations of Public Health & Insurance, licensed physicians, the Organisation of the Private Healthcare Insurers and the Federal and State Organisation of Statutory Health Insurance.

The Digital Care Act promotes the use of telehealth and better usability of health data and information for research purposes. It enabled **online consultations, e-prescriptions and electronic medical letters**. It also entitles all individuals covered by statutory health insurance (SHI) to **access for certain digital health applications**, allowing doctors to prescribe digital health apps, and predicts that health insurance companies will invest in digital health businesses. **The second act**, seen as a continuum of the latter, **drives a €3 million investment in modern emergency capacities, digitisation and IT security**. The items of this act include **patient portals, electronic documentation of care and treatment services, digital medication management, IT security measures and cross-sector telemedical network structures**. The funding can also be used to introduce or improve **telemedicine**, **robotics** and

high-tech medicine. In sequence of these two new regulations, a new law for patient data protection was also issued in 2020.

When it comes to register the new healthcare technologies, the process goes by the Federal Institute for Drugs and Medical Devices (BfArM). From 2020 onwards, manufacturers will be able to register digital health applications (DiGA) via the BfArM, if they cover all requirements, namely the overall quality of the application, standards of data privacy and cybersecurity concerns. After the registration in one year the DiGA must prove its benefits, in terms of improvements in the delivery of care, improving quality of life, economic benefit such as cost effectiveness or disease prevention or other medical benefits.

3.1.2. Spain

Spain is a constitutional monarchy based on a parliamentary democracy. The King, Felipe VI, is the Head of the State and the Prime Minister, Pedro Sánchez, the Head of Government. Spain is divided into 17 autonomous communities each with their own elected authorities, therefore power and decision-making process is quite decentralized.

Between 2018 and 2019 the country went through a major political crisis. After 7 years under the governance of the People's Party (PP) led by Mariano Rajoy, a corruption scandal prompted a no confidence motion filed by Pedro Sánchez, leader of the Spanish Socialist Workers Party (PSOE), that ended successfully, with the fall of Rajoy's mandate. This outcome was only possible due to the coalition between PSOE and Podemos and the support of other nationalist parties, and Pedro Sánchez assumed the Prime Minister responsibilities on June 2nd. Later, in April 2019, an extraordinary general election was held, giving victory to PSOE, with 29% of votes and winning 123 seats in congress. PP lost 69 seats, and Vox Party gained 29 seats which shows the right-wing ascendence following the Catalan independence referendum, in 2017. Besides from PSOE, that is a centre-left democratic socialist party, the PP, centre-right, and Vox Party, right wing, Podemos and Ciudadanos are also worth to mention, with the first one assuming a left-wing anti-austerity position and the other one revealing liberal centre-right ideals.

Health competences are shared between state and autonomous regions (AR) governments; therefore, we must take into consideration that the state is under the PSOE as well as the majority of AR – PSOE governs in 10 Ars, followed by PP in 5 AR. The supremacy of PSOE leads to a prevalence of its ideals on healthcare issues, which means a reinvestment in the health system and regulation changes to promote universal coverage. This cabinet believes that the

National Health System (NHS) must be public and financed by taxation and stands for the implementation of structural reforms that facilitate management of NHS. The two main actors in the NHS are the Ministry of Health (state level) and the Departments of Health (AR level). The first one has coordination and administration responsibilities and is advised by specialized entities and the late ones have regulation, planning and budgeting duties, also being assisted by third parties, namely concerning health services provision, public health action and, sometimes, a health technology assessment body.

Over the past years, diversified policies have been implemented, particularly to reduce tobacco consumption, a strategy on nutrition, physical activity, and obesity, and even traffic safety policies. **Several telehealth services have also been implemented in different regions to overcome physical distance barriers and promote care continuity**. In 2008, Spain adopted the **Strategy on Stroke of the National Health System**, composed by technical recommendations that cover 5 specific objectives – **promotion and protection of health, care in acute stages, rehabilitation and reintegration, training, and research**. Later, in 2016 the country's first **National Health System strategy for Neurodegenerative Diseases (NDs)** was approved, with 3 main lines of action – **improve diagnosis, give personal attention to patients and establish programs that facilitate respite for those who care for those affected by NDs**. In 2005, an agreement was adopted between the State and the regions, valid from 2006 to 2016 that represented **an investment of €500 million in eHealth**.

In economic terms, Spain is the 4th largest economy in European Union (EU-27) and 13th largest in the world. After the financial crisis of 2007-08, the Spanish economy was in recession until 2013, when it started to recover, reaching a 3,2% growth rate in 2015 and growing 2% in 2019, when the GDP value was $ 1.4 trillion. In 2019 exports also increased, at a 2,3% rate and imports grew 0,7%, however private consumption slowed although wages increased in the same year to an average €1.784. Last year, Spain saw a decrease in unemployment rates to 14%. While 2019 was a positive economic year for Spain, 2020 forced some steps back, in all Europe, but particularly in this country as the GDP growth is expected to be -13% and unemployment is estimated to reach 17% in 2020 (37). Pharma and medical products and telecommunications seem to be some of the less affected sectors, with approximately 7% revenue shock, while accommodation and entertainment are the most impacted, reaching a higher than 50% revenue shock.

Healthcare expenditures accounted for 8,9% of GDP in 2017, which is below the EU average 9,5%, but this value should be increasing in the following years, **reaching $3.649 per capita in**

2019, which can be explained partially by the growing needs for healthcare due to the aging population. **Public spending represented approximately 70% of total healthcare spending, 20% came from out-of-pocket payments, and the remaining from other sources. Health insurance is covered by the social security payments**, which allows for most of public healthcare remaining free, however **around 20% of the population has private healthcare coverage**.

Dementia, including AD, PD and CVD are the most frequent causes of dependence. The increase in prevalence of these affects not only patients, but families, caregivers, public and private healthcare and social institutions. The costs generated by these conditions include both direct and indirect costs, that consist of primary care, other levels of medical care, and treatments and decrease in productivity due to the patient's early retirement or decreased participation in the workforce on the part of the carer. In 2010, **dementia spending accounted for approximately 15% of total healthcare spending**, and families bear almost all costs. The annual European estimated cost of PD is almost $14 billion, and in Spain, this disease costs yearly more or less **$17.000 per patient**. In respect to CVD, its healthcare costs amounted **to €5.9 billion in 2014**, and this value was expected to increase to **€8,8 billion in 2020**. Between 2014 and 2020 there were expected to be more than 80.000 working-age deaths in the country. Together, **morbidity, mortality, healthcare and productivity losses, cost almost €8 billion in Spain**, which represents 0,7% of GDP. In consequence of this scenario, expense in long-term care is expected to increase more than total healthcare, also reflecting technological progress and efficiency gains.

The economic burden of these diseases and the need for healthcare focused policies are increasing mostly due to societal changes, both demographic, in lifestyle, disease prevalence and mentalities. At the end of 2020, the population of Spain was almost 47 million, which is equivalent to 0,6% of the world's population. Of those 47 million, approximately 80% live in urban areas with most populous cities being Madrid, with more than 3,2 million inhabitants and Barcelona with more than 1,6 million. **Life expectancy has been increasing reaching 84 years**, however birth rates are declining to 1,3 births per woman, consequently the percentage of people aged over 65 years represents a higher share of the population nowadays, of almost 20%, which is already superior to the population under 14 years old (15%). In 2019, Spain was facing a 30% old age dependency ratio, and this value is expected to reach 60% in 2100.

Although people are living longer, it doesn't necessarily mean a life in good health, seen that at age 65 people can only expect to live 9 more years without any disability. **The majority of deaths, 30%, are related to CVDs**, followed by cancer, respiratory diseases and nervous system diseases. These conditions are also responsible for the increase of disability-adjusted life years (DALYs), however in this case CVDs are not the leading cause but Alzheimer and other dementias. This is due to the aging population tendencies, but also to risk factors such as smoking, alcohol use, poor dietary, lack of physical activity, and others, with the last ones being the most representative. Smoking and alcohol use have been decreasing over the years, due to effective policies that are forcing people to quit these habits. This change in habits is stronger in younger generations, who are getting more self-aware about their health.

The infrastructure capacity should be considered as well, to understand how much the health system is prepared to respond to the demographic and health tendencies in the future. In 2009, the hospital bed density was 34, physician density was 37,6 and nurse density was 74,4. These numbers had an abrupt decrease until 2015 to 32 beds, 4,95 physicians and 5,67 nurses per 10.000 people. From the point of view of different stakeholders, there is **a rising awareness of the need to leverage technology to deliver better care**, **by giving better and faster tools to healthcare givers**, but the solutions must be cost effective, clinical results are not enough good drivers, there is a need for financial incentive.

Besides societal changes, the healthcare sector in Spain is impacted by technological progress, both from the consumer/patient and supplier/caregiver sides. On the side of the population, it is relevant to address the improvement of access to ICT. In 2017, Spain ranked 27/176 in the ICT Development Index on account of **the widespread use of mobile phones (110%), computers (77%) and the internet (81%)**, with the last one rising 62% in 2009. With this increasing level of ICT usage, the aversion and obstacles to introducing technologies will disappear with generation X and millennials. From the perspective of the healthcare institutions, in 2015 there were several telehealth programmes in course, namely teleradiology and dermatology were already established for at least 2 years at all levels of care[9]. **Telepathology, telepsychiatry and remote patient monitoring were implemented or in pilot** phase according to the system level. Electronic Health Records (HERs) were a reality

[9] International level: health entities in different geographic regions; Regional level: health entities in countries in the same geographic region; National level: referral hospitals, laboratories and health institutes (mainly public, but also private); Intermediate level: district or provincial facilities: public and private hospitals and health centres; Local or peripheral level: health posts, health centres providing basic level of care.

from the year of 2009 in most primary care facilities[10] and in some secondary[11] and tertiary[12] care centres, as well as in pharmacies and laboratories. Likewise, **mobile health programmes are established for or in pilot phase**, for example **health call centres, appointment reminders, mobile telehealth, patient records, patient monitoring and disease surveillance** (both in pilot type yet). Social media are also acquiring high importance especially in information sharing.

Health and environmental conditions are directly linked, particularly considering the recent pollution tendencies and its consequences. Since 2018, when the new government was established, efforts have been made to integrate the 2030 Agenda with political measures, which brought all administration levels, citizens, social institutions, businesses, universities and other entities, to work together to achieve the Sustainable Development Goals.

There are 17 SDGs, from which 7 are related to environmental changes. One of the main challenges is air quality, which has been deteriorating with industry developments, transports and energy, impacting mostly urban areas. According to the city of Madrid's Air Quality and Climate Change Plan (2017), road traffic is responsible for 51 % of NOx, 61 % of PM10, 55 % of PM2.5 and 55 % of CO emissions. Despite this scenario, only six urban regions had protocols in place to deal with high pollution episodes. Those were Madrid, Barcelona, Valencia, Valladolid, Gijón and Avilés being the main measures: information and recommendations, speed limits, restrictions on the most-polluting vehicles, free public transport, relocating bicycles to the most affected areas or raising parking fees. In the same year, Plan Aire II started with a €276 million budget to implement 52 measures for air pollution. The country accounted for 7,5% greenhouse gases emissions in the EU. Water pollution is also a major concern in Spain, once its geographic position and socioeconomic characteristics make it highly vulnerable to climate change, and the increase in average world temperature could mean decreases in water resources, loss of biodiversity and natural ecosystems and increases in soil erosion and extreme weather events such as floods, forest fires and heatwaves. The PIMA AdaptaAgua initiative was created to monitor the impacts of climate change on water and public water resource management. At the end of 2017, total peninsular water reserves were below 40% of reservoir capacity. Spain has increased its energy productivity by 30%, between 2000 and 2016, and in the later year the country contributed to almost 6% of EU environmental taxes (€20 billion). In 2016 more than half energy consumed was oil-sourced,

[10] Clinics and health care centres
[11] Hospitals and emergency care
[12] Specialized care

followed by electricity (24%) and gas (16%). Since 2000, renewable energy consumption has increased by 148 %, with the main source being solar power. In 2016 the Spanish generated more than 20 million tonnes of waste but recycling and energy recovery rates for packaging waste reached the highest values, respectively 70,3% and 76,8%.

Like it was briefly mentioned above, the health system in Spain is competence of each autonomous community and is based on universality, gratuity in access and public financing, so it is a social security health system. The role of the state is to ensure the coordination between the regions, one factor that led to the above-mentioned investment in eHealth, establishment of information systems and development and sharing of information and statistics that contribute to decision making in each region. In 2014, the legal framework for electronic health records was finished, however this seems insufficient, which together with problems related to interoperability, reluctance to change already established practices and patient behaviour has been a challenge to the successful implementation of eHealth strategies in Spain. In this scope there are some regulations that can be cited, of major relevance, like **Law 41/2002 that regulates patients' rights and obligations** in relation to clinical information, **Law 11/2007 related with the patients access to electronic public services**, **Royal Decree 4/2010 regulating the National Interoperability Framework** in the field of eGovernment, **Regulation (EU) 2017/745 on medical devices**, the **General Data Protection Regulation (EU) 2016/679**, **Law 3/2018 on data protection and digital rights**.

In the case of digital health technologies (telehealth, robotics, wearables, virtual assistants, mobile apps, software as a medical device, AI as a service, IoT and connected devices, natural language processing) there must be safeguards to particular issues, namely when data is processed outside European economic area, prevention strategies for hacking also need to be defined, the liability of data must be guaranteed. In the case of what is considered a medical device, here's a need to **comply with the requirements for medical devices, to obtain a CE mark, necessary to sell the products in the European market**. These challenges need to be addressed by policy makers, and considered in the moment of law definition, that must be "innovation friendly" but clear and objective at the same time.

In this field, there are some institutions that may intervene, they are the Ministry of Health, Consumer Affairs and Social Services, the Spanish Agency for Medicines and Medical Devices, regional authorities, and the Spanish Data Protection Agency.

3.1.3. Slovenia

Slovenia is a parliamentary representative democratic republic. Power is divided in three branches – legislative, executive, and judicial. The bicameral Slovenian Parliament is composed by National Assembly and the National Council and holds the legislative power. Executive power is vested in the Government which is headed by the Prime Minister elected by the deputies in the National Assembly. The president of the republic is the highest representative of the state, directly elected for a 5-year mandate.

At local level, there are 212 municipalities in Slovenia which are governed by the mayor, the municipal council, and the monitoring committee.

Since 2012, the President of the Republic of Slovenia is Borut Pahor. On his first mandate Pahor was affiliate of the centre-left SD (social democratic) political party, however he decided to run as an independent in the 2017 elections. In that year Pahor won the second round of the elections against the List of Marjan Šarec (LMS) candidate, only with 53% votes. The first round finished with 47% votes for Pahor, 25% for LMS, 14% for the Slovenian Democratic Party (SDS) and 7% for New Slovenia (NSi), which led to the second round between the two majority parties.

Janez Janša is the 4th Prime Minister governing along with Borut Pahor and was elected in March 2020, after a period of political instability, that led the former PM Marjan Šarec to step down and call for early elections. Janez belongs to the conservative SDS which formed a centre-right majority coalition for this government with three other parties – the liberals Modern Centre Party (SMC), the Christian democrats NSi and the Pensioners' Party (DeSUS). Janez started to work the day after the government proclaimed an epidemic in Slovenia with close support in fighting in from the centre-left opposition parties. This proximity has a second intention of monitoring PM actions due to his proximity to the right-wing conservative PM Orban (38). This recent change in the Slovenian government, the extraordinary pressure of the pandemic and the tensions between opposition parties all contribute to a fragile political environment in the country.

In December 2020, the DeSUS party decided to leave the coalition due to some policies pursued by Janša, leading to a possible political crisis. Health minister, Tomaž Gantar, resigned following that decision and Prime Minister stepped in as interim health minister. This was the second time Gantar resigned health minister position, the first was in 2013 when he failed to implement necessary reforms to address corruption in healthcare and it is also the second

change of minister during the incumbent government, after the Minister of Agriculture also from DeSUS.

The healthcare system in Slovenia is topped by the Ministry of Health, advised by the Health Council, and composed by various organisation subunits, namely the Long-Term Care Directorate, the Health Care Directorate, the Public Health Directorate, and others. The Ministry of Health is responsible for the national health care policy development and implementation, operation of the health care system, its monitoring and evaluation. Another relevant organisation is the National Institute for Public Health (NIPH) of Slovenia, responsible for strategic planning, coordination, development and implementation of an integrated national health information system, along with the development of nation-wide eHealth services. It the responsible institution for the collection, maintenance and use of all medical databases, granting access to this data to other stakeholders and commercial users.

Slovenia has a highly centralised system, and it favours public health care service providers while private providers act in a more complementary role, therefore representing less than 10%. The state owns almost the entire hospital capacity, most of the outpatient specialist care sector and the entire sector of tertiary care. Municipalities competencies are the organisation and provision of primary care, though they take little part in decision making regarding health system issues.

The country has a Bismarck-type social insurance system, which is fully regulated by national legislation. The mandatory Social Health Insurance (SHI) operated by a public company, the Health Insurance Institute of Slovenia (HIIS), which has 55 branch offices, 10 at the regional level and 45 at the local level. The HIIS collects contributions paid by employees within the compulsory health insurance system and finances the health services, therefore this system provides universal coverage. Nevertheless, about 95 % of the population also purchases complementary Voluntary Health Insurance (VHI) mainly used by patients to cover co-payments.

Faced with increasing chronic disease and obesity rates, the Slovenian Parliament adopted the **National Programme on Nutrition and Physical Activity for Health 2015–20**, an approach to promote healthy lifestyles. Later, in March 2016, Parliament approved the **National Health Plan "Together for a society of Health 2016–2025"**. Additionally, a national eHealth project is in course, promoting the implementation of 20 different solutions. Health promotion and disease prevention is mainly done through State's and HIIS's large scale programmes, GPs, and nurses. Recent health promotion campaigns included tackling regional health

inequalities, HIV/AIDS prevention, anti-smoking and alcohol policy, food and nutrition, enhancing physical activity, improving mental health and reducing all forms of addiction or dependency. **Improving health care and maintaining its financial sustainability is high on political agenda**. Work is ongoing towards the implementation of a reform of the healthcare sector. In 2019 the focus was to attend a general practitioner's crisis, to decrease waiting times, hospital management and the sustainability of the financing of the healthcare system. Increasing the share of public financing for health care is, as well, a top priority on the new government's agenda.

Since the healthcare system is mostly funded by public contributions, the monetary availability is relatively volatile, depending on employment which depends on other economic factors. In 2018 Slovenia's economic growth reached 4,1% but this value decreased to 2,4% in 2019 and it is expected to decrease much more significantly in 2020, due to the pandemic impact. According to the IMF latest predictions, the GDP growth is expected to fall to -8% in 2020 rising again in 2021 with the economic recovery plans to 5,4%. Unemployment was equally impacted by the outbreak of Covid-19, increasing to 9% in 2020, a set back from the continuous decrease of 5,1% and 4,6%, in 2018 and 2019, respectively. However, it is forecasted to decrease again in 2021, reaching 6%, closer to the unemployment values before the health crisis.

Healthcare spending has been increasing slowly for more than a decade, reaching €2.060 per capita in 2017, compared to the EU average of €2.884. Although it is still lower than EU average, in the same year, **healthcare spending accounted for 8,2% of GDP**, which is the third highest spending rate when comparing the newest European union state members. Public share of healthcare expenditure is also bellow EU average (79,4%) reaching 72,2% in 2017. On the other hand, **Slovenia has one of the lowest rates of out-of-pocket (OOP) spending compared to other EU state members, at just 12,3% of current health expenditure**.

Despite increasing importance and need for long-term care (LTC), due to ageing populations and increased years lived with disabilities, **LTC spending is lower than half EU average**, **accounting for only 10% of total spending in healthcare**. Additionally, in this case, spending is mainly finance by OOP payments, instead of public spending. In 2013, the HIIS spent €160 million, which accounted for 47% of all public expenditure on LTC. **In 2025 the total estimated expenditure in LTC is €715 million**, 35% covered by the HIIS and 30% by OOP, **increasing to €1.017 million in 2035**. This represents an increase of expenditure in terms of GDP from 1,3% in 2013 to 1,9% in 2035. These values are low, when compared to the EU average of public

spending in LTC that was already almost 2% of GDP in 2016 and to other European countries like Norway that spent almost 4% of GDP in LTC in 2016, or Italy where LTC spending reached approximately 1,7% of GDP in the same year. Most of this expenditure was destinated to **LTC institutions including homes for the elderly, followed by other institutions and then hospitals**. The rest was attributed to home-based LTC, which has been increasing. **In 2017 public expenditure on LTC amounted to almost three-quarters of total expenditures**, growing by 2,3% from the previous year. **Private funding of LTC rose more than the double of public funding (5,4%) from 2016 to 2017**, which reveals the increasing demand for LTC. **In 2018 the number of LTC patients rose to more than 66 thousand and total cost reached €547 million**, 2,7% more than in the previous year.

In the study conducted in May 2020 by the National Institute of Public Health in Slovenia, it was estimated that between 2015 and 2017 **the average yearly spending for dementia patients was € 11 million which represents 0,33% of all the public healthcare spending**. Also, **the combined spending for treating Parkinson's is estimated to be around € 2.5 million annually**. CVD has a much larger impact on finance since it affects the working population on a much larger scale. **It was estimated that 0,62 sick leave is due to CVD which annually represents € 33 million of sick pay**. Furthermore, **another € 4,5 million goes for patient hospitalization not including medications and treatments** (39) (40) (41).

Like the rest of the word, Slovenia is also facing a demographic tendency of an ageing population. At the end of 2020, the population of Slovenia was approximately 2,1 million, representing 0,03% of the world population. The country presents a 103p/km^2 population density and 55% Slovenians are living in urban areas. The capital city, Ljubljana, is the most populous city with 272.220 inhabitants, 13% of total population. In 2020, more than 20% of the population was aged over 65 years old, and while total population is expected to decrease in the next years, reaching an estimated value of 1,9 million in 2050, older population will represent 32% of total, with most population being aged between 70 and 79 years old. In 2019 the old age dependency ratio was 31% in Slovenia, which was 7 percentage points than just 8 years earlier. This is linked to the increase in life expectancy, that reached 81,2 years old in 2017, a value higher than the EU average.

Although life expectancy is increasing, late years are disability-adjusted life years (DALYs), decreasing the quality of life of the elderly as well as of those responsible for them. **In 2016 the main causes of DALYs were musculoskeletal problems** (including low back and neck pain), mental health problems (including depression and suicide) **and Alzheimer's disease**

and other dementias. In Slovenia, **hypertension is also common**, with a quarter of people living with it, which can later result in more serious cardiovascular problems. **In 2019 the main death causes in Slovenia were ischemic heart disease, stroke, and Alzheimer's disease**. The growing incidence of the last is evidenced by the increase of 53% from 2009 to 2019. **In 2017, there were almost 65 thousand people receiving LTC and 35% of that was home based**. A year later there were more than 66 thousand LTC patients.

In addition to age, behavioural risk factors have an influence on the number of DALYs and consequently on the disease burden for the country, being associated with approximately 37% of deaths. In Slovenia, smoking rates have been declining and were associated with 16% of all deaths in 2017, below the EU average, but there is still the need to lower this value. However, smoking rates are concerning among teenagers, like excessive alcohol consumption. Dietary risks remain the leading behavioural risk factor, associated with 19% of all deaths, which is higher than EU average. In 2017, 16% adults were obese and, in 2013-14, 1 in 5 15-year-olds were overweighted or obese.

The ageing population and risk behaviours above mentioned will probably increase demand for medical care, but the supply side will face many challenges in covering that. First, there are only 3,1 doctors per 1.000 people, which is well below the EU average and patients report difficulties registering with a general practitioner (GP), even in urban areas. In contrast, the health system can rely on 9,9 nurses per 1.000 population, if considering vocationally trained nurses, but this number decreases to 3,4 when counting only registered nurses.

The social health insurance covers primary, secondary and tertiary services, pharmaceuticals, medical devices, sick leave exceeding 30 days, and costs of travel to the closest health facilities for their conditions. **The Slovenian insurance is compulsory and one of the most effective European systems**, which can be deducted from the 2018 Annual Business Report of the HIIS, where it says only 0,17% people were uninsured, mostly due to unclear residence status.

Along with the demographic changes that are creating challenges for the healthcare system, technological progress is also disrupting the system, but, on the contrary, with the goal of easing the burden of the facing challenges. In this sense Slovenia has developed a particularly efficient information system, ranking 6 in EU members use of eHealth.

Some of **the Slovene eHealth solutions consist of eAppoitment, ePresription, Central Registry of Patient Data (CRPD), Patient Portal zVEM, TeleStroke, eTriage, and zNET**. The

"Telestroke" (Telekap) programme, in place since 2015, consists of early detection of signs of stroke and early administration of effective therapies, and should contribute to reducing this excess mortality. The ePrescription tool is also available since 2015 and it is currently used by 98% of healthcare professionals, allowing them to sign electronically and send to the system linked with pharmacies. zNET is a communication network providing information exchange between health system agents.

Besides healthcare, technologies are entering citizens daily lives, and according to the Digital Economy and Society Index (DESI), in 2015 Slovenia ranked 19th among 28 EU Member States. In 2018 Slovenia moved up 4 positions, ranking 15th. Then, **98% population had access to internet coverage and 83% to fast broadband coverage, but only 66% to mobile coverage**. **Internet users' rate was at 77%. Some households reported no access to internet because of high costs of equipment (47%) and high costs of access (39%). At the same time 39 % of them have access to the Internet elsewhere**. Others stated as a reason that they do not need the access, while the rest did not have internet access because of the lack of computer or internet usage skills. **Daily use of internet** was most common in the 16-24 age group (92%) and **least common in the 65-74 age group (18%)**. More than 30% people report to have high level of computer skills.

The development of digitalization is in progress through the initiative **Digital Slovenia 2020**, that includes the **S4 – Slovenian Smart Specialisation Strategy**, that follows the guidelines from the general programme and has **health-medicine as a priority**, alongside with smart cities, smart buildings and homes, and others.

This concept of SMART sometimes appears together with climate action and the environment, which are themselves linked to health issues as well. Slovenia allocates about €122 million (4%) of its cohesion policy fund to sustainable urban development and in 2016 Ljubljana received the EU Green Capital Award for its efforts into becoming a more sustainable city.

In 2017, more than 20% of people living in Slovenia reported that the area they lived in was affected by pollution or other environmental concerns. To address this issue, Slovenia allocates about €122 million (4%) of its cohesion policy fund to sustainable urban development and in 2016 Ljubljana received the **EU Green Capital Award** for its efforts into becoming a more sustainable city.

Municipal waste management has been upgrading in the past years, reaching an average value of 471 kg of municipal waste per person, per year. In 2017, Slovenia's municipal waste recycling rates were well above the EU-28 average, respectively 58% vs 46%.

Slovenia is also implementing initiatives to reduce GHG emissions, aiming to reach a 15% reduction in 2030 (compared with 2005), which includes increasing the use of renewable energy sources to 27%. To reach this goal, indicative scenarios may consist of at least two thirds of energy consumption in buildings to come from RES, at least a 30% share of RES in industry, 43% share in the electricity sector, 41% share in the heating and cooling sector, 21% share in transport (with a share of biofuels of at least 11%). Slovenia also intends to allocate at least 3% of GDP by 2030 (of which 1% of GDP is public funding) to renewable sources and to support businesses for in the transition to a climate neutral and circular economy.

In 2017, the sectors responsible for the highest share of GHG emissions were energy supply and transport and the trend for the next decade is that the second will surpass de first one. In line with the strategies implemented, some air pollutants have been found in less quantities, with one of those falling by 50% between 2014 and 2016. Nevertheless, the emissions of some gases are increasing. Commercial, institutional, and households and road transport are the sectors causing the highest chare of emissions.

Although there have been improvements, measures are still necessary and air quality continues to be an important concern since it was related with an estimated value of 1800 premature deaths due to fine particulate matter concentrations, 100 deaths related to ozone concentrations and 160 to nitrogen dioxide concentrations. To act on these, the reduction of emissions from energy production and heating is required, or an increase in the spread of clean energy.

Noise pollution is also on the table to improve life quality once it is cause for 50 premature deaths, approximately 150 hospital admissions per year, and triggers sleeping disorders to around 60 thousand people.

Water quality is also threatened by pollution, particularly from an unknown anthropogenic that is impacting 99% of surface water bodies. These are also under pressure from urban wastewater (73%) and physical alterations (59%). For groundwater bodies, agriculture activities (14%) are the most significant pollutant.

All the programmes and initiatives regarding climate action are relatively easy to implement, at legislative level, since these are supported and endorsed by the European Union, which facilitates the introduction of most measures.

In the case of eHealth, although its usage is relatively advanced in Slovenia, in general, there have been many setbacks in the implementation of the eHealth project throughout the years, that hindered the fully operationalization of eHealth solutions, but these are expected to be solved by 2020.

The eHealth solutions are regulated by the special 'Healthcare Data Records Act' (HDRA). This act clarifies the responsibilities of providers in relation to data collection, security, and privacy. The framework for further eHealth developments is outlined in "**Resolution on National Plan of Health Care"** between 2016-2025, that covers the integration of all existing health information systems in the country, the continuation and upgrade of the National eHealth Project until its full implementation, the development of all necessary interoperability standards and interfaces to provide reliable and secure data exchange among all eHealth stakeholders in the country, development of mHealth applications, which will provide easier access to health services in the country. The resolution also specifies some goals for 2021 like the **new law on health care data records**, the **integration of ICT solutions/ systems**, and **full operation of EHR/PHR** and the **unified standards for health data exchange** among all stakeholders in Slovenia.

Products classified as medical devices must comply with the **Medical Devices Act**, which corresponds to Council Directive 93/42/EEC, considering that this **covers all products used for the diagnosis, prevention, monitoring, treatment and alleviation of diseases, disorders, disabilities, anatomical functions, or physiological processes**. For insurance purposes, the device in question may be analysed particularly. To be placed onto the market, **medical devices must obtain a CE mark from a notified body, in line with the essential quality and safety requirements of regulations of the Republic of Slovenia and EU Council Directive 93/42/EEC**.

In relation with the introduction of innovative technologies, since most providers are publicly owned, **it is either the Ministry of Health or the municipality that decides on funding according to the investment plans of providers**. **In the event of investments in new technology, the Health Council decides based on national priorities, scientific justification, and economic sustainability of the proposed programme**. The HIIS introduced regulation for

the classification and reimbursement of medical devices used in primary health care and reimbursed from public funds in 2014.

Finally, **Slovenia still lacks legislation on long-term care services**, but it is expected that the Parliament decides on the new law to be adopted in 2020. Currently, long-term care is provided within different social protection systems and within the framework of different legislations.

3.1.4. Italy

The Italian Republic became a unitary parliamentary republic in 1946, when monarchy was abolished. The President is the Head of State, currently Sergio Mattarella, and the power is divided into executive, legislative, and juridical branches. The first one is exercised by the Council of Ministers and led by the Prime Minister, currently Giuseppe Conte. The legislative power is responsibility of the bicameral parliament – The Senate and The Chamber of Deputies. The judiciary power is vested in judges, chosen through exam results, that serve for life. The president is elected by the parliament and serves in 7-years mandates, while the members of the Parliament, both 630 seats in Senate and 315 seats in The Chamber of Deputies, are directly elected for 5-year terms (number of seats will decrease to 400 and 200). The President of Italy then appoints the Prime Minister and the misters for its cabinet, based on PM's suggestions.

The country is divided in twenty regions. All regions are then divided into provinces and there are also two autonomous provinces. Most regions do not have much power, particularly when compared to federal states such as Germany, however five of them – Aosta Valley, Friuli-Venezia Giulia, Sardinia, Sicily, Trentino-Alto Adige/Südtirol – have greater autonomy, meaning their governments have special constitutional powers.

Italy has several political parties, some of them active only in specific regions of the country. Nowadays, the Democratic Party (PD), the League (LEGA), Forza Italia (FI), and Five Star Movement (M5S) are considered the four main parties. For the 2018 election there were two large coalitions, one right and one left. The centre-right coalition includes LEGA, FI, the far-right Brothers of Italy (FdI) and Us with Italy (NcI). The centre-left coalition joins PD, the More Europe (+EU) and other parties with irrelevant representativity. However, the coalitions do not survive for long periods of time, leading to a certain degree of instability and to Italy being considered a "flawed democracy" in 2019 by the Economist Intelligence Unit.

In 2018 elections no political group had majority, which resulted in a hung parliament. Long negotiations mostly between the League and M5S ended with Giuseppe Conte as PM. Meanwhile, in 2019, a political crisis led to the end of that first coalition and the creation of one between M5S and PD, allowing Conte to stay in power and create a new cabinet. At the moment, the President Mattarella and Prime Minister Conte are independent of political parties, the President of the Senate belongs to Forza Italia and the President of the Chamber of Deputies to the M5S. Concerning regional government, 19 regions are under a centre-right government and only 1 special region, Aosta Valley is centre-left. Currently, there is another political crise due to repeated threats of the former PM to withdraw his party from the coalition, leading to the government's collapse. If Conte is removed and the is not an agreement on a successor, President Mattarella could be forced to call snap elections early than expected. In the case of upcoming elections, opinion polls reveal likely victory for the right-wing side.

Current Minister of Health if Roberto Speranza, from the Free and Equal left-wing parliamentary group. The Ministry of Health represents the central government in health matters, with legislative frameworks, principles, and objectives of the Italian national health system, and defines the benefit basket and health services provided. The regional governments are responsible for local planning, organizing, and managing health services and ensuring the delivery of services through a network of population-based local health authorities. Regions also have the authority to reform their health systems both at the organizational and financial level according to contextual, political, economic, and cultural needs. The Ministry of Health is supported by the National Health Council and advised by the National Institute of Health. The National Centre for Disease Prevention and Control (CCM) and the National Agency for Regional Health Services (AGENAS) consist of national-level agencies with supporting roles both at national and regional levels. **In 2014 the Italian Dementia National Plan was formulated** with the purpose promoting health- and social-care interventions and policies, creating/strengthening the integrated network of services for dementia, implementing strategies for promoting appropriateness and quality of care, and improving the quality of life of persons with dementia and their families. A national initiative designed to improve the coordination of chronic care was launched in 2016, the Agreement on the **National Plan for Chronic Diseases (NPCDs)**, under which some regions are piloting the **implementation of different health service models, that combine health and social care, to better respond to the needs of patients with co-morbidities**. In the same year, **the Digital Health Agreement was introduced to promote the diffusion of eHealth, mainly focusing on**

the development of Electronic Medical Records (EMRs), telemedicine systems and ICT innovations. Following this, the **Strategy for Digital Growth and Triennial Plan for Public Administration Informatics 2019-2021** was created to guide the digitalisation of the public health system. Another program still in place is the "**Gaining Health: Making Healthy Choices Easier**" that aims to raise awareness for risk factors to health.

The National Health System provides universal coverage and care is generally free. The system is funded mostly by taxes, supplemented by private expenditure and private insurance. Although Italy is the third largest European economy its healthcare expenditure is lower than EU average. **In 2018 the country spending in healthcare was almost 9% of the GDP, which corresponds to approximately €2.500 per capita**. Government and compulsory insurance accounted for three quarters of healthcare spending and the remaining we OOP payments, and private insurance contributions were residual values. In the same year, **the value of public spending surpassed €113 billion from which €1,4 billion were allocated to eHealth**. In 2018 as well, **eHealth revenue was equivalent to approximately €330 million**. **Public spending for long term care in Italy involves three different components – health component, care allowances, and social care addressed to persons with disabilities** – and amounted to 1.9% of GDP in 2015.

Healthcare costs of CVDs reached €14 billion in 2014 and is expected to rise to more than €18 billion. The costs arising from premature deaths may rise to more than €70 per capita in 2020. A study performed in Italy to analyse the burden of informal care associated with AD led to the conclusion that in the country **most costs of the disease are covered by the families**, since **total cost is approximately €20.000/year per patient but the public sector only covers about €4.500/year**. **The total costs associated with PD, in 2010, were almost €17.000/year per patient**, considering direct cost associated with items such as **inpatient hospital stays, rehabilitation, examinations, care personnel, and indirect costs like loss of work or early retirement**.

In 2017 almost half Italian population aged over 65 years reported at least one chronic disease and 17% reported two or more chronic diseases. Life expectancy at that age reached nearly 21 years and life expectancy at birth is currently at 83,3 years. However, slightly more than half of those additional years of life after 65 are lived with some health issues and disabilities. Of all chronic diseases, **CVDs are the ones responsible for the highest number of deaths, although this rate has been decreasing over the past 20 years**. On the contrary, **mortality rates from Alzheimer's disease have increased significantly**, although this

tendency is associated with improvements in diagnosis and changes in death registration practices. The prevalence of these diseases impacts the quality of life the elderly, which is noticeable since **one in six Italians cannot live independently in old age** and report limitations in basic activities of daily living, such as dressing and eating, which may require long-term care assistance.

The number of people in need for long-term care has been increasing and this increase is characterized by a shift from long-term care from institutions and preference to home care. **In 2017 approximately one million LTC patients were receiving predominantly home care, almost 300.000 were in residential facilities and even fewer were receiving care from semi residential facilities (16.000).** These three types of long-term care are cover by the compulsory insurance. Nevertheless, **LTC in Italy has a low degree of public financing and no financial support is available for caregivers but rare "care vouchers" awarded by some municipalities based on income, need, and clinical severity**.

The Italian population has at disposal almost 1.050 hospitals, equipped with 3,2 beds per 1.000 habitants, which is well below EU average. Considering healthcare professionals, Italy employs 4 doctors per 1.000 citizens, compared with EU 3,6 in 2017, yet more than half are aged over 55, which may lead to shortage of doctors in the future, particularly GPs. On the contrary, the number of nurses is one of the lowest in western Europe, with only 5,8 nurses per 1.000 population compared with 8,5 in the EU.

Only 10% population chooses to have voluntary health insurance once it is not possible to opt out of the NHS. Therefore, **private insurance can only play a complementary role, accounting for insignificant contribution for annual healthcare spending**.

In relation to eHealth, Italians reveal to be in favour of the introduction of technological tools in healthcare services, particularly in prevention. **In 2017 there were 43 million users of digital tools, 32% of which were using them to collect information on healthcare facilities, while 22% used them to book check-up services, and 18% used them to check medical reports or to receive reminders of previously booked medical examinations**. Another demonstration of this willingness to adopt technologies is the fact that **around 40% of doctors are using WhatsApp to communicate with patients and answer any questions or concerns**. **Doctors also use other digital solutions, for example to consult images or reports (76%), to manage patient information (47%), or to draw up their own medical diary (27%).**

Among the projects in course there is the establishment of **the Single Reservation Centre, the creation of the Electronic Health File, the experimentation and implementation of Telematic Disease Certificates, the application of telemedicine in some areas, and the activation of the electronic recipe – ePrescription.** This last program is already widespread, since currently 86% prescriptions are already issued electronically, despite there are some regional disparities in the integration of this.

To monitor the introduction of all digital solutions, a permanent eHealth Board (TSE) was established in 2004. The first pilots being launched then were, among others, e-Booking (only in five regions), an Oncology Excellence Centres Network, and telemedicine and tele-education instruments.

In respect to the general access to technologies and ICT by the population, Italy ranked 47 in the ICT Development Index in 2017. Although mobile telephone subscriptions are high (140%), **the percentage of households with internet access still needs improvements as well as computer ownership which are rated at 65% and 69%, respectively**. **The percentage of individuals using the Internet is also relatively low** at 61% (42). Despite lagging behind when compared to other countries, it is noticeable that a higher number of elderlies is going online over the years; **in 2016, 45% people aged 65-74 years used the internet at least once a week and 35% were using it on a daily basis (43)**.

Human health is affected by climate change. Today's environmental conditions have been boosting health problems from deaths associated with extreme weather events, to cardiovascular and respiratory diseases, and even malnutrition, due to poor water and food supplies, infrastructure, health systems and social protection systems.

Following the European efforts and guidance to combat climate change and its impact, Italy has been implementing different initiatives to improve the environment conditions and citizens quality of life. There has been some progress on waste management marked by an increase in recycling rates, associated with the good practices to promote better waste management at regional level. This is noticeable by a decrease in municipal waste generation to 489 kg per year per inhabitant, in 2017, which is now above the EU average, and 48% of municipal waste was recycled. Likewise, there were some developments in the circular economy national strategy and an action plan on sustainable consumption and production. According to a survey conducted in 2017 on attitudes of EU citizens towards the environment, most Italians support circular economy initiatives, environmental protection measures and are concerned about the impact of specific products, like plastics and chemicals, on the

environment. Regarding water management, results were not as good as expected in 2017, therefore investments must continue in land-use planning (to reduce soil sealing) and in flood control as well as initiatives like the green roofs which have the potential to reduce flooding by half. In 2016, there were 31 flood incidents registered all over the national territory, causing damage evaluated in at least €1,96 billion. Water quality is also a concern for the Italians since individual areas in Italy have problems with drinking water and 1,4% of bathing waters were of poor quality, in 2017. The most significant pressures on surface water bodies are pollution from agricultural (37%) and urban wastewater (20%), while for groundwater bodies pollution from agriculture (30%) is of major relevance as well as abstraction or flow diversion (19%). For 2030, Italy's is expected to reduce emissions by 33 % compared to 2005. However, greenhouse gas (GHG) emissions from transport in Italy increased by 1 % from 2013-2016. The national energy strategy predicts a 28%-renewables target in final energy consumption and 30% target in energy savings by 2030 alongside with increasing R&D investments in clean-energy technologies to €444 million in 2021. As of 2017, 35% of national production of electricity was from renewable sources, and the one that contributed the most was hydropower (35%), followed by solar power (23%), bioenergy (19%), wind power (17%) and geothermal power (6%). In the heating sector, less than 20% of overall energy consumption originated from renewable sources. Nevertheless, energy is still the sector that causes the highest value of GHG emissions but, considering the investment in renewable energies and other factors, it is predicted to be surpassed by transports from 2025. The reduction of emissions to improve air quality was limited, particularly due to the high level of traffic and commercial, institutional and households' sector, with some air pollutants decreasing significantly in contrast with others that have increased. Therefore, air quality is cause for severe concern in Italy since it about 60.600 estimated premature deaths were attributable to fine particulate matter concentrations, 3.200 were related to ozone concentrations, and 20.500 were liked to nitrogen dioxide concentrations. Another concerning death cause for the Italians is noise. Based on data from 2011, environmental noise causes at least around 1.500 premature deaths and 6.000 hospital admissions per year in Italy. In addition, noise disturbs the sleep of another 1.800.000 people. Likewise, weather conditions are cause of premature deaths. The ageing population together with a tendency to more frequent and intense heat waves together, will largely impact on health in the future. In 2015 there was a 13% increase in deaths attributable to heat among the population aged over 65. High risk subgroups more susceptible to the effect of heat comprise the elderly,

individuals living alone, those affected by chronic diseases such as diabetes, mental diseases, neurological diseases, or those taking medications for these diseases.

In the case of environmental actions, most countries are operating in the scope of the guidelines, recommendations, and objectives of the European Union. In the same way, in Italy, **the healthcare legal framework is highly based in the EU directives**. Despite the benefits of digitalization of healthcare already recognized are European level, **the integration of innovation solutions is still little in Italy, as well as the legislative development on this matter**. The National Guidelines for Telemedicine were endorsed in 2014, however **there is not yet a specific law to rule telemedicine solutions**. The flexibility of these guidelines is beneficial since this field is evolving fast, and rigid laws possible would not be able to keep up. In this sense, some most regulatory schemes are adapted from de EU or even US law on this matter. Some of the regulations applicable are the **Legislative Decree 206/2005**, the **"Consumer Code"**, the **Legislative Decree 70/2003 on e-commerce**, the EU Privacy Regulation no. 2016/679 (GDPR) and the **Italian Privacy Code**, and **Regulation 2017/745/EU**.

3.2. Competition

As mentioned previously, **the digital health market is growing fast** at a global scale, with most countries realizing the benefits of adopting disruptive technologies, both at efficiency and expenses levels. The COVID-19 pandemic has also brought to light the possibilities of telehealth and mHealth as well as many advantages of distance care. This has created room for many companies to enter this market, from multinationals already operating in the healthcare sector to new start-ups emerging in the sector as well as companies from other sectors leveraging their knowledge and capabilities into adaptations suitable for healthcare. In this scope it is relevant to analyse the competitors' strategies to understand how TeNDER can position.

In the first place it is relevant to look at the big players in the European healthcare sector like Philips, Medtronic, CISCO, GE Healthcare, Aerotel Medical Systems, and IBM. Most these organizations have global presence, and some have more than 100 years of experience operating in the European market. The above-mentioned tendencies are also allowing start-ups to succeed in the digital healthcare market, since these solutions are now valued by all, payers, providers, patients and investors. In this environment many start-ups are being born in Germany, for example AdaHealth, Caracare, KaiaHealth, mySugar, Teleclinic, Vitaphone, and others, mainly targeting the elderly and giving some solutions for remote monitoring and distant healthcare.

3.2.1. Industry (Application and Platform)

TeNDER will provide a digital platform mostly for physicians and a dedicated App for patients and their caregivers offering them services such as **appointment management**, **virtual assistant interaction**, **recognition of the emotional state**, **data exchange**, and **quality of life assessment**.

Concerning the patient appointment management module, there are already some solutions in the market, from which we distinguish a few. For example, GE Smart Scheduling, a platform that targets imaging practices and assists in managing exams scheduling, with the particularity of identifying, through AI algorithms, which patients normally miss appointments or show up late, thus avoiding equipment underutilization, and allowing a more efficient staff allocation and better patient access. RXNT offers a solution for practice management, that consists of a system that combines electronic medical billing software with digital patient scheduling and is designed to facilitate in administrative tasks. Another patient management solution is Doctolib, which was founded in France and entered the German market in 2017. In 2019 they expanded their offering to telehealth, with the goal of allowing their healthcare partners to reach more patients. In Spain, there are solutions of this kind as well, for example Top Doctors and Docplanner. Both platforms consist of an integrated solution, with more to offer than just patient management tools, like online consultations.

In relation with the virtual assistance module, we have identified some competitors, like the Dragon Medical Virtual Assistant | Nuance, that allows for easier interactions between patients and healthcare professional, based on artificial intelligence solutions. Nuance is present in at least 10 European countries, of which Germany, Spain, and Italy. Microsoft has also developed a solution in this field called Azure Health Bot Project. In 2020 this platform delivered approximately 1 billion messages to more than 80 million people worldwide. Currently, this solution is available only in the East US and West Europe, but it is planning on expanding to other regions. Another well-known virtual healthcare assistant is integrated in Verint Next IT, which a complete solution with tools for administrative management and clinical assistance. It makes possible to answer questions about health conditions, to tracking symptoms and medication, and many other services. Vernit has presence in over 40 countries worldwide, 12 of which are European countries. Additionally, Infermedica is also worth mentioning. It is a polish start-up, already present in more than 30 countries, that initiated strategic partnerships in 2020, namely with Microsoft, and, on the side of healthcare providers, Infermedica started a partnership with Sana Kliniken, one of the major healthcare groups in Germany, which shows its commitment with this market. Lastly, Babylon Health is

another healthcare app, that allows healthcare providers to assist patients 24/7 through different services such as health check-up, monitoring, symptom checker or virtual consultation. This solution is available for download on the App Store and Google Play and downloaded for more than 500 thousand times.

With regard to the emotional recognition module, there is an API-accessible software and dedicated online platform that parallels the human ability to discern emotive gestures, EmoVu, produced by Eyeris, which offers facial detection products, incorporates machine learning and micro expression detection that allow an agency to "accurately measure their content's emotional engagement and effectiveness on their target audience." With a Desktop SDK, Mobile SDK, and an API for fine grained control, EmoVu offers wide platform support, including many tracking features, like head position, tilt, eye tracking, eye open/close, and more. They also offer a free demo with account creation.

Relating to dedicated application we point out Scam Face, that detects facial emotion recognition from facial recognition.

As platform for emotional recognition, we point out Imotions research platform that provides software and hardware for monitoring many types of bodily cues. Imotions syncs with emotion's facial expression technology, and adds extra layers to detect confusion and frustration. The Imotions API can monitor video live feeds to extract valence, or can aggregate previously recorded videos to analyze for emotions.

All of these solutions mostly use facial detection and semantic analysis to interpret mood from photos, videos, text, and speech.

3.2.2. Industry (Monitoring Sensors)

Besides the platform and app developed for medical follow-up, TeNDER also delivers a set of sensors to control the users and the environment they are in. This includes movement sensors, depth sensors, wearables, and others.

When looking at the market we can identify other players offering monitoring solutions through sensors. An example is Kwido that offers two distinguished solutions, one focused on healthcare monitoring and another on home monitoring integrated with health monitor solution, mainly targeting the elderly. These services are available in Spain, United Kingdom, Portugal, Italy, Austria, Luxembourg, Austria, Romania, and Poland. VIVAIcare is another example of a comprehensive solution to monitor the elderly with fall detector, vital signs monitor, alert systems, and other features. This system was tested in three German cities - Dortmund, Duisburg, and Arnsberg. Moreover, TELEGRAFIK is a French company that

provides a distant monitoring solution. It targets the elderly in general, those suffering from Alzheimer's and their families and caregivers and it offers specific packages according to each place – home, residences, or nursing homes – that vary in the number of sensors available (1 to 5) and other features (possibility for telecare).

3.2.3. Research Projects

The importance of developing this market is visible in the creation of several EU calls for financing projects in this field. We will be looking in detail for some projects of the programme H2020-EU.3.1: Societal Challenges - Health, demographic change, and well-being, particularly the call H2020-SC1-DTH-2019: Digital transformation in health and care, in which the topics active ageing and self-management of health (H2020-EU.3.1.4) and health care provision and integrated care are included (H2020-EU.3.1.6).

The projects we will consider are the following: ADLIFE, AgeingatWork, BIONIC, CO-ADAPT, DigitalHealthEurope, e-VITA, GATEKEEPER, Homes4Life, IDIH, IN-4-AHA, PHArA-ON, PIPPI, PlatformUptake.eu, PROCarelife, See Far, SHAPES, SMART-BEAR, SMILE, sustAGE, VALUECARE, and WorkingAge. Other projects of the same call of TeNDER are mostly focused on cancer solutions, but are important to consider as well, such as CAPABLE, QUALITOP, LifeChamps, ASCAPE.

At first, we will focus on the projects that were financed under the same programme as TeNDER, namely ADLIFE, PROCarelife and VALUECARE. The first project, ADLIFE, is developing solutions like personalised care plan management platform, clinical decision support services, interoperability solutions and patient empowerment platform with just-in time adaptive intervention delivery engine, with a focus on people with chronic obstructive pulmonary disease (COPD) and heart failure (CHF). It targets the same group of people as TeNDER, however the latest is wider since it covers other CVDs, as well as Alzheimer and Parkinson's disease. Although the pilots are equally in Germany and Spain, the other countries are different namely Sweden, Denmark, UK, Poland, and Israel. The PROCareLife project is working on the development of an integrated scalable and interactive care ecosystem that will enable communication between all stakeholders, find the best actions both medically and socially that will facilitate and improve the awareness, the quality of life and the care management provide and allow personalized recommendation. Although the goal is to be adapted to several chronic diseases, at first it will focus on neurodegenerative disorders. This platform will be tested through pilots in Spain (under the responsibility of APM, which is also

one of the TeNDER partners, as well as UPM), Italy, Germany, Portugal and Romania. Finally, looking into VALUECARE, this project aims to provide "Value-based methodology for integrated care supported by ICT". It targets older people facing cognitive impairment, frailty and multiple chronic health conditions in order to improve their quality of life (and of their families), as well as the sustainability of the health and social care systems. Like the other two projects, one of the pilots will take place in Spain and others will occur in Ireland, Netherlands, Portugal, Italy, Croatia, Greece.

The PlatformUptake.eu was approved under the same call as TeNDER (H2020-SC1-DTH-2019: Digital transformation in health and care) and one of the same programmes (H2020-EU.3.1.4), nhowever it is also receiving funds under the programme H2020-EU.3.1.5.1. - Improving health information and better use of health data, therefore differentiating itself from TeNDER. This project aims to assess the societal impact of existing tools for integrated care and assistance, collect best practices, promote interoperability, and others.

The other projects mentioned are related to different calls, but under the same programme: H2020-EU.3.1.4. For example, PHArA-ON is a large-scale pilot project that aims to integrate digital services, tools and devices into open platforms, including connected devices (e.g., the IoT, AI, robotics, cloud and edge computing, smart wearables, big data, and intelligent analytics. This project will also run pilots in Spain, as well as in The Netherlands, Slovenia, Portugal, and Italy and it is focused on elderly people in general, by developing smart connected homes to support active aging and independent living solutions. SMART BEAR is another example as it is a platform that aims to integrate heterogeneous sensors, assistive medical and mobile devices to enable the continuous data collection from the everyday life of the elderly, which will be analysed to obtain the evidence needed in order to offer personalised interventions promoting their healthy and independent living. The platform will also be connected to hospital and other health care service systems to obtain data of the end users (e.g., medical history) that will need to be considered in making decisions for interventions. This project targets elderly in general as well, however it was motivated by the most common comorbidities like hearing loss, cardiovascular diseases, cognitive impairments, balance disorders and mental health. This solution will be tested in pilots in France, Greece, Italy, Romania, and, like most other projects, in Spain.

The CAPABLE project was launched in the beginning of 2020 and it is developing an AI- and Big Data-based post-primary intervention, home support system for long-term cancer patients. Like in TeNDER, wearables and sensors will be used to monitor the users at home,

as well as provide psycho-social support (coaching and therapy). LifeChamps is another cancer-related project, therefore with different target groups than TeNDER, however it presents similarities of other natures. For example, this project aims to monitor the symptoms revealed by the patients that most affect their quality of life, based on which personalized treatment and recommendations will be delivered in order to support caregivers and health professionals. One more project that can be mentioned is ONCORELIEF, in which our partners CERTH and MAG are involved, since this also provide a personalized smart digital assistant, tasks and activities recommendations and mental health monitoring, that can be compared with TeNDER quality of life assessment service. Some projects like AgeingAtWork, SmartWork and WorkingAge target the elderly as well, however in different conditions, since these should still be working. In diversified ways, these solutions aim to monitor the health of the elderly through smart wearable devices and to give recommendations.

In the annex at the end of the document, it is possible to find a table with all the projects considered relevant and potential competitors for TeNDER that were not mentioned in detail above.

4. Targeting and Positioning

As a modular platform that aggregates different services, TeNDER is adaptable to the user needs, therefore we can target different consumers and end users. It includes the app for patients use, the supporting services, tools for distant communication between patients and healthcare professionals, home call service, and the platform for health professionals' use. In this sense, we can look at different market segments, and distinguish different costumers according to each service provided or the solution as a whole. Consequently, we can look at the market both from a B2C perspective, as well as from a B2B view. In the first case, we directly target patients with chronic conditions such as Alzheimer’s disease, Parkinson’s disease and cardiovascular diseases and their family members. These patients are mainly aged over 65 years old, however there are some people with the same conditions at younger ages which should be considered as well, particularly when considering their higher familiarity and predisposition to use technologies and apps, such as those provided by TeNDER. In the scenario of a B2B approach, we can target different types of businesses such as insurance companies, public and private hospitals, and other healthcare providers such as residential homes, nursing homes, home-care providers, physiotherapy clinic or others. In this case, the

solution is set out considering that the buyer may not be the end user, for example in the case of hospitals, where the end user will be the health professional and the patients and in the case of insurance companies.

In the table below we have estimated the potential costumers and end users in each of the markets available. We expect the numbers to increase in the following years, at least population with these chronic conditions and population receiving long term care, as well as providers for long term care, as a result of the demographic tendencies displayed above.

Table 2: Target Market

	Spain	Germany	Slovenia	Italy
Total population	47 million	84 million	2 million	60 million
Population aged > 65	20%	22%	20%	23%
Population with dementia (per 1000)	19	21	12	23
Population with CVD	4 million	8 million	0.3 million	5.4 million
Long term care (LTC) recipients in institutions aged > 65	179 470	724 118	18 772	-
LTC recipients in institutions aged < 65	44 061	108 980	4 132	-
LTC recipients at home aged > 65	687 858	2 014 278	26 217	849 199
LTC at home aged < 65	266 622	666 205	15 312	-
Hospital LTC beds	20 469	0	292	8 526
LTC beds in residential facilities per 1000 aged > 65	44	54	54	19
Hospitals	779	3 084	29	1 063
Insurance Companies	110	44	13	126
Private Health Insurance	17%	34%	86%	-
Public Health Insurance	100%	89%	100%	100%

Source: own elaboration based on data from (44) (45) (46) (22) (47) (48)

Considering the different target groups, we can also assume different positionings near customers. In the table below we identify the components of the TeNDER solution and how TeNDER could position itself in order to be valuable for the customer.

Table 3: Value Proposition Canvas

Products/Services	○ Multi-sensorial component ○ System Personalization ○ Activity Sensor devices ○ Wearable sensors analysis ○ Activity Recognition ○ Affective computing of mood and emotional state ○ Decision Support System ○ Quality of Life assessment tool ○ App with multiple features for patients ○ Supporting centre services ○ Videoconferencing tools ○ Digital platform for healthcare providers
Gain Creators	○ Assisting and empowering patients ○ Job opportunities ○ Information sharing, communication, and coordination ○ Supporting treatment adherence ○ Quick recognition of any negative evolution in chronic conditions ○ Access to data at international level
Pain Relievers	○ Improving accuracy of clinical decision-making ○ Reducing healthcare spending ○ Ease access to healthcare
Customer jobs	○ Digital oriented decision-makers ○ Digital technologies users ○ Efficiency seekers ○ Looking for solutions to reach more patients
Gains	○ Increasing patient's quality of life ○ Improving patient's health ○ Increasing caregiver's quality of life ○ Better and quicker access to care
Pains	○ Low digital literacy

	○ Difficulties in implementing digital solutions

When targeting insurance companies and healthcare institutions TeNDER will play the role of an extensive segmented solution that will add value to what they offer their own clients. For healthcare institutions, TeNDER will also contribute to an increased productivity associated with the management tools provided and with the decision support system as well. The modular architecture will allow for each customer to adapt the solution to their own needs. In the perspective of healthcare professionals, like doctors and other caregivers, this platform should be positioned as a workflow facilitator and as a tool that will increase efficiency which, at ultimate stage, will be reflected as a gradually increasing number of patients assisted and monitored. Lastly, TeNDER should position itself near patients and families as a solution that will safely increase the independence of the patient while guaranteeing constant monitorization. Overall, TeNDER positioning will consist of a comprehensive modular integrated solution, developed with advanced technologies that will enhance access to healthcare in a cost-effective way.

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Annex

Table 4: Potential Competitors Projects H2020_SC1-DTH-2019-2020

Project - H2020-SC1-DTH-2019-2020	Information	Potential overlap with TeNDER services, tools, target groups, etc.
CAPABLE (Cancer-related + chronicity)	- Launched January 2020; 12 partners, unclear how many pilot sites (Lithuania, **Spain**, Poland, Netherlands, Great Britain, **Italy**, Israel). - Developing AI- and Big Data-based post-primary intervention, home **support system for long-term cancer patients (with and without multi-morbidities**), and those who surround them. It also aims to identify unknown patient and caregiver needs. - Technology and services include **wearables and sensors to monitor users at home, as well as provide psycho-social support (coaching and therapy)**.	- Devices: wearables and sensors. - Services: recommendations; (*to be updated*).
ADLIFE (Integrated care)	- Launched January 2020 (48 months); 7 pilot sites (Sweden, Denmark, UK, **Germany**, **Spain**, Poland, Israel). - Developing Early Warning and Clinical Decision Support Systems. - Focus on people with COPD and Heart Failure (though aim is broader chronicity). - WP10 Exploitation Plan not available online (to be carried out by Optimedis, DE)	- Target: patients with heart failure and multi-morbidities. - Services: early warning system; (*to be updated*).
PROCarelife (Integrated care + healthy ageing) (partners involved: APM/UPM)	- Launched January 2020 (36 months); 14 partners, unclear how many pilot sites (**Spain**, **Italy**, Romania, **Germany**). - Developing integrated care support platform. System aims: communication between stakeholders, improve care and quality of life, provide personalised med. - Focus on people with Parkinson's and Alzheimer's (though aim is	- Target: ageing people with multi-morbidities; particularly dementia and Parkinson's Disease; caregiver needs. - Devices: *to be updated*. - Services: communication between patients, caregivers, and social

	broader chronicity in older adults). - In preliminary stages – surveying caregiver and patient needs.	and health care professionals; daily routine recommendations.
VALUECARE (Tools for integrated care)	- Launched January 2020; 17 partners and 7 pilot sites (Ireland, **Spain**, Netherlands, Portugal, **Italy**, Croatia, Greece). - Large-scale pilot project; aims to provide "Value-based methodology for integrated care supported by ICT." - Focus on people with cognitive impairment, frailty and multiple chronic health conditions. - In preliminary stages – co-creation methodology, etc.	- Target: older adults with multi-morbidities. - Devices: *to be updated*. - Services: *to be updated*.
QUALITOP (Cancer-related)	- Launched 2020, unclear about pilots; 14 partners (Belgium, France, **Germany**, **Italy**, Netherlands, Portugal, US, **Spain**, UK). - Aims at improving the quality of life of cancer patients after the start of immunotherapy outside controlled environments. - Technology and services include Big Data- and AI-based **smart digital platform** – **will collect, analyse data, and provide real-time recommendations**.	- Devices: *unclear at this stage*. - Services: recommendations; (*to be updated*).
PlatformUptake.eu (Healthy ageing) (partners involved: UPM)	- Launched January 2020 (24 months); 12 partners. - Aims to assess the societal impact of existing tools for integrated care and assistance, collect best practices, promote interoperability, etc. - Preliminary stages – flagged for potential collaboration	
LifeChamps (Cancer-related)	- Launched 2020; 15 partners (Greece, Israel, Sweden, UK, Belgium, Netherlands, **Spain**, Portugal, Luxembourg). - Overall aim: **monitor symptoms that affect quality of life**. - Will provide support to middle-aged and **elderly cancer patients, their caregivers, and healthcare professionals**.	- Devices: *to be updated*. - Services: recommendations; personalised recommendations; physical and mental health monitoring; communication with

	- AI- and Big Data-based technology; services will include predictive engine; **personalised treatment and activities recommendations, physical and mental health monitoring; provide actionable insights to physicians**.	physicians; (*to be updated*).
ASCAPE (Cancer + A.I.-related)	- Launched 2020 - pilot project, though unclear in which countries; 15 partners. - Big Data, AI, Machine Learning – to support cancer patients' quality of life and health. - Services include physical and psychological support; monitoring of important health markers related to breast cancer and prostate cancer. - Aims to extend technology and services to apply to any type of cancer in future.	- Devices: *to be updated*. - Services: physical and psychosocial support; health monitoring; (*to be updated*).
FAITH (Federated A.I. solutions…) (Cancer-related – affective recognition system) (partners involved: SERMAS/UPM)	- Launched 2020, pilot project (Spain, Portugal, Ireland); 9 partners in total (other countries include Cyprus and Italy). - Aim is to give healthcare providers and recovering cancer patients advanced warnings to allow timely intervention, and increase awareness of patients' mental health situation, giving them the possibility to improve their quality of life and receive intelligent post-cancer support. - Key service is **AI-based affective recognition system**.	- Devices: *to be updated*. - Services: affective recognition system.
BD4 QoL (Quality of Life monitoring)	- *No information available online*.	
CLARIFY (Cancer-related)	- Launched 2020-2021; 9 partners. - Diagnostics-oriented.	
ONCORELIEF (Cancer-related) (partners involved: CERTH/MAG)	- Launched 2020; 13 partners. - Develop Quality of Life assessment tools to improve post-treatment health status. - Will provide: **personalised smart digital assistant; tasks & activities recommendations; mental health monitoring**. - Target groups include patients with two types of cancer: Acute	- Devices: *to be updated*. - Services: smart digital assistant; recommendations; mental health monitoring.

	Myeloid Leukemia and Colorectal Cancer.	
PERSIST (Cancer-related)	- Launched 2020; 13 partners. - Provide personalised, real-time survivorship care plans for cancer patients. - Will monitor patients and analyse data to make recommendations, as well as make Quality of Life assessments. - Aiming to include the following tools: **e-Health applications; sensing devices; mood recognition**.	- Devices: sensing devices; eHealth applications; (*to be updated*). - Services: health monitoring; mood recognition; recommendations; (*to be updated*).
iHELP (partners involved: UPM)	- Launches 2021; 14 partners (Greece, **Spain**, Bulgaria, Belgium, **Italy**, Romania, UK, Sweden, Taiwan). - User-centric and mobile health monitoring applications. - For patients with Pancreatic Cancer.	- Devices: mobile eHealth applications; (*to be updated*). - Services: health monitoring; mood recognition; recommendations; (*to be updated*).
WARIFA	- Launches 2021; 11 partners (Norway, **Spain**, **Italy**, Romania, Finland, Ireland).	- *To be updated*.
e-VITA	- Launches 2021; special cooperative project EU-Japan. - Virtual coach.	- *To be updated*.
SMILE	- *Not enough information available online*.	
I-CARE4OLD	- Launches 2021. - **Individualised care for older persons with multimorbidities** living in home care and nursing homes.	- *To be updated*.
RE-SAMPLE (partners involved: HOPE)	- Launches 2021.	- *To be updated*.
RETENTION	- Launches 2021. - Patient monitoring outside of hospital (heart failure).	- *To be updated*.

Table 5: Potential Competitors Projects H2020_"Active ageing, independent and assisted living"

PROJECTS UNDER TOPIC: "Active ageing, independent and assisted living"		
PHArA-ON (Smart and active living; ageing population)	- Launched January 2020; 41 partners and 6 pilot sites in 5 countries (**Spain**, The Netherlands, **Slovenia**, Portugal, **Italy**). - Large-scale pilot project; aims to integrate digital services, tools and devices into open platforms; range of digital tools including: connected devices (e.g., the Internet of Things, IoT), artificial intelligence, robotics, cloud and edge computing, smart wearables, big data, and intelligent analytics. - Focus on elderly population in general. - In preliminary stages.	- Target: elderly population in general. - Devices: smart wearables; connected devices; (*to be updated*). - Services: (*to be updated*).
AgeingAtWork	- Launched January 2019 - Market target - elderly workers, but will aim to support people in their homes in future. - Services will include: recommendations for workplace design; productivity enhancement; knowledge-sharing and collaboration; personalised virtual assistant.	- Target: elderly workers (stated aim to support elderly people in their homes in future). - Services: virtual assistant; (*to be updated*).
BIONIC	- Launched January 2019 - Market target – elderly workers and the elderly population in general - Developing a non-obtrusive monitoring wearable and developing best practices in user acceptance of monitoring devices amongst the elderly population. - Real-time alert system. - Public deliverables.	- Target: elderly population in general. - Devices: smart wearables; (*to be updated*). - Services: alert system; (*to be updated*).
SmartWork	- Launched 2019; 10 partners. - "unobtrusive sensing and monitoring of their health, behaviour, cognitive and emotional status, and responding to their needs." - Target group – elderly workers.	- Devices: smart wearables; (*to be updated*). - Services: (*to be updated*).
sustAGE	- Launched January 2019; 10 partners.	- Devices: *to be updated*.

	- Monitoring to support physical and mental health through personalised recommendations. - Target group – elderly workers in manufacturing.	- Services: *to be updated*.
WorkingAge	- Launched 2019; 11 partners. - Will use HCI methods (augmented reality, virtual reality, **gesture/voice recognition,** and eye tracking) to measure the user emotional/cognitive/health state and create communication paths. - Services will include: **reminders**, risks avoidance, and **recommendations**. - Target groups – elderly workers in office settings, manufacturing, and driving. However, **will try to extent to support home environment eventually**.	- Target: elderly workers (stated aim to support elderly people in their homes in future). - Devices: *to be updated*. - Services: mood recognition systeml; reminders and recommendations; (*to be updated*).
SMART-BEAR (Assistive medical and mobile devices)	- 4-year project launched September 2019. 27 partners. - "The aim of the **SMART-BEAR** platform is to integrate heterogeneous sensors, assistive medical and mobile devices to enable the continuous data collection from the everyday life of the elderly, which will be analysed to obtain the evidence needed in order to offer personalised interventions promoting their healthy and independent living. The platform will also be connected to hospital and other health care service systems to obtain data of the end users (e.g., medical history) that will need to be considered in making decisions for interventions." - Target groups – elderly population, and especially elderly people with comorbidities.	- Target: elderly population in general, particularly with comorbidities. - Devices: smart wearables; sensors. - Services: data analysis for personalised medical recommendations; communication across patients' health and social care ecosystem.
CO-ADAPT (Human and Work Adaptation Support to Ageing Citizens)	- Launched 2018; 10 partners. - AI-based technology to support the participation of elderly populations in the workforce.	- Services: language and physiological analytics.

	- Coaching, improving computer literacy, support mental health in the workplace. - Tools: **language and physiological analytics**.	
Homes4Life	- Developing certification standards for ageing in place.	
DigitalHealth Europe	- Supportive platform for those working to launch digital solutions for person-centered care. Building multi-stakeholder communities.	
SHAPES (Extension of AGE Platform)	- Like its predecessor, SHAPEs aims to build an open platform that gathers digital services for integrated care.	
IDIH - International Digital Health Cooperation for Preventive, Integrated, Independent and Inclusive Living	- Promotes international collaboration to support active and healthy ageing through innovation.	

Table 6: Potential Competitors Projects H2020_SC1-BHC-24-2020

SC1-BHC-24-2020 **Healthcare interventions for the management of the elderly multimorbid patients**		
CAREPATH	- Launches 2021.	- *To be updated*.
GERONTE	- Launches 2021.	- *To be updated*.
EHRA-PATHS	- Launches 2021.	- *To be updated*.
eMOTIONAL Cities (BHC-29)	- Launches 2021. - "Mapping the cities through the senses of those who make them."	- *To be updated*.

Sources: (49) (50)