





# Market Analysis: Digital Health in the Portuguese Healthcare Sector

For the Embassy of Denmark in Portugal

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# List of Acronyms and Abbreviations

ACSS Central Administration of the Health System

(Administração Central do Sistema de Saúde)

ADSE Institute for Sickness Protection and Assistance

(Instituto de Proteção e Assistência na Doença)

Al Artifitial Inteligence

ASF Insurance and Pension Funds Supervisory Authority

(Autoridade de Supervisão de Seguros e Fundos de Pensões)

AR Augmented Reality

CNTS National Centre of Telehealth

(Centro Nacional de Telesaúde)

CDMO Contract Development And Manufacturing Organization

DGH Directorate-General for Health

EHR Electronic health records

EC European Commission

EU European Union

GDP Gross Domestic Product

HTA Health Technology Assessment

IPSS Private Institutions of Social Solidarity

(Instituições Particulares de Solidariedade Social)

INE National Statistics Institute

IT Information Technology

MDA Medical Devices Act

MIPEX Migrant Integration Policy Index

MoH Ministry of Health

NHS National Health Service

RHAs Regional Health Administrations

RRP Recovery and Resilience Plan

SiNATS National Health Technology Assessment System

(Sistema Nacional de Avaliação de Tecnologias de Saúde)

SPMS Shared Services of the Ministry of Health

VHI Voluntary Health Insurance

VR Virtual Reality

# Context

This document was made at the request of the Embassy of Denmark in Portugal, with the objective of creating a market analysis to get a thorough understanding of the business potential within digital health, health tech and health IT infrastructure in the Portuguese healthcare sector for Danish businesses.

# **Executive Summary**

This report is focused on the characteristics and conditions of the Portuguese market for digital health companies. It describes the current conditions for starting or entering a business in Portugal, and also gives a thorough introduction to the current state of the healthcare market, its digital "maturity" and the ongoing initiatives in order for the authors to make their recommendations to the Danish business sector. Furthermore, it gives the operational perspective of the regulatory processes, bureaucracy and fees, identifying the country's most innovative players and highlighting some of the major business opportunities currently at stake.

Below is a quick summary of each chapter, finishing with a SWOT analysis and some final recommendations.

#### • Chapter 1, Portuguese Healthcare System

This chapter introduces how to navigate the Portuguese health system as a combination of public and private sectors. The access to care through these two sectors and the main stakeholders in each are explained. In the public sector, primary care centres, hospitals and municipalities are highlighted. While in the private sector, the business models relating to health subsystems and voluntary health insurance are addressed.

#### • Chapter 2, Status of Digital Health in Portugal

Summarises the advances made to digitise health in Portugal in the National Health System and research and development. The chapter analyses the level of digital literacy in the country and the adherence of the population and professionals to digital health solutions. The most active and receptive hospitals developing digital health projects are also highlighted. After this analysis, the current digital health drivers and barriers are identified.

#### • Chapter 3, Market Conditions

This chapter presents the relevant policies, regulation and estimated timings regarding medical device manufacturing, marketing, distribution and advertising. Some of the taxes and fees involved are also mentioned, along with the steps for setting up a business in Portugal. Regarding the prescription and reimbursement models, it is presented the current maturity of these schemes, as well as the entities involved in the processes.

## • Chapter 4, Investment Plans

This chapter presents the public investments foreseen in the Recovery and Resilience Plan approved in 2022 and the latest private investments made in the health and innovation sector in the last years. Channels are also listed where government public tenders business opportunities are announced, as well as projects and incentives in which startups and international projects can participate for being beneficial for their arrival in the Portuguese market.

#### • Chapter 5, Potential Entry Points for Danish Companies

This chapter exposes some potential entry points for Danish startups, SMEs and health IT companies. After presenting the Portuguese innovation ecosystem, the following entry points are highlighted: programs and incentives; accelerators and incubators; hospital innovation departments; and research partnerships and European Consortia. Possible bridges with municipalities are also addressed.

#### Chapter 6, Final Conclusions

This chapter highlights the main conclusions that can be drawn from the study. It is given a SWOT analysis and the compilation of some recommendations for strategic entries into the Portuguese market depending on the stage of the Danish entity: startup, SME or health IT company.

#### Appendix A

This appendix compiles the full written interviews done in the context of this study to three experienced profiles in the area of health and innovation in Portugal: a profile from healthcare IT services - Filipa Fixe, a Board Member at Glintt; a profile from the private healthcare sector - Patrícia Crespo Loureiro, Digital Health Manager at Hospital CUF and very experienced in the public sector too; and a profile from an overall healthcare sector association and think tank - Patrícia Patrício, Knowledge and Intelligence Manager at Health Cluster Portugal.

#### Appendix B

This appendix presents some graphs about Internet access and penetration in Portugal, the most used electronic devices by consumers and the most downloaded mobile apps in the health area.

# **About Portugal**

Portugal has a population of 10,33 million inhabitants (2021), occupying a total area of 92,212 km² that includes the mainland in southern Europe and two autonomous regions: the archipelagos of Madeira and Azores, in the Atlantic Ocean [1]. Portugal is becoming the hub for European entrepreneurship and a magnet to talented digital nomads. One of the reasons is the welcoming environment, being the 6th safest country in the world, one of the top 10 MIPEX countries with the best migrant integration policies, 300 days of sun per year and 15°C average temperature [2].

Portugal is also prepared with free public Health and Education, ranked 11th with higher fibre optic connectivity and 28th fastest average broadband speed. It is also talented, with a startup ecosystem that represents 1% of the national GDP and 7 unicorns, ranked 7th in the English Proficiency Index and the second-highest growing eurozone country in Q4 2021 [2].

# 1. Portuguese Healthcare System

The Portuguese healthcare system is characterised by three co-existing and overlapping systems [3], [4]:

- 1. The universal National Health System (NHS), which is a tax-financed system that covers all residents;
- 2. The **health subsystems**, which are special health insurance schemes that provide coverage for particular professions/occupational groups or companies such as the schemes for civil servants and the banking sector;
- 3. The private **voluntary health insurance** (VHI) schemes, which have a supplementary role, facilitating access to private hospital treatment and ambulatory consultations.

In this chapter, each system will be explored, as well as its role when integrated with the global Portuguese healthcare system.

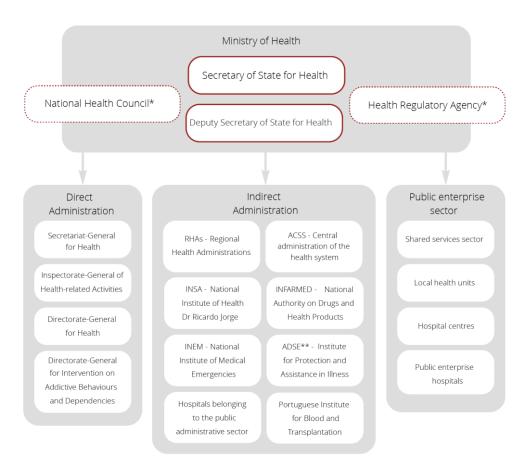
#### 1.1. Public and Private Sectors

The healthcare delivery system in Portugal consists of a network of public and private healthcare providers, each being connected to the Ministry of Health (MoH) and the patients in its own way. Since 1979, Portugal has had a health system based on a highly centralised NHS in which the MoH is responsible for developing health policy, overseeing and evaluating its implementation, and managing other institutions, as shown in Figure 1 [5]. The MoH is also responsible for regulating, auditing and inspecting private healthcare providers, whether they are part of the NHS or not [3]. Institutions with key roles in the administration of the system are:

- **Directorate-General for Health** (DGH), responsible for health promotion, disease prevention, and planning and coordinating health care activities and public health programmes;
- Central Administration of the Health System (ACSS), responsible for managing financial, human, and equipment resources;
- Regional Health Administrations (RHAs), responsible for implementing national health policy regionally and in coordinating all levels of health care;
- Shared Services of the Ministry of Health (SPMS), responsible for technological products and services for citizens, professionals and health institutions.

According to the Patrícia Loureiro (Digital Health Manager at Hospital CUF) interview, "SPMS plays a relevant and responsible role in the digital transformation of the health area". In fact, "the Portuguese National Center of Telehealth was created according to the Resolution of the Council of Ministers (RCM) 67/2016 of October 26 and was integrated into SPMS. It acts to promote, manage and coordinate the telehealth services and initiatives and carries out R&D and teletraining activities".

Regional and local level governance focuses on delivering primary care and public health services. In theory, RHAs are responsible for implementing national health goals and therefore are responsible for coordinating public hospitals, public primary care centres, and the long-term care network, and integrating private health care units and pharmacies [5]. Figure 2 represents an overview chart of the health system and the coordination between its entities.



- \* Has some degree of independence from the Ministry of Health.
- \*\* ADSE is under the indirect administration of both the Ministry of Health and the Ministry of Finance.

Figure 1 - Organisational chart of the Portuguese Ministry of Health. Adapted from Oliveira et al. [5].

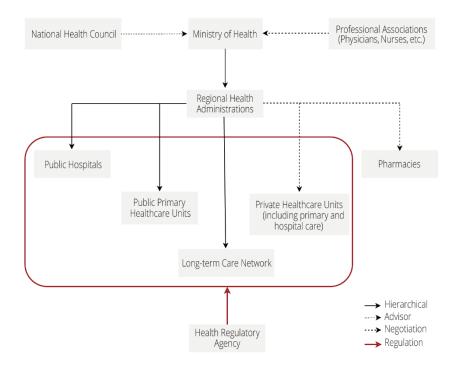


Figure 2 - Overview chart of the health system. Adapted from Simões et al. [3].

#### 1.2. Access to Care

Health care in Portugal can be accessed via public or private sector (in some cases, a combination of both), depending if the services are provided by the NHS, or by healthcare subsystems or VHI, respectively.

Health care provision in mainland Portugal is concentrated in large urban areas (Lisboa, Oporto, Coimbra, and other medium-sized cities). Rural areas and the inland areas of the country face some shortages in health care professionals, specifically physicians. People in these areas face healthcare access problems related to distance and transport, where telemedicine can play an important role [5]. Regarding the most recent data about medical staff, in 2020, 57,198 doctors were enrolled in the Order of Physicians, corresponding to 5.6 doctors per thousand inhabitants [6].

#### 1.2.1. Public Sector

The NHS is a tax-financed system that covers all residents, irrespective of their socioeconomic, employment or legal status. Access to NHS is nearly free because only moderate fees (or user charges) must be paid. However, given the poverty and income inequality level, until 2022, nearly 60% of people had been exempted from user charges (e.g., household income insufficiency, chronic diseases, age under 18 years, and pregnancy). Therefore, in 2022 user charges were abolished in the entire NHS, except for emergency care without referral onpatient care [5].

The NHS covers a comprehensive range of primary and differentiated care, including general practice visits, outpatient specialist care, and other services prescribed by doctors, such as pharmaceutical products. Some gaps exist in health care coverage, but in some cases, they are overcome through NHS contracts with the private sector, as is the case for oral health, physiotherapy, psychology, diagnostic services, renal dialysis, and rehabilitation [5]. Primary Care Centres, Hospital/Hospitals Centres and Municipalities are responsible for providing these services.

# Primary Care Centres

A Primary Care Centre (or simply health centre) is the basic unit of the NHS, which provides primary health care to local communities in non-urgent situations. These units offer routine consultations, nursing and family planning appointments, and administration of all the vaccinations included in the National Vaccination Programme. In terms of healthcare professionals, health units provide general practitioners, doctors of public health, nurses, social services technicians, nutritionists and psychologists.

A Group of Primary Care Centres covers several health centres in a municipality. And the Local Health Units include all health centres and hospitals in a city or region in a single integrated facility responsible for providing primary and differentiated health care

# Hospital Centres and Hospitals

Hospitals mainly provide differentiated healthcare services such as inpatient, outpatient, and urgent care. Most are part of hospital centres, which gather hospitals that provide care within the same geographic area (city or region). Since 2018, the NHS has also adopted home hospitalisation, a modality that ensures the provision of healthcare at home for a limited time.

According to the most recent annual edition of "Health Statistics" published in 2022 by the National Statistics Institute (INE), with complete information for the year 2020, in that year there were 241 hospitals [6]. The hospitals were divided into 128 private hospitals, 110 public hospitals and 3 hospitals in public-private partnership. Thus, private and public hospitals represented 53.1% and 45.6% of all hospitals, respectively. Public hospitals comprised 105 universal access hospitals and 5 military or prison hospitals [7]. Also according to INE, in 2020, the capacity of hospitals was 36.3 thousand beds (23.4 thousand in public hospitals, 11.9 thousand in private hospitals) [6].

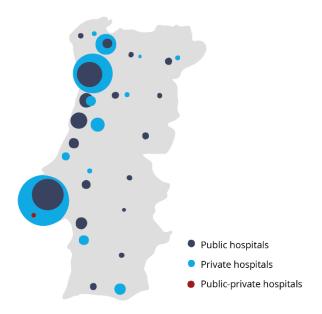


Figure 3 - Distribution of hospitals by geographical area. Adapted from FI Group [7], [8].

# **Municipalities**

There are currently 308 municipalities, 278 of which are on the mainland, 19 in the Autonomous Region of the Azores and 11 in the Autonomous Region of Madeira [9].

In 2022, the MoH carried out the process of decentralising competencies from the RHAs to municipalities. Municipalities became responsible for the operational and financial management of the health centres in their respective geographical area, namely the maintenance, conservation and management of equipment (except medical equipment), participation in the planning, management and investment in new primary health care units, including construction, equipment and maintenance [10]. This transfer of responsibilities also presupposes the transfer of funds so each municipality can manage it. In January 2023, approximately 55 of the 308 municipalities had accepted these additional responsibilities [11].

Private Institutions of Social Solidarity (IPSS) develop social solidarity activities in social security, health and education. These institutions, with a close link to the local municipalities and occasionally funded by them, are responsible, for example, for senior residences and day centres, where healthcare is also provided to elderly or disabled people [12]. At the end of 2022, Social Security reinforced the financial support to IPSS by EUR 2,6 million [13]. It should be noted that these institutions have also been adopting technological solutions to keep their residents physically and mentally active (e.g., Sioslife, a startup that develops interactive systems for the elderly) [14].

#### 1.2.2. Private Sector

In addition to the health insurance coverage provided by the NHS, approximately 30% of the population is covered by a health subsystem or voluntary health insurance (VHI). Considering that some people are double covered by individual and company coverage [3], [4].

The role of the private sector has increased during the last decade, moving from a supply model based on outpatient care and medical diagnostic and treatment procedures, to investment in more differentiated health services capable of competing in some areas with public health services [3]. A patient covered by subsystems can benefit from health services in private healthcare units (including primary and hospital care), typically with shorter waiting times, better facilities, wider choice, and fewer language barriers.

# Health Subsystems

The health subsystems are special health insurance schemes that provide coverage for particular professions/occupational groups or companies - such as the schemes for civil servants and the banking sector (and their families). Health subsystems are typically financed through employer and employee contributions, with the most significant portion paid by the employer.

The main health subsystem is the ADSE (Institute for Sickness Protection and Assistance), covering 10% of the population. ADSE guarantees protection to public administration workers regarding health promotion, disease prevention, treatment and rehabilitation. In this subsystem, holders and family members of the household benefit from consultations, exams and other medical care at lower prices [3].

# Voluntary Health Insurance

The private voluntary health insurance (VHI) schemes have a supplementary role, providing faster access to private hospital treatment and ambulatory consultations with the possibility to choose the provider.

#### **Market Share**

In 2022, more than 3.3 million Portuguese had at least one health insurance policy [15]. The number of VHI subscribers has been increasing over the years (Figure 4), with a sharp rise in 2020 during the pandemic. Around 43% of health insurance beneficiaries are individual subscribers, while the remaining 57% are placed in groups, where company insurance predominates and the average prices are lower.

According to the ASF, the insurance sector regulator, the sale of health insurance exceeded EUR 1 billion in 2021, and registered an annual growth of 10.8% in 2022 [15].



Figure 4 - Health insurance sales and number of subscribers between 2015 and 2021. Adapted from Eco Seguros [16].

#### **Top Companies**

"Insurance companies are changing their positioning, becoming healthcare providers by hiring companies such as Teladoc<sup>1</sup>, among others", commented Patrícia Loureiro (Digital Health Manager at Hospital CUF) in her interview answers.

In 2021 there were 25 insurers in Portugal, groupable into 21 groups or companies, operating in health insurance. The top 3 billed 78% of premiums, the top 5 achieved 89%, and in the top 10 were 96% of health insurance sales. The largest market operators in the disease/health branch – which represents 7.5% of the total annual premiums of the insurance sector –, almost coincide with the largest groups or companies in the sector (Table 1) [16].

<sup>&</sup>lt;sup>1</sup> Teladoc Health is a company of virtual care and telehealth solutions.

Fidelidade has a 37% market share through its brand and Multicare and OK! Teleseguros. Ageas Group concentrates 29% of premiums with Médis, Ageas Seguros and Ocidental Seguros brands, and commercialises insurance through Millennium bcp banking network. Through Tranquilidade brand, Generali obtained a 12% share in 2021 [16].

Table 1 - The biggest groups and companies in the health insurance sector in 2021. Adapted from Eco Seguros [16].

#	Group/Insurance Company	Prizes (EUR thousands)	Market Share	Variation 2021/2020	Companies/Brands
1	Fidelidade	380 630	37%	5.9%	Fidelidade, Multicare, Via Directa (OK!)
2	Ageas	295 689	29%	9.3%	Ocidental Seguros, Ageas Seguros, Médis
3	Generali/Tranquilidade	127 045	12%	10.5%	Tranquilidade
4	Allianz	76 663	7.4%	5.6%	Allianz
5	Victoria	36 782	3.6%	7.7%	Victoria Seguros
6	Crédit Agricole Assurances	24 878	2.4%	-0.8%	Mudum Seguros
7	Lusitania	17 738	1.7%	18.6%	Lusitania Seguros
8	CA	12 868	1.2%	7.9%	CA Seguros
9	UNA	11 762	1.1%	9.2%	Una Seguros
10	Zurich	11 666	1.1%	3.6%	Zurich Insurance
11	Liberty	9 631	0.9%	3.0%	Liberty Seguros
12	Santander	7 686	0.7%	212.6%	Aegon Santander Seguros
13	Planicare	6 282	0.6%	171.5%	Planicare
14	Mapfre	3 981	0.4%	15.0%	Mapfre Gerais
15	Chubb	3 579	0.3%	-11.3%	Chubb European
16	Real Vida	2 110	0.2%	115.7%	Real Vida
17	Cardif	1 599	0.2%	-2.4%	Cardif Drivers
18	Caravela	1 060	0.1%	10.3%	Caravela
19	Asisa	462	0.0%	670.0%	Asisa Seguros
20	Prévoir Vie	47	0.0%	683.3%	Prévoir Vie
21	RNA	6	0.0%	-	RNA Seguros

#### **Business Models**

Private health insurance in Portugal is widely available from well-known international private insurers as well as local private insurance companies. Quotes vary wildly depending on the level of coverage. In June 2021, an individual subscriber paid EUR 325 per year, an average of EUR 27 per month [16].

The VHI policies covering inpatient, ambulatory, and/or external consultations dominate the market. VHI plans do not usually cover NHS user charges, and only a few expensive plans cover co-payments for medicines. Most plans offer limited coverage, multiple exclusions apply (dental coverage, pre-existing, chronic and psychiatric diseases), and few products cover individuals over 70 and at high risk. VHI premiums are based on risk, measured mainly by age and, to a lesser extent, by health status [17].

However, in recent years, other companies have provided cheaper healthcare insurance with slightly different business models. Private hospitals have created health insurance for patients to use their health services exclusively, as is the case of CUF with the +CUF Plan [18]. Wells, a retail shop in the health area, has also created its keepWells health plan in partnership with the insurance company AdvanceCare, where it also offers advantages in other brands of the SONAE company (e.g., supermarket, electronic products, etc.) [19]. Even telecons have developed partnerships with health insurance, as is the case of MEO, which created the MEO Care Health plan, in partnership with Multicare, in which customers pay a symbolic extra to their monthly fee to have access to health services, among which teleconsultations [20].

# 2. Status of Digital Health in Portugal

#### National Health Service

Multiple advances have been made in the adoption of digital technologies. Investments in computer application architecture to enable new communication, interoperable channels for professionals and healthcare users, and effective e-prescribing solutions. In 2016, an NHS portal, called MySNS, was launched to allow users to access and manage their health information, access relevant information (e.g., waiting times for emergency surgical care), and use linked mobile applications. NHS, specifically the SPMS and CNTS, has made several apps related to health available: MySNS, MySNS Tempos, SNS24, Telemonit SNS24, eMed, and Dador. Several other NHS and private pilot projects have explored remote patient monitoring in hospital care delivery [14].

Electronic health records (EHR) are used by all primary healthcare providers and most hospitals, and some interoperability has been achieved among different EHR systems. Investments coordinated by SPMS have been made so that the data infrastructure uses common unique patient identifiers that enable recording information in the Portuguese Health Data Platform (*Plataforma de Dados da Saúde*). This platform includes patient, professional, institutional, and international portals on the NHS website (www.sns.gov.pt) for different types of users, and offers functionalities related to electronic prescriptions, scheduled appointments, disease-specific registers, and information from the long-term care network. SPMS is also responsible for managing the information systems of the NHS units, including SONHO, the single system that supports all hospital administrative services [21], [22].

Despite these advances, not all information can be linked and accessed, and difficulties exist in following patients across healthcare settings (e.g., primary care physicians cannot access all data from patients' hospitalisations because of data formats) [14].

# Research and Development

Research and development (R&D) in health is an area of focus in Portugal, but the economic value of that investment remains lacking. R&D expenditure has increased over the past 5 years and reached EUR 32 million in 2020, representing 1.6% of the GDP (low by European standards), owing to increases in its private component (entailing 57% of total R&D expenditure) and partly reflecting qualified employment and technological capacity (Figure 5). The remaining research is performed mainly in public universities with master's and doctoral programs [23].

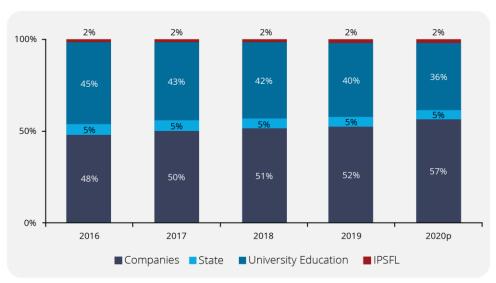


Figure 5 - Distribution of R&D expenditure (%) by sector (2016 to 2020). Adapted from DGEEC<sup>2</sup> [23].

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<sup>&</sup>lt;sup>2</sup> Directorate-General for Education and Science Statistics

Portugal has successfully positioned itself as a technology hub in the Smart Health area (including real world data, virtual assistance, laboratory applications, and robotics), thus attracting foreign investment projects, which have tripled (from 15 to 42), and increasing the number of jobs created from 1,610 to 3,766 in 2019 [5], [24].

In terms of Clinical Trials performed in Portugal, to implement a strategy to leverage the number of trials, the Clinical and Biomedical Research Agency (AICIB) was created in 2018, with the participation of Infarmed (Health Authority) and of the Portuguese Foundation for Science and Technology and industry partners [107]. The number of clinical trials has been increasing, with phase III trials at their greatest extent in 2021 (Table 2). Most of the trials have been sponsored by a commercial entity.

Tahla 2 -	. Clinical trial statistics	, 2012-2021, Adapted	from Oliveira et al [5]	
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	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Total number of clinical trial applications submitted	118	114	127	137	142	137	159	142	187	175
Clinical development phase I	3	10	10	15	26	30	27	29	41	39
Clinical development phase II	25	20	24	24	26	24	38	33	36	32
Clinical development phase III	82	75	81	90	82	75	90	69	99	99
Clinical development phase IV	8	9	12	8	8	8	4	11	11	5
Commercial sponsor	112	98	115	124	132	132	148	128	167	167

## 2.1. Adherence

# 2.1.1. Population

By the Digital Economy and Society Index (DESI) 2022 [25], Portugal is in 18th place in the "connectivity" dimension, being one of the best-performing Member States in terms of fast broadband coverage and fixed network coverage with high capacity [26]. More statistics about Internet assessment in Portugal can be found in Appendix B.

• In 2021, 83% of the population between the ages of 16 and 74 used Internet. Despite having a lower Internet penetration rate, Portugal has been approaching the EU average of 90% (Figure 6);

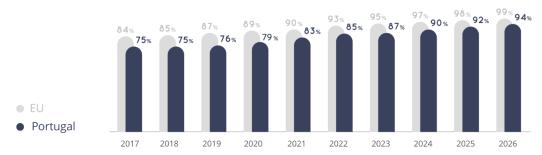


Figure 6 - Penetration rate of Internet use, in Portugal and European Union. Adapted from ACEPI<sup>3</sup> [26].

- In 2021, 87% of Portuguese households had internet connection (Figure 19). In terms of fixed broadband at high speed, Portugal passed the EU average (Figure 20). However, measures are still being taken to improve internet access in rural and less populated areas, where fixed network coverage with high capacity is not yet available;
- Regarding mobile broadband, Portugal remains below the EU average, despite a 4G mobile coverage of almost 100% and advancements on 5G network (Figure 21);

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 $<sup>^{\</sup>rm 3}$  Portuguese Association for the Digital Economy

- Smartphones, followed by laptops and tablets, are the most commonly used to access the Internet. The trend for 2023 is towards a reduction of laptops and an interruption in the growth of smartphones (Figure 22);
- Smartphones are the most sold devices with Internet connection. However, in recent years, new types of devices have been growing, namely smart wearables (e.g., Apple Watch, Google Glass, Samsung Gear, among others) or smart home speakers (e.g., Google Assistant, Siri, Alexa). These new technologies show a growth trend in the coming years (Figure 23).

Consumers are increasingly participative regarding their health and use technologies to monitor their data, measure their fitness and for medication prescription requests (through SNS24 App or website). The population has shown increasing adoption of digital health solutions such as telemonitoring, Al and EHR. On the other hand, they have demonstrated unfamiliarity with technologies related to voice recognition, robotics, radiofrequency identification and virtual reality [27].

- According to the Eurofound survey, 44% of Portuguese people reported using teleconsultation services during the first 12 months of the pandemic, which is a higher proportion than the EU average of 39% [4], [28];
- In the downloadable or subscribed e-content, 7% of online users purchase health or fitness applications, the same percentage as the EU [26];
- At the top of Health and Fitness apps are the SNS24 app, followed by private hospitals apps and the ones to control vital signals (Figure 24).

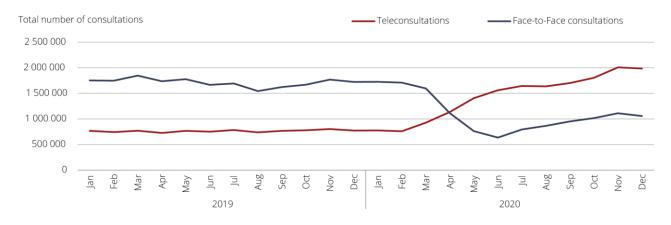


Figure 7 - Teleconsultations during COVID-19 crisis. Adapted from European Commission et al. [4].

#### 2.1.2. Healthcare Professionals

Portugal outperforms the EU average in basic and advanced digital skills among the overall population (Figure 26). However, regarding healthcare professionals, most (56%) require more training with technology, and 47.3% have never received any training [29]. Physicians aged between 61 and 65 are the group that has increased the most over the years and is characterised by following more classical methods of medicine. However, by 2020, around 53% of doctors were aged between 31 and 60 [6].

More and more healthcare units are offering online health services to book appointments, access individual health records and find alternative ways, via App or website, to replace face-to-face consultations without the need to go to a doctor's office or hospital [26]. The pandemic has also accelerated clinical staffing, reskilling, upskilling and adoption of a virtual workspace that otherwise would be a process that would take years to achieve [30].

#### Telemedicine and Teleconsultations

- The pandemic led to a surge in telemedicine in the sense that the Government expanded the regulations and payments for teleconsultations for physicians and psychotherapists during the pandemic to enable them to substitute for face-to-face consultations [4], [28];
- More than 80% of NHS public hospitals use some type of telehealth service, with frequent online tracking and teleconsultation. However, Al projects have yet to reach half of the health institutions in Portugal [31];
- In 2021, out of 194.7 million primary care appointments, 14.6 million (7%) were face-to-face and 20.2 million (12%) were non-face-to-face. The remaining 159.9 million (79%) were home medical appointments [5].

# Digital Solutions

- The industry has been integrating new technologies within the scope of digital medicine, including digital therapeutics [32]:
- After telemedicine and telemonitoring, most of the digital solutions doctors adopt are mobile apps they suggest to
  their patients. Apps for medication management, chronic diseases monitoring (asthma, diabetes, cardiac diseases,
  hypertension, cholesterol) or mental health are the most common ones;
- Portugal has lower availability of some equipment than other EU countries. Investment in medical equipment in the past decade has been low, translating into a large increase in the proportion of aged equipment. From 2008 to 2020, the percentage of computer tomography and magnetic resonance imaging equipment more than 10 years old increased from 7% to 28%, and from 12% to 24%, respectively [5].

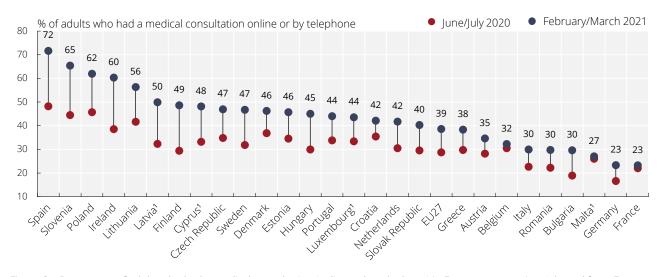


Figure 8 – Percentage of adults who had a medical consultation (online or by telephone) in European countries. Adapted from European Commision et al. [4]. Note: EU average is weighted. 1. Low reliability for 2021 data from Cyprus, Latvia, Luxembourg (and 2020 data) and Malta because of low sample size.

# 2.1.3. Literacy in Digital Health

Data from the Health Literacy Population Survey Project 2019-2021 (HLS<sub>19</sub>) a survey that measured health literacy in 17 countries of the WHO European region, including Portugal, reveal that 65% of the population has a sufficient level of health literacy, 22% have a problematic level and 7.5% an inadequate level [33]. These results show an evolution compared to previous research published in 2016 [34], according to which 42.4% of the population had a sufficient level of health literacy, 38% had a problematic level and 11% had a knowledge considered inadequate.

Despite the positive results, improvements are still needed as only about one-third of the Portuguese considered that they have the literacy to navigate the health system. As Figure 9 shows, the data revealed poorer levels of navigational health literacy lying below the general health literacy levels, suggesting that navigating the Portuguese healthcare system is more challenging than the other specific health literacies [33].

Hence, although people have greater access to health information and a better understanding, they still find it challenging to translate the information into practical actions when navigating the Portuguese health system. In fact, several initiatives have been aimed at promoting literacy and addressing inequalities in access to digital health [5].

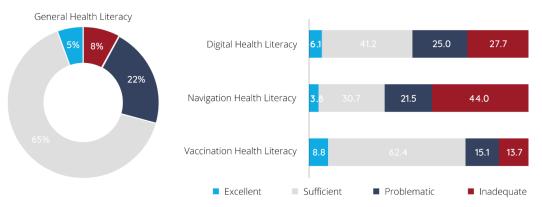


Figure 9 – Distribution of the general health literacy levels and specific literacy levels of the Portuguese HLS19 sample: digital health literacy, navigational health literacy, and vaccination health [33].

#### 2.2. Drivers & Barriers

The following drivers and barriers (Table 3) are a mix of the points extracted from the analysis made throughout this chapter, the authors' knowledge of the Portuguese system and the 3 interviews made in the context of this study to profiles from IT services, public and private sectors of healthcare (see Appendix A).

Table 3 - Main drivers and barriers of digital health in Portugal.

#### Drivers Barriers Population Population High-quality Internet access; Digital skills of health professionals (especially the older Growing interest of the population to monitor their classes); data and using AI tools [26]; Digital literacy of citizens (especially in advanced Increasing acquisition of connectable devices such as technology); smart wearables by the population. Conservative mindset that fights innovation and Population with technological skills [26]. adoption of new tools. Digital Transformation Digital Transformation The health sector has been investing in new Preparation/Capacity of the NHS, mainly regarding technologies: Al, mobile apps, telemedicine and interoperability, privacy, ownership and security of remote monitoring and interoperability [30]; personal data; Hospitals have been investing in home-based health There is no established prescribing and reimbursement to free up hospital resources [5]; system for digital health solutions; There is a lot of regulation, bureaucracy and time to pilot Al and robotics are most frequently used by Portuguese companies than by the EU average [26]; new digital health solutions in hospitals. SaaS is a new business model for many companies [26].

The barriers mentioned are mainly social and political. Strategies and initiatives that are in place to tackle them will be discussed further. Some examples are the digitalisation of NHS, the population training for the use of technologies and other initiatives foreseen in the Recuperation and Resilience Plan.

Regarding barriers, Filipa Fixe (Executive Director at Glintt) mentioned that "Portugal needs to focus on citizens, which will only be possible through data interoperability and measurement of results, leveraging the most appropriate technologies and well-defined strategies and processes. Change management is more important than technological disruption". Filipa also added, "it is important to define a reference architecture for ICT, for processes and governance with the right and coherent business model, a business model that delivers economic and social value".

# 2.3. Top Hospitals & Projects

#### Hospitals

According to a study elaborated by Health Cluster Portugal and Fraunhofer [8], among the Portuguese public and private hospitals and clinics, 198 hospitals and clinics were identified as potential main users of digital/smart health solutions. Private clinics and hospitals are the majority, with 104 entities, followed by public hospitals, with 92 entities. The North region is the most represented, with 71 potential user entities, followed by the regions of Área Metropolitana de Lisboa e Centro, with 58 and 51 entities, respectively, and the regions of Alentejo and Algarve, which have 9 entities each.

The 3 major private hospital groups - Luz Saúde, CUF/José de Mello Saúde and Lusíadas - have their own innovation department and/or acceleration programs and are willing to do pilots and test new technologies. The most innovative hospitals in Portugal belong to these groups, such as Hospital CUF Descobertas, Hospital CUF Tejo and Hospital da Luz Lisboa. However, public hospitals also stand out for their degree of innovation and digitalisation, such as Hospital de São João (Porto), Hospital de Santa Maria (Lisboa), Centro Hospitalar Universtário da Universidade de Coimbra and Hospital Central e Universitário da Madeira.

- CUF, belongs to José Mello Saúde group, and it is composed of a network of 10 hospitals, 10 clinics, and one institute spread throughout the country. In terms of innovation, CUF distinguishes itself with the CUF Academic Centre and its Simulation Centre, a national and international reference healthcare professional training unit equipped with highly specialised technology in the biomedical area. CUF also has its portal and App My CUF, where patients can book appointments, check in automatically, make payments and access their medical results [35], [36];
- Lusíadas Saúde is a network of 6 hospitals and 5 clinics. It is known for its commitment to the innovation of advanced medical technologies, such as robotic surgery, advanced medical imaging technologies and information technologies, such as the electronic record system and telemedicine [37]. In 2022, Lusídas announced LUSI, a virtual voice assistant developed in partnership with the Portuguese startup AgentifAl. LUSI is a virtual voice and text assistant for appointment management using Al [38]. Lusídas also has its portal and App +Lusíadas, where patients can book their medical acts, make automatic check-in, make payments, consult results and communicate with the media by messages or video calls [39]. Lusíadas also created the Lusíadas Knowledge Center, responsible for teaching and research at Lusíadas Saúde, in partnership with other UnitedHealth Group operations;
- Luz Saúde has 11 hospitals and 30 clinics throughout Portugal. In Lisbon, the Hospital Saúde Learning Health specialises in digital health and innovation and is dedicated to training professionals and research. It has a simulation centre that uses technologies such as AI, VR/AR, robotics, telemedicine and EHR. With the telecom NOS, Luz Saúde gave rise to the first Portuguese hospital covered by 5G (Hospital da Luz, Lisboa) [40]. Luz also offers its customers the Digital Clinical Centre, dedicated to monitoring and surveillance chronic disease. This data can be visualised by the respective doctor, to have a complete view of the evolution of patient's health condition. Luz Saúde has a 15 years partnership with Outsystems, a leading Portuguese software company that develops applications that allow its

customers to create innovation. Outsystems developed over 500 systems and in several successful cases, such as LUZ 24, Luz Link, MY LUZ app. In 2022, Luz Saúde renewed this partnership to be even more agile in its processes, having more user-friendly systems for the company's professionals [41].

#### **Projects**

In recent years, the government has also adopted several organisational changes that increased the involvement of primary health care, including the use of digital consultation or tele-expertise between primary health care teams and specialists, and the establishment of mobile health clinics to reach the most vulnerable populations in some rural areas, to help alleviate workforce shortages [4], [42]. Some examples are given below.

- Hope Care, a company from Óbidos Park, joined the Hospital de Avelar in the largest telemonitoring project of
  patients made outside hospitals in Portugal. The "S@úde+Perto" will monitor over 500 chronic patients over 65 years
  old, in 6 municipalities [43];
- GENTIL is a Porto IPO project awarded in Compete 2020 (EUR 13M European programme). This project applies Text Mining (TM) and Natural Language Processing (NLP) to the consultation diaries recorded by physicians in the electronic medical record, which is currently done in free text. GENTIL is an Al tool to aid clinical decision-making, extracting large amounts of valuable clinical data for statistical purposes and identifying important clinical indicators [44];
- The University Hospital Centre Cova da Beira was another project funded by the COMPETE 2020, to develop the Telemonitoring of Patients at Risk Project TERI, an investment that exceeds 369,000 euros. TERI allows the reduction of in-hospital cardiac arrest episodes, complications due to delays in therapeutic interventions, and a decrease in inhospital mortality and incidents [45];
- The Value for Health Collaborative Laboratory (VOH.CoLAB) has been working with Hospital de Santa Marta on telemonitoring patients who have undergone cardiac surgery. The use of technology allows patients to be discharged earlier, thus being able to free beds for other patients and reduce costs to the hospital [46].

#### 3. Market Conditions

The NHS is funded mainly through general taxation, and the MoH is responsible for managing and coordinating spending of the government budget for the NHS, allocating resources to the institutions according to the financial flows depicted in Figure 10 [5].

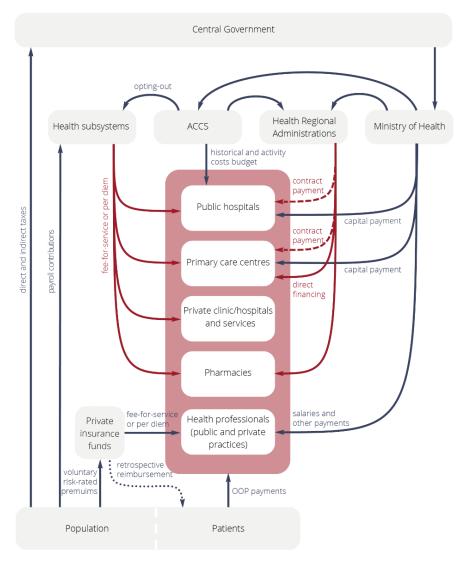


Figure 10 - Key institutions and main financial flows within the Portuguese health system. Adapted from Oliveira et al. [5].

#### 3.1. Relevant Policies

As a member of the EU, Portugal follows directives and regulations from the European Commission (EC) and the same medical device classification as all other EU member states. The main regulations in this area which are a common law in all member states are the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) [31].

When complying with the MDR or the IVDR, the medical device needs to be CE marked, which signifies the product's conformity with current EU regulations, allowing the device to be sold freely in the EU market [47]. The bodies involved in assessing the conformity of a medical device are following presented and depicted in Figure 10.

• National Competent Authority, which evaluates, authorises and regulates the manufacture, marketing and advertising of medical devices, guaranteeing the protection of public health. The Portuguese Regulatory Authority is Infarmed (National Authority of Medicines and Health Products), an agency within the Portuguese Ministry of Health [31], [48];

- **Notified Body**, evaluation body appointed by the national authority and recognised by the EC, responsible for the conformity assessment of medium and high-level risk medical devices [31], [47]. Up to now, Portugal does not have a Notified Body. An example of a Notified Body process can be found in Figure 11;
- **Manufacturer**, responsible for having the conformity assessment procedure by drawing up a CE declaration of conformity and notifying the component authority (Infarmed) [48].



Figure 11 - Overview of the main entities involved in the device certification process. Adapted from Complear Health [47].

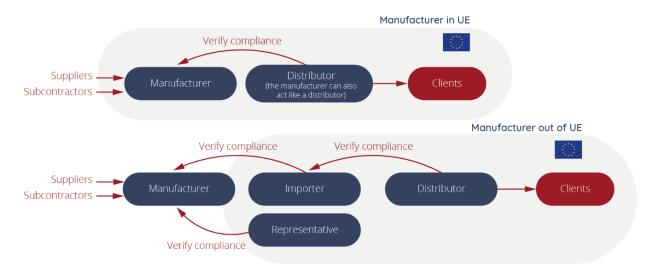


Figure 12 - Example of a Notified Body process. The steps before and during submission vary from Notified Body to Notified Body [47].

# 3.2. Regulation and Estimated Timings

The authorisation, pricing, and reimbursement of drugs, biologicals, and medical devices are governed by the following Portuguese laws and regulations:

- Decree Law 176/2006, 30 August 2006 (Medicinal Products Act);
- Regulation (EU) 2017/745, 5 April 2017 (Medical Devices Regulation);
- Decree-Law 145/2009, 17 June 2009 (Medical Devices Act), on the matters not covered by the Regulation referred to in the previous paragraph;
- Decree-Law 97/2015, 1 June 2015, Ordinance 195-A/2015, 30 June 2015, and Ordinance 195-C/2015, 30 June 2015 (Pricing and Reimbursement of medicinal products and medical devices).

The manufacture and distribution of medical devices in Portugal are subject to prior notification to Infarmed. The Medical Devices Act (MDA) sets out specific rules on medical device manufacture, commercialisation, distribution and advertising [48].

#### Manufacturing

The manufacturing of medical devices is subject to prior notification to Infarmed, 60 days before the activity's start date. After the notification, Infarmed can inspect if the manufacturer satisfies all the premises. If an inspection does not take place 60 days after the notification, the manufacturing activity can begin.

A manufacturer that places medical devices in the EU market under its own name and does not have its headquarters in an EU member state must appoint a representative for each medical device. The representative must be established in an EU member state and act on behalf of, and receive notifications addressed to, the manufacturer by EU authorities and bodies on compliance with legal obligations [48]. The representative must also be presented with the following: EC Declaration of Conformity; CE Certificate; Labeling (must be in Portuguese); Instructions For Use (must be in Portuguese); Technical File. After the documentation review, manufacturers outside the EEA can proceed with the registration with Infarmed [31].

#### Marketing

In addition to the CE marking, all classes of medical devices to be placed on the Portuguese market must undergo a device registration process. The requirements for registration of Class I medical devices are different than the ones for registration of Class IIa, IIb, III and implantable active medical devices [31]. Medical devices can only be placed on the national market if they [48]:

- Satisfy the essential requirements set out in the annexes to the Medical Devices Act;
- Have the CE marking;
- Have had a conformity assessment.

#### Distribution

The distributor, among other duties, must notify Infarmed through an online registration platform of the list of medical devices placed in the market to be distributed, identifying the respective brand, group, model, description and purpose [48]. If a manufacturer ever decides to end their relationship with their distributor, he would be required to remove the product completely from the market until it is re-registered [31].

Wholesale distribution is subject to prior notification to Infarmed 60 days before starting distribution. After the notification, Infarmed can inspect if the distributor satisfies all the premises. If an inspection does not take place 60 days after the notification, the distribution activity can begin.

Distributors of medical devices that are CE marked and have already obtained a conformity assessment in another EU country must notify Infarmed [48]. A wholesale distributor in Portugal can buy medical devices from other jurisdictions if they comply with the rules for placement on the market. For imported medical devices, the Portuguese Tax and Customs Authority must verify the:

- CE mark on the device;
- CE conformity declaration issued by the manufacturer of the device;
- Copy of the certificate issued by Infarmed proving notification of manufacture or distribution activity, as applicable;
- CE conformity certificate or manufacturer declaration attesting that the device did not require the intervention of a notified body and is therefore exempt from the requirement to notify a CE conformity certificate.

#### Advertising

Regarding advertising medicines and medical devices, the applicable law for medical devices is the Regulation on Medical Devices and Related Accessories (Decree-Law 145/2009, of 17 June), and for medicines is the Legal Regime of Human Medicinal Products (Decree-Law 176/2006, of 30 August) [49]. Regarding the Decree-Law 145/2009, it is the manufacturer's responsibility to notify Infarmed through the Infarmed Transparency and Publicity platform. These responsibilities may also apply to distributors [47].

Infarmed is responsible for the supervision and enforcement of the provisions on advertising to health care professionals and the general public. Before manufacturers can start marketing their medical devices in Portugal, they must ensure that their product has been CE-marked. Medical devices that did not have a conformity assessment or were not notified to the competent authority cannot be advertised [48], [49].

Certain medical devices cannot be promoted or advertised to the general public and can only be advertised to health care professionals in technical publications (e.g., medical devices that require mediation and decision of use to be taken by health professionals). Advertising on the internet is subject to the same rules.

## 3.3. Taxes and Fees<sup>4</sup>

# 3.3.1. Startup/Company Foundation

Portugal is ranked as one of the best countries in the world to work remotely and a good country to start businesses and startups. The steps to build a tech startup in Portugal are the following [50].

#### 1. Legal Residency Requirements

- Non-EU/EFTA national people must obtain a Portuguese work visa and residence permit <sup>5</sup>. Those wishing to come to
   Portugal and invest in the country may also be eligible for Portugal's Golden Visa programme;
- EU/EFTA national people are free to travel and work in Portugal. However, a registration certificate from the original local city council is needed to formalise the residence and open a business. The costs are around EUR 15;
- Sign up for a Tax Number from the Portuguese Tax Office. As well as Social Security Number from the Portuguese Social Security.

#### 2. Company Registration

- Set the business name and address (in Portugal) to formally register the company with the Portuguese Government. The name can be chosen from the list of pre-approved names, or by a Name or Denomination Approval Certificate;
- The registration can be done through an accountant or independently. By doing it alone, it can be through *Empresa Online*, which takes 1-2 business days, or *Empresa na Hora* (in person) which takes an hour. Both methods cost EUR 360;
- To open a branch or subsidiary of a foreign company in Portugal, the branch needs to be registered with the IRN (Institute of Registration and Notary Affairs) and the Commercial Registry Office.

### 3. Taxes Payment

 The VAT rate in Portugal is 23% and is paid to the state every three months minus VAT the company spends on its purchases;

<sup>&</sup>lt;sup>4</sup> Disclaimer: The prices shown are indicative and not absolute values, according to the references we have to date. They may be revised periodically.

<sup>&</sup>lt;sup>5</sup> More information on the Portuguese Immigration Office's (SEF) website.

- It is a requirement that all invoices are produced by an authorised accounting software product that is linked digitally
  to the tax authority, so it is advisable to sign up for accounting software or get an accountant;
- The payroll taxes include a social security tax of 11% (paid by the employee) and 23.75% levee paid by the company.
   In addition, there is a progressive Income Tax that is partly paid by the company;
- When the business becomes profitable, a progressive corporate tax has to be paid. Most companies pay around 21%, one of the lowest in Europe. For a large company, the profit will be progressively taxed up to slightly above 30%.

#### 4. Employing Staff in Portugal

Employers in Portugal are obligated to pay each employee 14 months per year. The extra two months are because holiday pay and Christmas bonus are equivalent to one month's salary each. Employers are also obligated to social security contributions as mentioned above.

#### 3.3.2. Medical Devices Commercialization

Regarding selling medical devices, the manufacturer is also responsible for paying local sales taxes for each national market. This means that each entity selling in a given country must check potential local fees, regardless of where the product is manufactured. In the case of Portugal, this fee is due to Infarmed, which applies to 0.4% of local sales of the product (by the manufacturer, if selling directly, or by the distributor, when it is the first entity to make the product available in the national territory). There is also an additional fee of up to 4%, paid to the Portuguese Tax Authority, for the sale of certain medical devices to the NHS, established in the Portuguese Annual Budget Law since 2020 [47].

In the drug market, Portugal has one of the lowest regulatory fees in the EU, which can be a good incentive to choose Portugal as a Reference Member State for submissions. National Procedures have substantially lower fees and a 40% discount on variations. The list of official fees regarding regulatory expenses in the Portuguese drug market can be checked in the Infarmed website [51].

# 3.3.3. Penalties

Ultimately, a National Competent Authority may challenge a product's qualification as a medical device or not, based on the intended purpose claimed. In Portugal, penalties and liability for non-compliance are set out in Decree-Law No. 51/2014 of 25 August 2014, Article 2, for the case of medical devices and Decree-Law No. 189/2000, Article 19, for the case of in vitro diagnostic devices. These Decree-Laws set for different compliance issues a fine between EUR 2,000 and 15% of the entity's sales volume (up to EUR 180.000). In addition to penalties, National Competent Authorities can issue market removal notices for non-compliant products, which are distributed to healthcare professionals and institutions, meaning that even if the compliance situation is resolved, there is a risk of reputational and business damage for the manufacturer. Similar actions can be taken by each National Competent Authority of the countries where the product is marketed [47].

## 3.4. Reimbursement Schemes

Regarding medicinal products, there is a national reimbursement system in which the Government co-pays part of the price of the medicinal products prescribed to the users of the NHS. There are four categories of reimbursement levels that range from a co-payment by the State of 15% to 90%. In addition, there is also an exceptional reimbursement regime where some medicinal products duly specified may benefit from a 100% public financing. The sale of prescription drugs

can only be made through pharmacies [52]. The evolution of health digitalisation in Portugal has been accompanied by solutions developed by the public and private sector, with different prescription and payment models [32].

The Health Technology Assessment (HTA) process is carried out through evaluation criteria defined by SiNATS in the context of decision-making for financing and payment of health technologies other than medicine (e.g. medical devices) [32]. SiNATS is an Infarmed system created prior to the development of the HTA [32]. SiNATS enables a technical, therapeutic, and economic evaluation of health technologies and provides information on technology quality, economy, efficiency, and effectiveness [5]. SiNATS foresees the possibility of administratively setting the sale prices of medical devices and approving their reimbursement, as well as conditioning these products to a prior evaluation procedure, similar to that which exists for medicines, to be used or purchased by NHS hospitals [52]. Figure 13 summarises the market introduction of digital solutions by public initiative regulated by SiNATS.

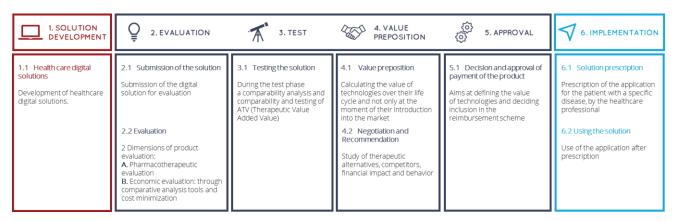


Figure 13 - Market introduction of digital solutions by public initiative regulated by SiNATS. Adapted from Health Cluster Portugal [32].

Currently, the public sector is developing a digital solution for users of the NHS, used on prescription by the attending physician. It is a mobile App called Telemonit SNS 24, where patients can record vital signs or other biometric measurements. This solution allows telemonitoring patients with heart failure, lung disease and post-COVID-19 recovery [53]. In the private sector, solutions are developed and funded by e-Health companies and startups [5], [32]. Figure 14 summarises the processes for developing, prescribing and paying for digital solutions in the public and private sectors.

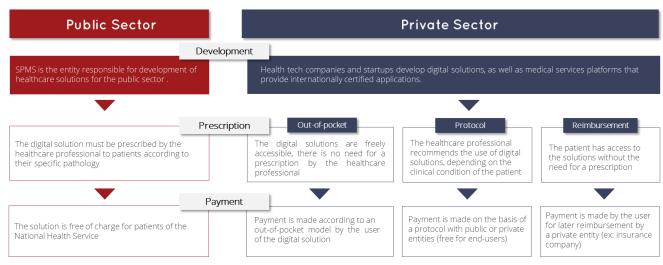


Figure 14 - Private and public processes for developing, prescribing and paying digital solutions. Adapted from Health Cluster Portugal [32].

The maturity of prescription and payment models for digital health solutions in Europe differs between countries, and Portugal is at an early stage of implementation [32]. To maximise the impact of digital technologies on the healthcare ecosystem, the following steps still need to be taken:

- Conceptualisation and development of new models for efficient integration in the health ecosystem of new digital technologies;
- Formalisation and adoption of efficient prescription and payment models (including reimbursement) of digital health solutions:
- Introduction of data protection mechanisms and compliance rules to increase patient trust in digital applications.

Figure 15 presents an international benchmark comparing the prescription and payment mechanisms in European countries. Currently, only one digital solution can be prescribed and reimbursed in Portugal, which is the Telemonit SNS 24 mobile app mentioned above. However, several solutions are under development, and some mechanisms are already being used by patients in the private sector, for example, in mental health, with devices that collect parameters from the user and suggest the doctor's intervention [54].

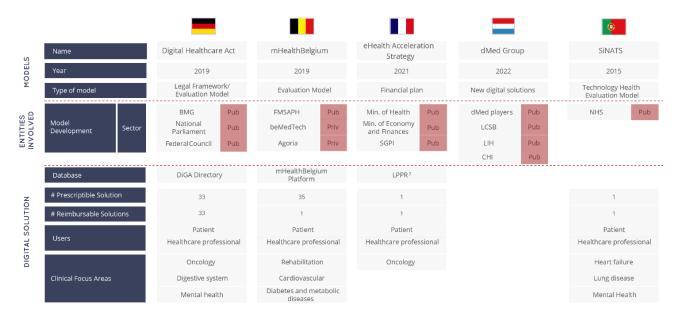


Figure 15 – International benchmark. Comparison of prescription and payment mechanisms in different European countries. Adapted from Health Cluster Portugal [32].

# 3.5. Public Tendering

There are different types of public procurement procedures that can be consulted on the ePortugal.gov.pt portal. In particular, public tender is a competitive procedure that must be advertised by institutional channels (see section 4.2). Several factors prevent an economic operator from bidding for public tenders, namely, not being in good standing concerning Social Security contributions and the taxes payment [55].

Regarding submitting bids to public tenders, they must be submitted through a set of public sector procurement websites, such as IMPIC. The proposal is considered to be submitted when the bidder completes the submission process, and when submitted on an electronic platform, it must be signed with a qualified digital signature. More information about the documents requested from the bidders can be consulted at ePortugal.gov.pt [55].

When regarding purchases for hospitals under the NHS are centralised at the SPMS, which advertises and opens official tenders. There is a pre-selection process among the competing companies before the open bid. During pre-

selection, the bidding vendors submit a proposal with the product description and their quote to the hospital. After accessing the proposals, the hospital elects the best fit. Typically, private hospitals do not use tenders and select their suppliers from whom they make direct purchases. Non-EU and US companies need to have either a Portuguese distributor or their branch in Portugal to participate in official tenders, seek market opportunities and provide the after-sales service and aftermarket support required by law [31].

#### 4. Investment Plans

#### 4.1. Public Investment & RRP

#### 4.1.1. Public Investment

Funding sources of the Portuguese NHS are not diverse: most funding is obtained through the governmental budget. This budget is funded primarily through direct (mainly progressive) and indirect (regressive) taxes, and represented approximately 44% and 56% of the Government's revenue, respectively, in 2020. Most of the 2021 government budget (59.3%) for the NHS has been allocated to hospitals and vertical programs (national organised programs), followed by funding directed to RHAs (37.5%) [5].

In December 2022, the Government injected over EUR 1,000 million into NHS hospitals for overdue payments to external suppliers. This financial reinforcement allowed hospital entities to end the year for the first time without accumulated debts, a historic result on the path of budgetary consolidation of the NHS. Therefore, NHS entered the new year with the largest budget ever of EUR 1.383 million [56], [57].

The list of public investments for 2023 includes the construction of new hospitals and infrastructure improvement of others. The construction of 4 central or proximity hospitals, namely Lisboa East, Seixal, Sintra or Alentejo, will begin by 2023 [58].

# 4.1.2. Recovery and Resilience Plan (RRP)

Portugal's Recovery and Resilience Plan (RRP) was adopted in June 2021. The main objective of the plan is to help Portugal become more sustainable, resilient and better prepared for the challenges and opportunities of the green and digital transitions [59].

Portugal's RRP supports the digital transition in the following areas: skills, digitalisation of education and business, and digitalisation of the public sector (general public administration, health, justice system and tax administration) [59].

- In the area of qualifications and skills, a reform aims to update the offer of courses and qualifications for vocational education and training and for lifelong learning programmes. The reform is supported by investments of EUR 666 million to modernise vocational education and training institutions;
- In the area of health sector digitalisation, there are investments of EUR 300 million to modernise the computer systems of the NHS and increase the digitalisation of medical records;
- In the area of business sector digitalisation, there are benefits from EUR 650 million to support small and medium enterprises and their workers with tailored digital skill training, coaching and support to adopt digital technologies.

On the Resilience dimension of RRP, the National Health System is one of its nine components, allocating a total investment of EUR 1.383 billion. Among its various investments (Table 4), three of them represent direct opportunities in digital health: Digital Health Transition, Digitalisation of Health in the Autonomous Region of Madeira and Digital Hospital of the Autonomous Region of Açores [60].

Table 4 - Component of National Health System and its investments. Adapted from the Ministry of Planning [60].

More responsive primary health care	EUR 467M
National Network for Integrated Continued Care and National Network for Palliative Care	EUR 205M
Conclusion of the Mental Health Reform and implementation of the Dementia Strategy	EUR 88M
Equipment of the Seixal, Sintra and Lisbon Hospitals	EUR 180M
Strengthening of the Regional Health Service of the Autonomous Region of Madeira	EUR 89M

Digital Transition in Health	EUR 300M
Digitalization of Health in the Autonomous Region of Madeira	EUR 150M
Digital Hospital in the Autonomous Region of the Azores	EUR 30M
Universal Active Life Support System	EUR 10M
	EUR 1,383M

#### 4.2. Public Tenders

Portugal government public tenders business opportunities have to be announced in institutional channels, such as the Diário da República and the Official Journal of the European Union. However, there are other addresses in which these tenders appear aggregated by sector, highlighting opportunities in health and innovation.

- Latest Portugal healthcare services tenders and bids no Global Tenders (www.globaltenders.com);
- Open applications for the RRP investments in Recuperar Portugal (recuperarportugal.gov.pt);
- National and European tenders and applications on the ANI (www.ani.pt);
- Public hospital and health tenders on the site of the ACSS (www.acss.min-saude.pt).

#### 4.3. Private Investment

### In terms of Venture Capital investments

- Venture Capital investors are always looking at healthcare startups. In 2022, there was a total VC investment of EUR 816M in startups in Portugal, in which EUR 25M were invested in healthcare startups [61];
- Figure 16 shows a list of the last rounds invested in Portuguese healthcare startups [61].

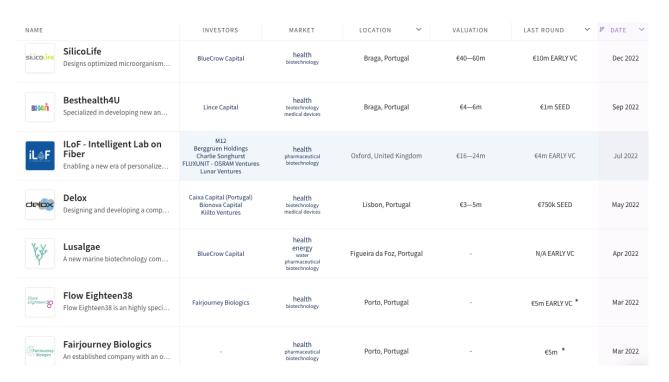


Figure 16 - Last VC investments in healthcare startups. Adapted from Startup Portugal [61].

#### In terms of education

- CUF and NOVA Medical School have established a partnership to develop the CUF Academic Centre Simulation Centre, inaugurated in 2020 at the CUF Tejo Hospital, after an investment of EUR 170 million [62];
- Luz Saúde Group and the Católica University have established a partnership to open the first medical course in a private school in 2021 [63], [64]. In this context, Luz and Católica University also created a clinical academic centre (CAC Católica Luz).

#### In terms of building new hospitals

- A new EUR 12.8M private hospital of the HCA Healthcare group is expected to open in Caminha in 2024. This new hospital will have a permanent patient service, surgical block, inpatient units and nuclear medicine [65];
- Since 2023, the Cascais Hospital (previously managed by Luz Saúde), has been managed by the Ribera Salud group, the first project in Portugal of this Spanish company, based in Valencia [66];
- In 2023, Vivalto Santé, a French company, bought Lusíadas Saúde, previously owned by US company United Healthcare [67];
- In 2022, Healthcare Activos, a Spanish real estate firm, bought 2 of the 26 hospitals and clinics operated by Luz Saúde and managed by insurance company Fidelidade [68];
- In 2021, CUF invested EUR 50 million in constructing a hospital in Leiria, with completion scheduled for 2025 [69]. In the same year, Vanguard Properties, the leading real estate developer, invested EUR 2 million to build a CUF clinic in Comporta [70]. In 2022, a CUF hospital opened in Montijo after an investment of EUR 10 million [71];
- In 2021, the new Alentejo Central Hospital in Évora began to be built, following a EUR 210 million investment in a public tender. EUR 30 million are earmarked for cutting-edge technology equipment [72].

#### 4.4.Processes & Stakeholders

As seen in the previous sections, investments in health in Portugal can be carried out by public or private stakeholders. As presented in Table 5, public stakeholders can be NHS, SPMS, Infarmed, ERS<sup>6</sup>, ACSS and ANI; and private stakeholders such as health insurers, telecom operators, IT companies or laboratories. The investment process with these entities varies according to the type of digital technology and its interest for the stakeholder itself.

Table 5 – Private and public Portuguese stakeholders for digital health.

Public	Private							
ANI	Hospitals	Telecoms	IT Companies	Laboratories				
SNS, SPMS, ERS, ACSS Public hospitals	CUF Luz Saúde Lusíadas Saúde Trofa Saúde	Altice Portugal (MEO) Vodafone NOS	Glintt NTT DATA First Solutions	Joaquim Chaves Germano de Sousa UniLabs				

Of the relevant stakeholders in the public sector, more and more NHS hospitals have established partnerships to implement technological solutions essentially for telemedicine and telemonitoring of patients. However, not as often as private hospitals due to budget limitations. ANI, the National Innovation Agency, assumes the role of an aggregator Hub

<sup>&</sup>lt;sup>6</sup> Health Regulatory Authority

for innovation in Portugal, and is supervised by the Ministries of Economy and Science. It frequently announces events, calls and incentives to boost and finance start-ups and innovation projects.

Telecoms are relevant stakeholders for solutions related to telemedicine and patient telemonitoring. Telecoms also promote awarded competitions for startups.

- NOS made a EUR 4.4 million investment in Knok, a Portuguese startup that develops integrated telemedicine solutions. The investment was in 2021, co-lead by NOS 5G Fund managed by Armilar Venture Partners and Triple Point, including Social Innovation Fund and the Mustard Seed MAZE social and environmental impact fund [73]. Altice also promotes awarded competitions for startups, such as the Altice Innovation Award;
- Altice Portugal, which is the telecom that manages the SNS24 line [74], in 2021, partnered with Centro Hospitalar Universitário Lisboa Central (CHULC) to launch a telemonitoring pilot for patients with Covid-19 sequelae [75].
- Vodafone also developed a telemedicine kit in partnership with Garcia da Horta Hospital, which allows patients to be successfully transferred from the hospital to their homes, taking a backpack with a box, a tablet, health measuring instruments and a panic button that calls directly to the hospital [76];

Laboratories are relevant stakeholders in biotech solutions, either in terms of investment or support of clinical trials and pilots. These entities had also shown interest in digitalising their processes and, to this end, partner with IT companies.

- Germano de Sousa, the largest Portuguese clinical pathology group, is a clinical trial partner of Ophiomics, a Portuguese biotech company developing new diagnostic products for liver cancer [77];
- Grupo Joaquim Chaves, in 2022, started the Cort-X project that aims to digitalise all company processes. This project is under the coordination of Deloitte and Salesforce [78];
- Unilabs has launched, in 2022, a new Al-based appointment service developed in partnership with IT company 7egend [79].

IT companies are relevant stakeholders in making beneficial partnerships to project solutions to the market.

- Glintt is an Iberian leader in the health market, investing and supporting health startups. Glintt has the Glintt Inov platform, which supports international projects, with participation in European initiatives financed by EU funds. It also promotes innovation and acceleration programmes, such as IdeaUp, created with the support of Portugal Ventures, after an investment of EUR 30K [80], [81];
- NTT DATA (ex-Everis) has the Open Innovation Contest, where they partner with some of the most promising startups and entrepreneurs worldwide to create innovative solutions for their client's business challenges [82];
- First Solutions develops many solutions for health in the consortia context. Transparent Artificial Medical Intelligence (TAMI) project, developed in consortium with INESCT TEC, Fraunhofer Portugal Research Association and the Regional Health Administration of the North, and with the participation of researchers from Carnegie Mellon University. TAMI is a platform that uses AI to provide medical exam results and explain how the results were achieved. This project was co-funded by the COMPETE 2020 European programme [83].

# 4.5. Special Projects

There are also other projects and incentives in which startups and international projects can participate and which are beneficial for their arrival in the Portuguese market.

An example is the Test Beds initiative, which provide infrastructure and equipment to SMEs and startups through entities that can provide these services. These services aim to increase the number of commercially viable product pilots, shortening their innovation cycle, particularly in the transition from laboratory validation (TRL 4) to the commercialisation phase (TRL 9). Technological Free Zones (ZLT) are a good choice for technologies that need specific and adapted regulatory regimes. ZLT are a "safe space" in which companies can test innovative products, services, business models, and delivery mechanisms without immediately incurring all the normal regulatory consequences. The Digital Innovation Hubs are also spaces where SMEs and Public Administrations can test and validate digital solutions proposed by startups or other SMEs before investing in them and adopting them to their business. These initiatives are run by ANI, the National Agency for Innovation.

Another relevant project is Health Cluster Portugal, which creates a favourable environment for health-related activities (business, R&D, health care services), influencing relevant policy decision processes for the sector or attracting talent and foreign direct investment, for example. Members of the Health Cluster Portugal have advantages, such as access to the Health Cluster Portugal network (members, national and foreign organisations), participation in events that bring together relevant stakeholders and leaders in the sector, facilitation in applications submission, visibility, access to services in the area of intellectual property and insurance for clinical trials.

Digital Health Portugal is also a relevant society initiative that congregates a diversified network composed of founders and top managers from startups, patients associations, health services and technology providers and Ministers of Healthcare.

Projects such as HL7 Portugal are useful for software companies, consulting firms and other healthcare business stakeholders to ensure that their solutions are implemented following the best interoperability practices. HL7 Portugal members have access to valuable resources that guide them in the sustainable implementation of their solutions, as well as contacts of industry leaders where they want to operate, saving time and resources.

# 5. Potential Entry Points for Danish Companies

Regarding potential entry points for Danish companies, Filipa Fixe (Executive Director at Glintt) mentioned that "the opportunities for different players, from large telecom companies to start-ups dealing with niches in the healthcare ecosystem, are growing and will make the patient journey simpler and more empowered. To be able to enter the market, companies need to have access to end users and institutions and have a clear understanding of how they fit into the eHealth ecosystem and strategy in Portugal".

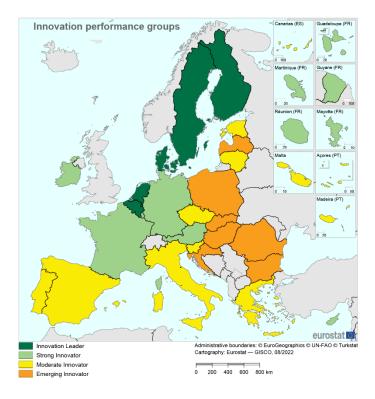
To present more potential entry points in the Portuguese market, this chapter will present the Portuguese innovation ecosystem and European funding and consortia opportunities.

# 5.1. Innovation Ecosystem

Portugal is a Moderate Innovator with a performance of 85.8% of the EU average (Figure 17), counting with more than 3.800 startups, out of which 2.500 are incubated [84], [85]. Currently, Portugal counts 7 unicorns: Feedzai, Farfetch, Anchorage Digital, OutSystems, Talkdesk, Sword Health and Remote. Only Germany and France have more unicorns than Portugal in the EU.

In terms of incentives and programs, Portugal promotes the Startup Voucher and Startup Visa.

- Startup Vouchers: Financial support for startup projects. The open call ends in February 2023 and is for startups that operate in Portugal, in green and digital areas, amounting to EUR 30,000 per beneficiary [86];
- Startup Visa: Operated through IAPMEI<sup>7</sup>, is a residence visa for entrepreneurs, which aims to attract investment, talent and innovation capacity to Portugal. It is aimed at foreign entrepreneurs, without permanent residence in the Schengen area, who wish to develop their project in Portugal, even if they have not set up a company, or entrepreneurs who already have business projects in their countries of origin and wish to carry out their activity in Portugal [85].



<sup>&</sup>lt;sup>7</sup> Agency for Competitiveness and Innovation





Figure 18 - Portuguese incubators network. Adapted from National Network of Incubators and Accelerators [88].

Among the national network of 135 incubators and accelerators, some stand out:

- Healthtech Lisboa, a Venture Builder specialised in healthtech industry founded by a small group of entrepreneurs and in a joint venture with StartUp Lisboa.
- Instituto Pedro Nunes (IPN), a private non-profit institution, which provides technological research and development, incubation and acceleration of ideas and companies and specialised training and dissemination of science and technology.
- Startup Braga, created as an innovation hub of InvestBraga, supports projects of high entrepreneurial potential with global ambitions. They work in the creation, acceleration and incubation of startups in the area of nanotechnology, health technologies and digital economy.
- UPTEC (Parque de Ciência e Tecnologia da Universidade do Porto) develops acceleration programmes for entrepreneurs and researchers and innovation programmes for large companies and municipalities. They offer spaces (office, laboratory and coworking) for companies to host their business.
- PACT (Parque do Alentejo de Ciência e Tecnologia), leader of the Regional Technology Transfer System, aims to position the Alentejo as a driving centre of innovation of global reference through the stimulation and promotion of synergies between the academic and business ecosystems.
- Biocant Park, specialised in Biotechnology, with a unique innovation environment in this sector in Portugal. Set up in Cantanhede, the park aims to promote, develop and apply advanced knowledge in life sciences, supporting highpotential business initiatives.
- UbiMedical, which has a laboratory that supports technology transfer, and comprises a set of resident laboratories coordinated by UBI faculty members in the areas of health and life sciences. Its incubator welcomes entrepreneurs and innovative companies in the same areas.

## 5.1.1. Acceleration Programs

Several innovation and acceleration programmes are promoted in collaboration between various entities, such as insurers, IT companies and (mainly private) hospitals, and often receive international startups.

- Protechting, an international open innovation program that connects top startups in the areas of healthtech and insurtech with successful global companies such as Fosun, Fidelidade, and Hospital da Luz Learning Health.
- Techcare, a Novartis startup program run in Lisboa in partnership with Deloitte Digital and Beta-i, with a one-week bootcamp with Novartis professionals and the possibility of running a pilot with the best solutions to reimagine the future in the healthcare ecosystem. Designed for teams working on MVPs or in testing phases in the area of Cloud Health, mHealth, healthcare gamification, AI, IoT, Big data and analytics, AR/VR.
- Maze, an accelerator programme based in Lisboa for startups that want to become unicorns. It is 3-months long
  followed by 6-months of ongoing support and includes an equity-free cash stipend to help through participants' stay.
   It counts with the support of some entities as Fundação Calouste Gulbenkian, BNP Paribas, Hospital Luz Saúde
  Learning Health, Caso do Impacto and Microsoft.

# 5.1.2. Hospitals Innovation Departments

Private hospitals are the most mature and receptive to innovation, seeking to promote programmes that bring digital technology closer to healthcare (see section 2.3).

For instance, CUF promotes Grow Health, which aims to connect startups, researchers and students with medical doctors and other healthcare professionals in order to validate and test their solutions. Startups will develop their solutions faster and boost their launch by gaining access to real life market feedback. Grow Health looks for digital solutions in mental health, comprehensive virtual care experience, innovative solutions in the dental medicine market and solutions to improve customer experience in home care and hospitalisation.

Most public hospitals do not have an innovation department - but APAH (Hospital Managers Association) and other entities are working on this. Centro Hospitalar e Universitário de Coimbra (CHUC) and Centro Hospitalar e Universitário do Porto (CHUP) are two examples of hospitals that invest on innovation.

CHUC stands out for its Innovation and Development Unit (UID), which supports the hospital's board of directors in defining innovation, development and research policies. With an emphasis on innovation, the UID identifies the needs of users and professionals, and promotes the development of internal solutions and/or through partner entities, protecting innovative technologies generated at CHUC that may be patented. The results of innovation have an impact on the provision of services [89].

In 2022, the CHUP launched the Digital Health Laboratory, a pioneer in developing digital health solutions that may be replicated in other hospitals. They have highlighted teleconsultation, telemonitoring and telerehabilitation projects using Mobile Apps, Web and voicebots. Among the laboratory's partners, there are Microsoft, Roche, Vodafone, Ascom and UpHill [90].

#### 5.1.3. Research Institutes

There are 38 universities in Portugal and over 30 research institutes with different specialisations. The more active ones are presented following.

- CINTESIS Health Technologies and Services Research Centre is a large R&D unit, in Porto, whose mission is to find answers to specific health problems.
- i3S is an Institute for Research and Innovation in Health that merges research intitutions, schools and hospitals (CH S. João, CHPO and IPO) from Porto, which is unique in Portugal.

- Fundação Champalimaud\_is located in Lisboa and integrates research and clinical operations under Champalimaud Research (CR) and the Champalimaud Clinical Centre (CCC). The CR aims to perform world-leading fundamental and translational research and hosts programmes that explore the core research areas of the Foundation: neuroscience, physiology and cancer.
- INESC TEC has 13 R&D centres spread across Porto, Braga and Vila Real. Among several domains, the institution has a research centre in Biomedical Engineering developing activity in bio-instrumentation and biomedical imaging. INESC TEC promotes strategic partnerships with clinical partners, research institutes, and fosters international cooperation.
- Institute of Molecular Medicine (iMM) a leading biomedical research institute associated with the University of Lisboa. IMM is devoted to human genome research and engages in competitive international funding.
- Centre for Neuroscience and Cell Biology (CNC) is a scientific institute at the University of Coimbra that fosters biomedical research in biomedicine and biotechnology. CNC has partnerships with the Clinical Faculty and the pharmaceutical industry, and is a founding partner of the Biotechnology Innovation Centre (Biocant) and Health Cluster Portugal. In parallel, CNC trains new researchers and collaborates with international universities.
- Life and Health Sciences Research Institute (ICVS) is an R&D unit incorporated in the School of Medicine of Minho University. The ICVS integrates the ICVS/3B's Associate Laboratory, which results from a partnership with the 3B's Group and is a member of the Clinical Academic Centre Braga, Association (2CABraga).

Table 6 - Portuguese research institutes.

Drug formulation	Biomedical Research	CDMO	Medical Device & Automation	Biomedical Simulation Centres
Hovione	I3S	Genibet	IPN	CUF
Hikma	Champalimaud	Stemmatters	Cintesis	Luz Saúde
iMM	Foundation		INEGI	FMUP
	CNC		INESC TEC	2CABraga
	ICVS			

# 5.2. European Funding & Consortia

# 5.2.1. Programs and Initiatives

- EIT Health is a program funded by the European Commission EIT (Europe Institute for Technology and Innovation). EIT Health Bridgehead is a programme that combines European health entrepreneurs who want to grow their business beyond their home market with the world's top incubators and accelerators (catalysers). As a matter of fact, LabToMarket is a partner with catalyser TecLabs, which supports startups from other countries to reach the Portuguese market.
- EIC (European Innovation Council) promotes projects that provide coaches, mentors and expertise, partnering opportunities with corporates, investors and others, and other services and events. The EIC 2023 work programme opens funding opportunities worth over EUR 1.6 billion for breakthrough innovators to scale up and create new markets
- Horizon Europe is the EU's key funding programme for research and innovation, with a budget of EUR 95.5 billion until 2027. The programme supports innovations with potential breakthrough and disruptive nature with scale-up potential that may be too risky for private investors. This is 70% of the budget earmarked for SMEs. Generally, historically, many Portuguese startups, biotechs and research centres, participate in these programs and are available for partnering up in specific consortia. In the last meeting (January 20th, 2023) almost 100 entities participated.

#### 5.2.2. Research Partnerships

Most of our research is funded by EU funds and grants. Therefore, most innovation is done in collaboration between university/research centres and hospitals - sometimes in an international consortia format. Incentives such as those mentioned above (Horizon Europe and EICs) are conducive to establishing these partnerships.

Several Portuguese research institutes are very open and interested in partnering with companies or start-ups from other countries. This is the case, for example, with INESC-TEC and CINTESIS, which carry out many research projects in collaboration with hospitals to test and validate new technologies in the area of health.

AICIB seeks to stimulate clinical research and biomedical innovation by supporting Portuguese innovation structures: Clinical Academic Centres and Clinical Research Centres. In 2021 alone, it funded 17 projects developed by the clinical research centres of the hospital health units of the health system. Projects have been awarded such as research webportal, platforms for clinical trials submission, creation of clinical research centres, hospitals mobile apps, etc [91].

#### 5.2.3. Municipalities

As mentioned in section 1.2.1, after the decentralising competencies from the RHAs to municipalities, municipalities became responsible for the management of the health centres in their respective geographical area. In this sense, several have been the initiatives promoted by municipalities.

#### Active/Healthy Ageing

- Porto4Ageing, a member of the European Partnership for Active and Healthy Ageing, is a multidisciplinary working group based at the Porto University in the areas of ageing, digital health, entrepreneurship and innovation. Porto4Ageing promotes the construction and management of national and international collaborative work networks, design and implementation of national and European research and innovation projects, training and capacity building of the population and validation and scaling of innovative solutions [92].
- Ageing@Coimbra, a member of the European Partnership for Active and Healthy Ageing, is a consortium between Coimbra City Council, the Coimbra Hospital and University Centre, the Regional Health Administration of Centro and the Instituto Pedro Nunes. The goal is to improve the lives of senior citizens in the Centro Region of Portugal through better social services and healthcare, as well as the creation of new innovative products and services and the development of new diagnostic and therapeutic tools [93].

#### Telehealth

- Lisboa promotes Lisboa 65+, a free health plan that guarantees access to health care for citizens over 65. The plan creates a 24-hour telephone hotline to ensure access to a teleconsultation or, where appropriate, to a home doctor and home delivery of medicines [94].
- Cascais created Vida Cascais, a new channel of the Cascais Municipal Council that enables its citizens to have a General and Family Medicine and Paediatrics teleconsultation within half an hour, as well as to have the medicines prescribed in these consultations delivered to their homes [95], [96].
- Torres Vedras participated in a 6-months pilot programme Assessment and Telemonitoring of Vulnerable Elderly People. Torres Vedras Municipal Council signed a protocol with Knok Healthcare to implement the pilot programme in 15 private social solidarity institutions in the municipality [97].
- Sernancelhe, a council in Douro Sul, is home to Aldeias Humanitar, a project that provide free intervention in health and social care of inland communities of Portugal. At the beginning of 2023, Knok Healtcare started a pilot project for assessing and telemonitoring elderly people living in the remote southern Douro region with the support of NOS telecom (implementing 5G capacity) [98], [99].

#### 6. Final Conclusions

Portugal is definitely an attractive market to bring digital health solutions to its population. Albeit its market size, it can bridge to an overall market of 250 million Portuguese-speaking people in geographies across the globe and a gateway to its neighbouring country, Spain. Internet connectivity, quality of life, talented and multilingual labour, competitive costs and a thriving entrepreneurial and innovative ecosystem are all advantages that many companies (from multinationals to SMEs) have recently discovered and have been moving operations into Portugal.

Focusing on the healthcare market, being one of the most well-functioning, robust and efficient healthcare systems in the world, it has its downsides as (sometimes) obsolete technological hardware, little investment in innovation and digitalisation and a very hierarchical structure with old-school management policies.

However, the pandemic created an overall push and forced everyone to adopt (and accept) a digital mindset and technological usage, from hospital managers to clinicians and, of course, patients. This has created a common acceptance into discovering innovations, understanding digital technicalities and working (and integrating) with several vendors and providers, looking at the solutions as a general response to a common goal or problem to solve. Moreover, having more and more patients at the centre has enabled a wide focus on implementing value-based healthcare metrics and quality-of-care indicators.

This new state of mind has opened doors to collaborating with startups, research centres that have numerous cutting-edge technologies, and other healthcare units but also partnering up with foreign entities in other to share knowledge, expertise and results. There is a true sense that the healthcare market will only overcome its existing challenges and provide care to this new context of society and ageing population, many with chronic diseases, by learning from the best, collaborating beyond borders and relying on existing (and future) technology to achieve the expected results. But also by thinking outside the box and looking at other ways, such as the new role of municipalities in providing care to their local population and using telemonitoring solutions for constant proximity care, just like what we see happening in many nordic countries in Europe.

Strengths	Weaknesses
<ul> <li>Ecosystem</li> <li>Use of English language bridge to a market of 250 million people;</li> <li>Innovative and entrepreneurial ecosystem, ready for cooperation opportunities.</li> <li>Friendly and attractive market, social and business-wise.</li> <li>Service Delivery</li> <li>Extensive primary care network throughout the country [4];</li> <li>Private sector supply is complementary to the NHS, with a flexible supply [4];</li> <li>Adherence</li> <li>Strong know-how and expertise in digital solutions and its challenges (such as interoperability);</li> <li>Openness for digital and innovative solutions;</li> <li>Openness for partnerships and collaboration beyond borders.</li> </ul>	<ul> <li>Technologies</li> <li>Little evaluation of health technologies other than medicine [5];</li> <li>Financial risk related to health technology innovation [5];</li> <li>Ageing healthcare professionals, not very digital savvy.</li> <li>Governance</li> <li>Challenges in implementing health in all and inter-sectoral policies [5];</li> <li>Lack of interconnectedness among independent health institutions [5];</li> <li>Bureaucracy and hierarchically-heavy structures: long sales cycle and approval process.</li> </ul>
Opportunities	Threats
<ul> <li>Technologies</li> <li>New data integration initiatives enabling higher efficiency in care delivery [5];</li> <li>There are prospects for advanced digital solutions to integrate with healthcare and telemedicine devices, teletriage, teleconsultation, and telemonitoring systems [31];</li> </ul>	<ul> <li>Financing</li> <li>Systematic budget deficits and debt creation in NHS driving a form of retrospective financing [4];</li> <li>Chronic low investment in equipment, digitalisation and professionals [4];</li> <li>Excessive average time for paying NHS suppliers [4].</li> </ul> Governance
<ul> <li>Ecosystem</li> <li>Local structures and knowledge to support regulatory sandboxes, proof of concept and validation as: Test Beds, Technological Free Zone and Digital Innovation Hubs;</li> <li>New stakeholders are coming into the equation to provide care, such as municipalities.</li> </ul>	<ul> <li>Non-clear or defined yet reimbursement schemes for digital health.</li> <li>Some still have an old-school mentality as a barrier to break.</li> </ul>
Financing	

Open tenders related to RRP investments (see section 4.2).

#### 6.2. Recommendations

From a pragmatic perspective, the recommendations from LabToMarket would be:

- 1. Identify both private and public hospitals working in the same area (clinical or process) that your solution is focused on, and understand to what stage the entity has developed solutions or been involved in projects for this need.
- 2. Identify the Key Opinion Leaders and Innovation 'champions' willing to test new technologies and will push for an experiment, collaboration or pilot with your solution.
- 3. In terms of market opportunities, invest in solutions that meet challenges regarding to<sup>8</sup>: prevention and wellness; longevity and chronic diseases; mental health and neurodegenerative diseases; shortages in human resources (doctors, nurses and other health professionals).
- 4. Spend time locally to understand your stakeholders' needs in a more detailed way and create a relationship with these future clients. It is cultural.
- 5. Identify potential local partners who could help identify these stakeholders, coordinate a pilot with a care unit and provide technical support in commercialising your solution in the local market.
- 6. Partner up with a telecom or health IT company and enter market opportunities, namely in the public sector.
- 7. Another option could also be to participate in acceleration programs and/or get in touch with hospital innovation departments that could provide this information and mentor your journey into the Portuguese healthcare market.

Specifically, if you are:

- A **Startup**: look for R&D and piloting opportunities in the public sector by identifiying the centres that work in the same field as your technology. Also, getting in touch with the private hospitals' innovation departments, applying to acceleration programs and through EIT Health the startup can get introduced to key opinion leaders (both clinical and business wise) and get mentorship on how to enter the market, leading to concrete opportunities and potential deals.
- An **SME**: link up with bigger players such as Telecoms and Health IT companies to penetrate the market, specially the public sector. For private opportunities, associating with Health Cluster Portugal or Digital Health Portugal, showing your solutions at local events and tradeshows and starting a relationship with the private players would be the best option.
- An established **Health IT company**: partner up with big think tanks such as Forum Hospital do Futuro or Forum Saude XXI, getting in touch with C-suite members of private groups and political decision-makers. Bringing an expert team to show the evidence of your solutions and how the private group, for its full hospital base, could benefit from your solution. A tactical 'roadshow' could be profitable and impactful in the market.

 $<sup>^{\</sup>rm 8}$  Regarding Patrícia Loureiro (Digital Health Manager at CUF) interview.

#### **Appendices**

#### A. Interviews

#### Filipa Fixe, Executive Director at Glintt

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#### 1. How would you characterise the current state of digital health in Portugal?

Portugal has a good dimension to be a showcase in the digital health space, including biotechnology and medtech. Human resources and the innovation landscape are also assets that can be applied to define the future roadmap of health and wellness in the digital world. To achieve this, it is important to define a reference architecture for ICT, for processes and governance with the right and coherent business model, a business model that delivers economic and social value.

Today, Portugal needs to have a focus on citizens that will only be possible through data interoperability and measurement of results, leveraging the most appropriate technologies and well-defined strategies and processes. Change management is more important than technological disruption.

### 2. What opportunities do you see in the digital health market? In particular, for international private companies and startups that want to enter the market?

To have a complete eHealth ecosystem, digital must come first and the citizen/patient must be the point -of-care. Hospitals will become "hospital-homes".

Thus, the opportunities for different players, from large telecom companies to start-ups dealing with niches in the healthcare ecosystem, are growing and will make the patient journey simpler and more empowered. To be able to enter the market, companies need to have access to end users and institutions and have a clear understanding of how they fit into the eHealth ecosystem and strategy in Portugal. Public and private healthcare institutions need to have their innovation departments with the capacity to invest, test, learn and adapt in order to move from start-ups to SMEs to large healthcare/tech companies. This is critical for the future of healthcare and for the future of Portugal: having a core of leading healthcare tools, solutions and resources that can co-create and deliver the most innovative healthcare solutions for all citizens with equity, transparency, and sustainability.

#### Patrícia Patrício, Knowledge and Intelligence Manager at Health Cluster Portugal

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#### 1. How would you characterise the current state of digital health in Portugal?

Portugal has a strong and well-articulated national health service (NHS) with universal access, since 1979, with pioneer digital solutions implemented, highly qualified human resources and top notch R&D. It is a modern, technologically advanced NHS, with the first national electronic health record being implemented in 2012, and an electronic medical prescription service in place since 2016. Portugal has currently 240 hospitals [100] of which more than 50% are private. In the private sector, there are as many as 3 hospitals with Electronic Medical Record Adoption Model (EMRAM) stage 7, by HIMSS Analytics.

Regarding the entrepreneurial ecosystem of Digital Health in Portugal, a recent study from the Health Cluster Portugal, estimates that there are more than 160 companies, mostly SMEs, working on this segment [8]. These are young companies (the majority were founded after 2012<sup>9</sup>), dedicated to activities that include software development, medical devices and IVD, with a strong focus on software development (>60%) [100]. Moreover, most of these companies have private and public hospitals as their main clients [100].

There are around 50 institutions dedicated to R&D and innovation in the fields of Digital and Smart Health in Portugal. These include academic and non-academic research institutes, and also CoLabs and technological interface centres, which serve as links between academic institutions and companies in the valorization of products and services, and technology transfer.

Over the next 3 years, the Portuguese digital health ecosystem is expected to see great developments, with two major contributing projects funded by the Recovery and Resilience Plan. One encompasses an investment of 300 million euros for the digital transition of the public Health sector, and the other, promoted by Health Cluster Portugal together with 90+ of its members, has a 90 million euros investment to promote the digital transformation of the health sector in 4 main verticals: Smart health solutions, value-based healthcare, secondary use of data and clinical studies.

# 2. What opportunities do you see in the digital health market? In particular, for international private companies and startups that want to enter the market?

The Portuguese health ecosystem presents several characteristics that make it a nice place to test and pilot health solutions. These include the size of the country, the good articulation between the private and the public healthcare sectors, and also between the R&D institutions and the companies.

Specifically, there are important opportunities regarding the testing and validation of new solutions in Portugal. For instance, in 2021, the Portuguese government and then the European Commission approved a Digital Innovation Hub (DIH) - DigiHealthPT - exclusively dedicated to Health. This infrastructure, coordinated by the Health Cluster Portugal and run together with 6 other institutions, presents a great opportunity for companies to develop their digital solutions in the country, at discounted prices. Moreover, Portugal (via the involvement of 6 public and private institutions) is part of the Testing and Experimentation Facilities (TEF) Health, a European initiative under the Digital Europe Programme for piloting novel solutions in Al and robotics, coordinated by Charité Berlin.

The collaboration of Portugal, through the Health Cluster Portugal, in the Scanbalt metacluster, namely to promote the dialogue and the inclusive involvement of stakeholders in the development of a European Health Data Space (EHDS), as

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<sup>&</sup>lt;sup>9</sup> Report of the Questionnaire for Identifying and Segmenting Portuguese Companies in the eHealth Sector, AICEP 2021

well as other initiatives led by other Portuguese institutions in this domain, are also of relevance for international companies who want to enter the market.

Although, up to now, there is no formal mechanism for reimbursement/payment of digital health solutions in the country, the Health Cluster Portugal has been working closely with other member states and has recently published a Roadmap for the implementation of such models taking into account the German, the French and the Belgian examples [32].

Of note, in June 2023, Portugal will host HIMSS23 Europe, the most influential digital health conference in Europe to explore "Health that Connects + Tech that Cares".

#### About the Health Cluster Portugal:

The Health Cluster Portugal, the national competitiveness cluster dedicated to the promotion and development of the health sector in Portugal. It represents a coherent ecosystem of more than 220 members of the health value chain, including companies (medtech, pharma, biotech, services providers, consultancy, ...); R&D institutions and academia; healthcare providers including private and public hospitals), and also patients' associations, professional associations, public organisms, science and tech parks.

www.healthclusterportugal.com

www.healthportugal.com

### Patrícia Crespo Loureiro, Digital Health Manager at CUF

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#### 1. How would you characterise the current state of digital health in Portugal?

Portugal is recognized in Europe as a role model in the area of eHealth innovation. The Portuguese Health System (Public and Private) started more than 20 years ago a path in digital health, something that had very practical results in Portugal's response to the Covid-19 Pandemic and in the speed with which the necessary remote and digital services, circuits or responses were implemented.

#### In the National Health Service (Public Sector)

SPMS - Shared Services of the Ministry of Health, EPE plays a relevant and responsible role in the digital transformation of the health area. It is responsible for technological products and services for citizens, professionals and health institutions. The Portuguese National Centre of Telehealth was created according to the Resolution of the Council of Ministers (RCM) 67/2016 of October 26 and was integrated into SPMS by the Decree-Law No. 69/2017 of June 16. It acts to promote, manage and coordinate the telehealth services and initiatives and carries out Research & Development (R&D) and teletraining activities.

The CNTS mission is to "facilitate the citizens' access to health, to ensure its equity and to increase the efficiency of national resources by taking advantage of information and communication technology" (CNTS, 2018) and its vision is "Health without space and time barriers" (CNTS, 2018).

The SPMS had and has a fundamental role in the progress of these strategies both through the successful development of telehealth initiatives and the implementation of IT systems and platforms to support the health information ecosystem, of which the following stand out:

- I. The clinical registration software SClínico. It computerises and systematises clinical records in primary and hospital care. It contributes to the records standardization, in order to guarantee the normalization of the information and to increase its quality. It enables the sharing of data among health professionals in different areas, thus contributing to a more effective, efficient and coordinated performance by the health professionals at local and national levels.
- II. The Live Health Data Platform (PDS Live), as a means to perform real-time video teleconsultations with the possibility of sharing information (for example, images and medical results) in clinical context, associated with an episode of provision of care.
- III. The Electronic Health Record (EHR). It integrates the citizen's contacts into the health system and leads to a single citizen's clinical record. It allows gathering key information about each citizen that can be accessed by them, by the health professionals and by the entities providing the health services involved in their care. It enables a better management in terms of quality, safety and efficiency.
- IV. The Electronic Health Records Referral (EHR-RSE) electronic system for referral among SNS providers. Supports deferred teleconsultation based on the clinical information in digital format.
- V. Since 2013, the Medical Electronic Prescription (PEM), with the functionality Paperless Prescription, made it possible to prescribe and dispense medications electronically. It, thus, allows the citizen to receive the prescription from afar and also creates conditions for the acquisition of medication remotely. And since 2019 the mobile version of PEM is available.
- VI. The Paperless Exams project. It allows the dematerialisation of the procedures for requesting, executing and billing Complementary Diagnostic and Therapeutic Means (CDTM), and ensures that their results are integrated into the RSE.

In this way, gains for the SNS in information management and efficiency are guaranteed while the convenience of the citizen and health professional is also improved.

VII. SNS 24, an omnichannel access - More than just a telephone line, SNS 24 is now an omnichannel service that allows access to a set of digital and telehealth services of the National Health Service, ensuring fairness, transparency and simplicity in access. Throughout 2022, several updates were implemented and new services were made available.

In digital, the SNS 24 app was one of the most searched for in our country, in the Health category. Consulting test results, vaccine bulletin, viewing the health agenda with upcoming events, for example, appointments, surgeries, exams, making a previously scheduled teleconsultation, or consulting medical leaves, are just some of the various services available.

The new SNS 24 portal, launched in October, is another good example of digital services. More innovative and accessible, it features a more intuitive menu, making available several SNS services and differentiated content about public health.

The SNS 24 counters facilitate access to SNS services and teleconsultations for those who need to use them remotely. There are 318 of which 195 were opened this year in parish councils, residential establishments, and prisons.

2022 represents the year with the highest number of calls to the SNS 24 Hotline ever, exceeding more than 9 million calls. The app has so far registered more than 8 million downloads and the SNS 24 Portal has counted more than 27 million users this year alone.

January was the month with the most calls of the year, close to 3.3 million, followed by May, with over 1.4 million, and February with over 1.1 million. By 2021, the Line had exceeded 6 million, and by 2020, 4 million calls had been answered.

Still at the telephone level, the Psychological Counseling Line, a proximity response in mental health, provided support to more than 191 thousand people. This year alone, it has exceeded 64 thousand calls. Since April, this service is also available in English.

The electronic prescription of medical tests in primary health care started to cover all areas in April 2022 and, since then, about 19 million electronic requisitions have been issued, of which more than 90.8% were completely dematerialized (paperless). Gastroenterological endoscopies, physical medicine and rehabilitation, pulmonology-immunoallergology and radiology are some of the areas covered, with CT and colonoscopy results available, among others.

More than 20 million medical test results have been shared digitally in the last 8 months, and can be consulted via the app and the SNS 24 website.

Digital Tools	Telehealth Services	Digital channels for citizen use SNS24	Strategic tools
ePrescription  - Drugs  - Home Respiratory Care  - Medical devices  - Exams	Teletriage Teleconsultation Telemonitoring Telediagnosis Telereabilitation Teletraining	Website Mobile app Phone line Front desk	ENESIS 2020 PENTS 2019-2022
Sympton Checker Telemonitoring app			

#### Some Milestones in the NHS

- 1998 First telemedicine projects (Paediatric Cardiology teleconsultations and between primary care units and hospital).
- 1999 Creation of a Commission for the development of Telemedicine, with several working groups being established after that.
- 2006 Specific hospital teleconsultations prices were set for the first time.
- 2008 Regional telemedicine coordinators responsible for dynamizing telemedicine in each regional health authority.
- 2013 PEM e RSE
- 2014 First telemonitoring programs payments.
- 2016 Telehealth National Centre (CNTS) was created, promoting innovation and the use of ICTs, encouraging synergies via a network that brings citizens closer to health providers. By coordinating, contributing to regulations and providing services, the CNTS supports the regular practice of telehealth at national level.
- 2017 SNS 24 NHS Contact Centre was resized to include more services (then again in 2020 to face de pandemic).
- 2019 PENTS e PEM Mobile
   2020 2021 Trace Covid, Symptom report, Vaccine schedule request, Self-test registration, Covid digital Certificate

#### Private sector

The private sector also shows a growing investment in digital health, whether in the implementation of services (teleconsultation, telemonitoring or telerehabilitation), or in dematerialization and digitalization of processes, robotics, symptom checkers, and other solutions capable of responding to remote and hybrid health care.

## 2. What opportunities do you see in the digital health market? In particular, for international private companies and startups that want to enter the market?

Three major areas of trends are identified for ehealth:

- Demographic trends
- Economic trends
- Disease Trends

Ageing, increasing life expectancy, the growing burden of chronic disease, and rising healthcare costs are taking a heavy toll on societies. The new challenges require new solutions and new approaches. EHealth needs the power of data and technology to be able to solve these problems.

Health has to become preventive, proactive, continuous, personalized, and home-centreed. Its financing has to be results-oriented and has to be based on the value it delivers to patients and society. Think about solutions outside the hospital walls, with more mobility and portability.

People, process, and technology will always be the drivers for which we must seek the best solutions. Combination of self-service tools with remote health care delivery by health professionals in hybrid or fully digital journeys.

The opportunities in the digital health market will be in the solutions that allow these challenges to be met:

- Prevention and wellness
- Longevity and chronic diseases

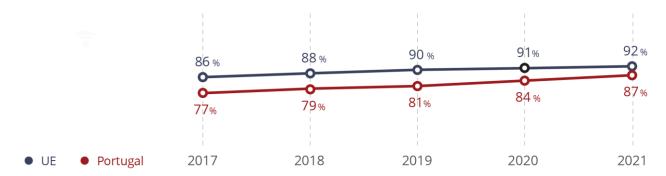
- Mental health and Neurodegenerative diseases
- Shortage of human resources in health (Doctors, Nurses and other health professionals)
- Access
- New contexts of personal and professional life (Example: Telework)
- Environmental sustainability and economic

The Recovery and Resilience Plan (PRR) will be an opportunity for the healthcare sector as it provides for an investment in the digital transition with a strong focus on data, systems for professionals, for citizens and for infrastructure.

Insurance companies are changing their positioning, becoming healthcare providers by hiring companies such as teladoc, among others.

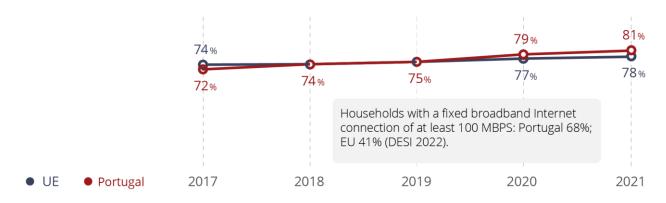
Think digital first is not a trend, it's a necessity for the scarce resources that are already being felt in healthcare and healthcare organizations have to prepare for it.

#### B. Internet Assessment in Portugal



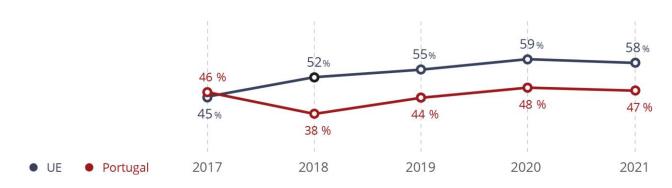
Fonte: Eurostat, Households - level of internet access

Figure 19 - Percentage of households with an Internet connection in Portugal. Adapted from ACEPI<sup>10</sup> [26].



Fonte: Eurostat, Households - type of connection to the internet

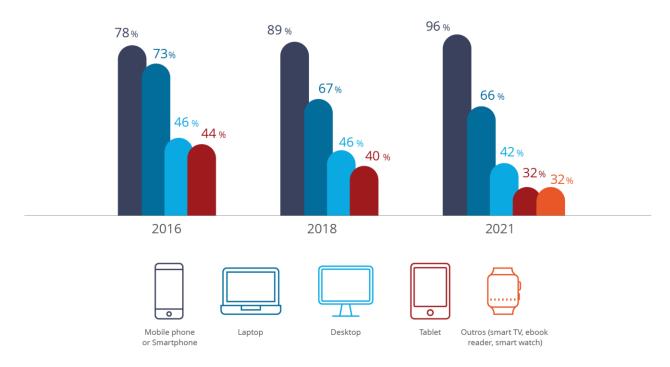
Figure 20 - Percentage of households with fixed broadband Internet connection. Adapted from ACEPI [26].



Fonte: Eurostat, Households - type of connection to the internet

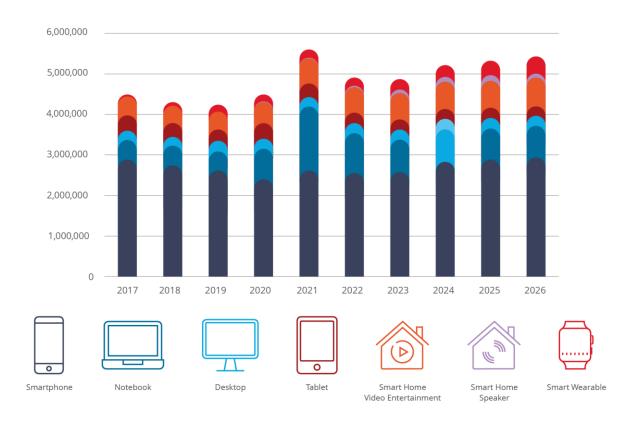
Figure 21 – Percentage of households with mobile broadband Internet connection. Adapted from ACEPI [25].

<sup>&</sup>lt;sup>10</sup> Portuguese Association for the Digital Economy



Source: Eurostat, Percentage of individuals who used internet in the last 3 months - devices used to access the Internet

Figure 22 - Percentage of devices used to access the Internet. Adapted from ACEPI [25].

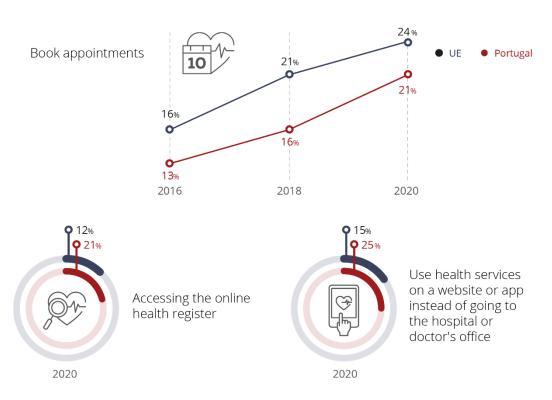


Fonte: IDC, Quarterly Device Trackers 2022 (previsão 2022 - 2026)

Figure 23 - Number of devices with Internet access sold in Portugal. Adapted from ACEPI [25].

	Aplic	ativo ①	Publisher (i)		Aplic	cativo (i)	Publisher (i)	
1	0	SNS 24	SPMS - Serviços Partilhados do Ministério da	1	SNS 24	SNS 24	SPMS-Servicos Partilhados do Ministerio da Saude, EPE	
			Saúde	2	D/	MY LUZ	Luz Saude, SA	
2		Blood Pressure Pro	Desarrollos Técnicos	3	čuf	My CUF	JOSE DE MELLO SAUDE	
	_		Beijing Xiaomi Mobile				II, S.A.	
3	0	Mi Fitness (Xiaomi Wear)	Software Co.,Ltd	4		Fitness Hut	Intelligent System Vitale S.L.	
4	113 19 19	Blood Pressure	Zhuang Weather Studio	5		Flo Period Tracker & Calendar	FLO HEALTH UK LIMITED	
5	D)	MY LUZ	Luz Saúde	6	Me.	BetterMe: Health Coaching	BetterMe Limited	
6	, Series	Blood Pressure App	QR Code Scanner.	7	7	•	myAdvanceCare	ADVANCECARE - GEST • O DE
7		Blood Pressure App Pro	Hitchhike Tech				SERVI�OS DE SA�DE, S.A.	
8	A	myAdvanceCare	Advancecare S.A.	8	iN!	Impulse - Brain Training	GMRD Apps Limited	
9	<b>©</b> 2	Blood Pressure: Heart Health	Roji Osi	9	Ris e:	Rise: Energy & Sleep Tracker	empty	
10	čuf	My CUF	CUF, S.A.	10	<b>大</b> &	MyFitnessPal: Calorie Counter	MyFitnessPal, Inc.	

Figure 24 - Top Health and Fitness apps downloaded at Google Play Store (left) and Apple App Store (right) [101].



 $Fonte: Eurostat, Percentage \ of \ individuals \ who \ used \ internet \ in \ the \ last \ 3 \ months \ - internet \ activities$ 

Figure 25 – Percentage of Internet users in health services. Adapted from ACEPI [26].



Fonte: Eurostat, Individuals' level of digital skills

Figure 26 – Percentage of people with digital skills. Adapted from ACEPI [26].

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