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THE ROADMAP TO HEALTHCARE DIGITALIZATION: FACTORS THAT AFFECT THE PORTUGUESE APPROACH TO eHEALTH

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Abstract

Healthcare systems worldwide need to improve health outcomes while reducing costs. Increasing demand for chronic disease management, such as pulmonary disease, is driving digital transformation in healthcare. The Kata® inhalation app aims to improve patients' inhalation techniques through a data-based algorithm. This study aims to classify Portugal's proneness to healthcare digitalization. Specifically, it investigates to which extent Portugal is lagging compared to digital pioneers and how it can keep up with advancements in a rapidly evolving technological world. The results suggest that Portugal is a positive example of eHealth but its main challenges are patients' low digital trust and inoperability across infrastructures and health subsystems.

Keywords: *Digital Healthcare, Digital Technologies, Telemedicine, Electronic Medical Records, eHealth, Portugal, Patient-Centered Care*

Common Part

1 Introduction

Digitalization has impacted all industries, but the health care industry is prone to lagging in integrating new technologies into operations and clinical practice. Heavily regulated and with a "first, not harm" oath. The challenge is to rapidly adopt new digital technologies while avoiding and managing incremental operational risks to healthcare organizations. The COVID-19 Pandemic diminished barriers to entry in the digital healthcare market through an urgent need for digital innovation in healthcare while showing critical disparities across healthcare systems that hinder this opportunity across the EU.

At the same time, the idealization of accessible and affordable healthcare has been driving tech innovators, financial incentives, governments, and patient demand from traditional health care services to digital solutions. Telemedicine, electronic medical records, and distance monitoring are a few examples of how technology can simplify and improve medical processes for both patients and providers. One great advantage of digital health is the empowerment of the consumer. Smartphones and apps are already integrated into the daily lives of many people. There is an app for practically everything with varying functionality, and health apps are becoming increasingly popular. The commercial providers of apps and programs that focus on users' health constantly develop new solutions. A sizeable commercial market has emerged in this area, whether for simple fitness and lifestyle applications, health diaries, or even complex programs for diagnostics and therapy. According to a survey, in 2017, the global mobile health app market had a market volume of around USD 2.4 billion. The mobile health app market forecast calculated a potential growth of about $11.2 billion by 2025 (Statista 2021). This increase in health apps can be attributed to the interest in taking control of one's health and having greater autonomy in managing one's condition.

Digital health can improve healthcare services, and technological innovations have the advantage of being widely available. However, the digital globalization of medicine is a process that is unique for every country, and the adoption of new technologies and their importance for healthcare systems is highly dependent on policies, regulations, social and cultural factors, and financial capabilities.

1.1 Objective of the thesis

The fundamental purpose of this master thesis is to clarify essential fundamentals in the jointly written part to build the following individually written parts of the thesis on elaborated terms, business models, and theoretically presented foundations. Part of the common part is to gain deeper insights into the role of digital technology in pulmonary rehabilitation and give the digital future of respiratory care with practical solutions and new business models that have emerged. Furthermore, it also includes the subject's digitalization of the healthcare sector and healthcare apps, as these are central to the thesis. One of the main objectives of the common part is to create a theoretical foundation of respiratory diseases and adequately introduce the Kata® App and elaborate on its market.

1.2 Structure of the thesis

After the introduction, consisting objective of the thesis (1.1.) and the structure of the thesis (1.2.), the current state of digitalization in healthcare in Europe and the world is illustrated (2.). It is important to emphasize that particular attention is paid to the European Commission, EIT 2020, and the World Health Organization (WHO). The central constituent part starts in chapter 3 with the theoretical foundation of respiratory diseases. The chapter begins with the definition of chronic respiratory diseases to understand respiratory diseases. Afterward, Chronic respiratory diseases (CRD) are brought into a global context, followed by their reasons and drivers. The subsequent section about the Inhalation therapy section is primarily based on Haidl (2018) and Ingelbo and Wildhaber (2013). Building on the inhalation therapy, the theoretical part focuses on the inhalation device types and their requirements. To give a chronological background for health apps, the story of transition to health app is presented and is followed by 4.2. well-being services for the work, and 4.2. a comparison of medical and well-being usage. Finally, the fourth chapter picks up from the first part of the thesis- digitalization in healthcare- and focuses mainly on the drivers of digitalization in healthcare which are primarily due to digital health, 3D printing technology, Artificial Intelligence, Big Data, and Point-of-care-testing (Chawla 2020 and Kraus et al. 2021). The fifth chapter covers digital health tools and respiratory applications. The more extensive possibilities for digital developments in the respiratory field are listed based on the previous chapters. First, the role of digital technology in pulmonary rehabilitation is defined. Afterward, acceptance and academic outcomes of digital technologies in respiratory diseases are discussed. Finally, an outlook on the future of digital treatment is given. This includes closer monitoring of conditions and symptoms, empowering chronic patients, and avoiding triggers that worsen clinical conditions (Abrashkin et al. 2018). Chapter six describes the business model of the Kata® app. The health app Kata® enables more effective use of inhalers, helping patients improve their treatment, become more stable, and increase their quality of life (Kata 2021).

First, the problem that Kata® is trying to solve is discussed, followed by a detailed description of the solution of the Kata® App and in 6.3. the market for VisionHealth (VH). After explaining the need for the health app, a new opportunity is dedicated to how to distribute it: DiGA (Digital Health Applications). Selected health apps have been eligible for prescription coverage in Germany so that the statutory health insurers will refund the costs under certain conditions. DiGA is explained in more detail here and challenges that arise for apps and the Kata® app. It also compares the Kata® app to its competition and previews VH's roadmap in the end. Chapter seven discusses Apps on-prescription in Europe, the opportunities of digitalization in medical diagnosis, treatment, and education, obstacles for mHealth Implementation and AI (Artificial in medical science has significantly increased life expectancy worldwide. However, as longevity increases Intelligence) value, and revisiting patient trust in AI digital healthcare applications.

2 The future of healthcare systems

Progress, healthcare systems face increasing demand, patients develop more complex needs, with increased costs, and qualified human resources are scarce in health organizations. (Haynes 2014). Thus, some strategic objectives demand alignment among health organizations in the EU: Pan-European optimization of performance and quality of health workforces on human resources for health; aligning investment in human resources for health with the needs of the population and of healthcare systems; to build standardized capacities at national and European levels, in public regulation, leadership and governance of human resources and technology applications in healthcare; and to increase trust across health organizations and patients in the EU health network (EIT Health 2021).

2.1 Digital innovation in healthcare and chronic disease burden

Non-communicable diseases alone amount to 80% of health care costs in the EU (Horizon Europe 2021, Cauchi 2016). To tackle this, capable health professionals are required, but so are competent professional health managers, scientists, innovators, planners, and policymakers. Political commitment and effective regulation at national and European levels are necessary for effective national and EU level strategies targeted at health workforce challenges. However, some human resources for health management issues are transnational and require international commitments and trust, namely: creating and sharing global evidence; assurance of the availability and effectiveness of technical and financial assistance across the EU health network. For example, poor adherence to treatment recommendations for chronic disease management is a worldwide health problem, as even developed countries average a 50% adherence rate to long term treatment recommendations (Sabaté 2003). Poor adherence to long-term therapies deteriorates public health outcomes and increases healthcare costs by severely compromises the effectiveness of treatment. It is thus a critical issue in population health both from the perspective of quality of life and health economics (Haynes 2002). It is important to note that interventions to improve adherence bear a return on investment (ROI) through primary prevention and secondary prevention of adverse health outcomes. The negative impact of poor adherence grows as the burden of chronic disease increases and as populations become older in the EU. Studies consistently find significant cost-savings and increases in the effectiveness of health interventions attributable to low-cost interventions for improving adherence. Without a system that addresses the social and cultural determinants of adherence, advances in biomedical technology will fail to realize their potential in reducing the burden of chronic illness. Access to medications is necessary but insufficient for the successful treatment of disease as patient-tailored interventions are required (GE Healthcare 2020).

Consequently, interventions targeting adherence must be tailored to the illness-related demands experienced by the patient. To accomplish this, health systems and providers need to develop a means of accurately assessing compliance and those factors that influence it (Navarro 2014). The creation and agile adoption of patient-centred health care approaches are required, considering the very specific needs of patients and the opportunities offered by new tools, technologies, and digital solutions. A reliable, secure, and competitive European system of health care service developers, suppliers, and providers, or a strong and trustful European health network is needed.

The Digital Europe Programme will provide strategic funding to answer these challenges, supporting projects in five key capacity areas: supercomputing, AI cybersecurity, advanced digital skills, and ensuring a wide use of digital technologies across the economy and society. With a planned overall budget of €7.5 billion, it aims to accelerate the economic recovery and shape the digital transformation of Europe's society and economy, bringing benefits to everyone but strategically minded for Small and Medium Enterprises (SMEs) (European Commission 2021). Research and innovation will be instrumental in developing these innovative approaches and increasing the knowledge, understanding, and expertise that underpin innovation in healthcare practice in preventing, treating, curing, and recovering from diseases. Digital technologies and health data are already drivers of value co-creation in healthcare networks, but current applications still lack in scale and applicability across the European health network. Likewise, cooperation with sectors in healthcare settings will drive innovation and align towards EU’s strategic goals of unlocking the full potential of new digital tools and reducing disease burden across populations (EIT Health 2021).

2.2 The crucial role of European SMEs in digital healthcare innovation

European SME's and tech firms developing innovative health services have focused primarily on enabling tech for health providers, or software that optimizes health provider’s daily tasks via software business process tools. Second are screening and diagnostics digital applications, such as image recognition AI, a promising area for AI integration. Last is software used for drug discovery, clinical trials and providing secure access to patient health (Faltin 2021). Most health systems today are at the beginning of the journey. Most countries still use a mix of paper based and digital health records for primary care. This inconsistency means that Health records are available only to the health provider network that created and are not routinely used in the context of machine learning by other organizations in different settings or systems (Tapscott

2020). While policies are available for many conditions and settings, they require periodic reviews from teams of experts and are not linked to decision-support tools leveraging the maximum amount of data, as they historically rely on the outcomes of clinical trials for updating clinical practice (Colclough 2018). HCPs end up relying on their experience, and judgment to make decisions for individual patients. This is increasingly the case for managing aging populations and their intensive needs.

AI and automation can handle the interdependency of the EU healthcare network, impacting the health of populations by targeting improvements in individual patient outcomes through a competitive environment of digital healthcare applications available across different healthcare systems (EIT 2019). The consensus among healthcare leaders, AI companies, and investors is that the prospect of AI in healthcare is significant (Vanlare 2018). Addressing the need for more efficient healthcare delivery and services in the many healthcare systems in the EU. Healthcare delivery and services can be transformed, currently administrative or repetitive tasks can take up to 70% of HCPs actual work hours. AI applications can reduce time spent on these tasks while improving the speed, accuracy of prognostics as well as improving and monitoring adherence to therapy or medication recommendations. Organizations leveraging this technology can create technological capabilities across healthcare networks to proactively meet patient's needs and allocating financial and human resources to the most impactful activities (Bajwa 2021).

3 Artificial Intelligence, clinical decision making, patient monitoring, and Data Science

"Healthcare leaders today can steer the next wave of progress by harnessing advances in data science to generate valuable insights from the large, complex data sets accruing in health systems." (Colclough 2018).

The technological capabilities to efficiently transform operations in health organizations and clinical decision making at different stages of development across the EU health network and have initially been met with scepticism by HCPs and health organizations. But, increasing volumes and quality of health data in an increasingly interconnected health network, as well as advances in cloud computing technology and Data Science applied to healthcare, are strong enabling factors for a wave of innovative applications across EU's healthcare systems.

3.1 Regulation's role in AI's adoption into European healthcare systems and services

Some areas demand guidance and aligned action across the EU to effectively adopt AI into healthcare systems across all member states homogeneously: increase the robustness and security of storage, exchanges, and processing of patient Health Data; guidance on data management procedures, standards, and governance; guidance on regulation and risk assessment of AI applications in healthcare (EIT Health Germany 2020).

Lacking regulatory efforts would open the way to unsafe developments and excessive regulation would represent a considerable opportunity cost to European Healthcare Systems through an ineffective rollout of these technologies (Ferguson 2021). Collaboration between innovators and clinicians in achieving user-centred design, close cooperation between developers and practitioners from the clinical sector is crucial to producing AI solutions that have real practical benefits. Currently, developers, start-ups, and innovative think tanks have limited involvement in establishing national digitization concepts as high-risk AI applications still miss clear compliance benchmarks to ensure legal certainty among stakeholders (Colclough 2018). Cooperation of relevant national authorities across the EU is necessary to ensure convergence of technological capacities of different member states, and to establish standards in testing and verifying AI empowered health services. (European Commission 2018). This is an especially favourable opportunity for Europe with very mature B2B industry applications but weak consumer platforms. Europe can combine its' industrial technological capabilities with a high-quality digital infrastructure and regulatory framework based on its strong and shared fundamental values, to become a global leader in digital healthcare applications. The European Commission identified funding an impediment to integrating AI applications into healthcare organizations and practice. Noting the importance of recognizing Return on Investment (ROI) as complex in these projects as they are not necessarily revenue generating. The need for new financial models focused on outcomes-based and value-based healthcare reimbursement was universally agreed upon. Empirical data shows that North America dominates the AI market, and Europe lagging so far (Scalia 2017). Pioneering regulation will set the ground for the innovation of digital applications using AI or machine learning in healthcare.

At the forefront of Europe is Germany, with the Digital Healthcare Care Act (DVG) aimed at catalysing the digital transformation of the German healthcare system. Its timely introduction will differentiate Germany from Europe in adopting and disseminating digital technologies to improve patient outcomes. "Prescribable" Applications software, SaaS, mobile, and browser applications under a central registry of vetted apps that HCPs can prescribe and are reimbursed by Germany's statutory health insurance providers, covering around 90% of the population or 73 million individuals (Ariel 2020). Current clinical trial methodologies, for example, are often based on subjective clinical scoring systems, which fail in providing an accurate and updated record of a patient's condition. It is possible to tackle this problem by identifying, validating, and integrating emerging technologies that could reliably and securely measure patients' clinical conditions in real time (European Commission 2019). Governments, private insurers, and tech companies are incentivized to subsidize these devices and proliferate their use (Ghose 2021). The German Digital Healthcare Act for example, (DVG) provides an innovative and flexible regulatory approach that provides a fostering environment for organizations developing digital health tools can deploy innovative and value-based pricing strategies as they co-develop digital health applications into clinical practice and patient's therapy and medication recommendations. Entry to this new market is strict, requiring incumbents to fulfil the data protection, security, and interoperability standards of the GDPR, while showing preliminary evidence on the service's benefits to patients to auditing authorities. These applications will create a be references on how digital tools for remote patient care work in practice (FIDMD 2021). Findings that mobile, wearable devices, and apps lead patients to change their behaviours positively provide patients and care providers and insurers with opportunities and new potential business models. In the long term, digital apps' prices will be determined by their clinical performance, leveraging real-world evidence derived from real-world health data as a crucial factor to demonstrate digital health tools' effectiveness. Germany's approach can be a model for other European Health Care Systems focusing on integrating digital innovation into their systems, processes, and workflows (Gerke 2020).

3.2 The role of co-development and trust in EU's healthcare digital innovation

When AI systems are introduced into the German healthcare system, the impetus for technical innovations comes primarily from research and industry, including small start-ups. To date, clinical leadership in hospitals has not been well represented. AI's impact in this area and the goals that can be achieved have not yet been defined, in part due to the diversity of AI applications. In Germany, expansion of the digital infrastructure has been underway for several years, although without the broad involvement of patients. This omission, which is crucial in data protection law since patients must actively consent to their health data being passed on, needs to be solved. The aim should be for patients to develop into digitally competent administrators of their data and make individual decisions about its use in the context of AI applications in each case (Stern 2020). However, despite their criticality for hospitals and the optimal functionality of care systems, these technologies also raise concerns for the privacy of sensitive health data due to their high connectivity. Four main clusters of stakeholders exist in the health data value chain: healthcare providers, patients, research organizations, and medical device and drug manufacturers (Gnúbila 2019). While patients and hospitals share heterogeneous and sensitive datasets in the network, research organizations and industries need streamlined and homogeneous ways to access, filter and search these datasets (Jeffreys 2018). A significant barrier for emerging technologies in healthcare is the lack of trust seen from the end-users. Patients are seen to lack trust AI applications in healthcare, holding an assumption that AI fails to accommodate their unique medical needs and performs worse than human providers, as well as recognizing a lack of accountability in AI decision-making errors. This resistance to AI healthcare is a challenge to both policymakers and organizations aiming to co-develop innovative health services across medical systems in the EU (Longoni 2021).

3.3 The imperative of trust in the adoption of AI in EU's healthcare systems

To promote the development and adoption of AI technologies in the healthcare sector, the European Commission and healthcare organizations in the EU should address the challenges related to policy and trust. Supporting the further development and adoption of AI in healthcare by increasing investment; enabling the access, use, and exchange of healthcare data; developing initiatives to upskill healthcare professionals; and educating AI Developers on current clinical practices. Addressing cultural issues impacting trust in AI in healthcare by aligning national and EU level policy regarding the collection and use of health data for research and health organizations is paramount for meeting projected public health needs in the EU by 2030 (European Commission, and PWC 2021).

4 Theoretical Foundation of Respiratory Diseases

Chronic respiratory diseases (CRD) are umbrella terms covering long-term lung diseases that affect the lungs and other parts of the respiratory system. CRDs are not curable but preventable (WHO 2021a). The big five preventable global conditions are chronic obstructive pulmonary disease (COPD), Asthma, Acute respiratory Infections, tuberculosis (TB), and lung cancer (Bousquet, Dahl, and Khaltaev 2006). However, there are more conditions in the cluster that affect fewer people. COPD and Asthma are further explained as they are most important for this paper. In COPD, the airways are constantly constricted. As a result, the alveoli are partially destroyed and overinflated, leading to breathlessness, coughing with phlegm, and tiredness due to missing oxygen. Symptoms appear from mid-life onwards caused by external factors like smoking, occupational exposure to smoke, dust, chemicals, indoor air pollution, prenatal factors, Asthma in childhood, and a rare genetic condition called alpha-1 antitrypsin deficiency (WHO 2021a). Asthma is a long-term disease that affects children and adults. The airways in the lungs narrow due to inflammation and constriction of the muscles around the small airways. Symptoms occur in episodes and are Coughing, wheezing, shortness of breath, and chest tightness. These symptoms are often worse at night or during physical exertion (WHO 2021a). The big five are among the biggest causes of death worldwide, killing millions of people, mainly in low- and middle-income countries (LMIC) (Schluger and Koppaka 2014). COPD caused the deaths of 3.23 million people globally in 2019 (WHO 2021a). In addition, around 334 million people have Asthma (WHO 2021b). About 4 million people die from acute lower respiratory tract infections annually (WHO 2006). Significantly children are affected as it is the leading chronic disease(Ferkol and Schraufnagel 2014). In addition, 10 million people develop tuberculosis (WHO 2021c), and 1.4 million die of lung cancer each year (Forum of International Respiratory Societies 2017).

4.1 Drivers of CRDs

CRDs constitute a significant burden to human health, but they are preventable and treatable. However, to understand how to treat them, it is necessary to discuss the drivers. Four main drivers create and worsen CRDs - indoor air pollution (mainly from biomass fuel burning in cookstoves), outdoor air pollution, occupational exposures to lung toxins and irritants, and tobacco. The first three drivers have one thing in common. They produce inhaled toxins through incomplete combustion. These drivers are ubiquitous, making preventive measures more potent than disease treatment(Schluger and Koppaka 2014). The world's poorest regions are the most affected because they are the least protected. For instance, 80% of Sub-Saharan Africa and South Asia people use solid fuels for energy production, compared to only 20% in Europe. Furthermore, they are more affected by outdoor air pollution, as the industry is less regulated by governments, leading to unplanned development and construction (IQAir 2020). In particular, delicate particulate matter from industry and vehicles increases the risk of CRDs immensely. This problem will worsen in the future as the global urbanization trend continues (Schluger and Koppaka 2014). For instance, Bangladesh has the highest levels of air pollution globally by domestic and transboundary pollution, resulting in 200,000 deaths annually. The country is considered a negative example of policy failure, lack of control, and industry monitoring. However, Bangladesh is not solely responsible for this condition. Air pollutants can travel up to 500 km, so Bangladesh faces additional pollution from its neighbors India and Nepal. South Asia is the most polluted region globally, with Bangladesh, India, and Pakistan making up 42 of the 50 most polluted cities globally (IQAir 2020). In addition, more than one-third of the population in South Asia lives below the poverty line worsening the situation (Nationmaster 2021). Due to working conditions, developing countries are also significantly more affected by occupational exposures to lung toxins and irritants because 70% of the workforce work in agriculture. Hence, they are exposed to traditional and emerging hazards like silica and asbestos(Schluger and Koppaka 2014).

Furthermore, surveillance systems and diagnoses are poorly developed, making it hard to assess the actual health burden of CRDs in these countries (Bousquet, Dahl, and Khaltaev 2006). The fourth leading CRD driver is tobacco. Smoking affects LMIC and people worldwide, approximately killing 1 billion people in the twenty-first century (Forum of International Respiratory Societies 2017). For instance, in Europe, the tobacco-use prevalence is more than 29%, causing a third of the burden of tobacco-related diseases (World Health Organization Regional Office for Europe 2019). Smoking tobacco causes cardiovascular and respiratory diseases, like COPD and lung cancer. Smokers are 25 times more likely to die of lung cancer than non-smokers (Thun et al.2013).

Further, people suffer from second-hand smoke, particularly children, at a young age (Forum of International Respiratory Societies 2017). For instance, in Portugal children, between 13 and 15 years have a prevalence of 40% to be exposed to second-hand smoke at home. In enclosed public environments, the prevalence increases to 50% (WHO Regional Office for Europe 2019).

Second-hand smoke is one of the main constituents of inside air pollution containing at least 250 toxic chemicals, indicating no safe level of second-hand level smoke. The only science-based measure to protect adults and children is eliminating it from inside environments. As a result, by 2030, mortality will increase to 8.3 million, with a proportion of 80% in low- and middle-income countries. Moreover, tobacco consumption is linked with poverty and low education, causing a vicious circle of spending money on tobacco instead of necessities that worsens people's life conditions (Bousquet and Kaltaev 2007). For decades the WHO has tried to protect humans from smoking by agreeing to several policy frameworks that aim to reduce the adults-prevalence by 30% until 2025. The goal is to improve people's living conditions and lower the economic burden, which amounts to $1.4 trillion globally for healthcare expenditures and productivity losses annually (WHO Regional Office for Europe 2019). By describing these drivers, it is stated that prevention can significantly improve people's health and life conditions and even reduce health costs for each country.

4.2 Economic burden of CRDs

In general, CRDs are a considerable burden for the global economy. To frame the costs, they need to be differentiated by direct primary and healthcare expenses, loss of production costs, and the loss of monetized value of disability-adjusted life-years (DALYs). DALYs depict the years lost due to ill-health, disability, or death (WHO 2021d). The European Respiratory Journal assessed the economic burden of CRDs in 2011 and stated that the total costs for all European countries are $380 billion. Primary and healthcare costs account for a minimum of $55 billion; $ 42 billion can be assigned to the loss of production. However, the highest amount is the value of DALYs with $280 billion (European Respiratory Journal 2011). As a reference, Portugal's GDP in 2020 was around $230 billion (Worldbank.org 2020). Further, in Europe, 5.2 million DALYs are lost annually due to CRDs (European Respiratory Journal 2011).

4.3 Inhalation therapy

Prevention will not be enough to protect everyone from CRDs. Patients need to be treated in the best way possible. Today, inhalation therapy is the fundamental treatment of CRD patients worldwide (Arora et al. 2014). Medication is delivered to the lungs in aerosols (a heterogeneous mixture of solid or liquid particles). Hence an aerosol is a therapeutically effective substance dispersed in a gas or an airstream in the inhalation process or already in the inhalation device itself. Through the respiratory flow, the drug reaches the lungs' airways in particles and can be deposited at the locus of the disease. This direct deposition in the bronchial mucosa and the lower occurrence of side effects are advantages of inhalation therapy compared to the oral application (Petro and Schuppenies 2005).

However, the disposition of the aerosol particles in the respiratory tract can be influenced and affected by three factors, the quantity of medication, aerosol properties (particle size, shape of particles, hygroscopicity, electrical charge), and the patient (respiratory flow rate, inhalation volume, respiratory pause as well as airway morphology (e.g., obstruction) and airway anatomy). Accordingly, each therapy has different effects on the patient (P. Haidl 2018; Th. Voshaar et al. 2001). The healthcare professional and their expertise determine the dosage. Three mechanisms (impaction, sedimentation, diffusion) affect the aerosols due to their different properties (Ingelbo and Wildhaber 2013). Fast and large particles are influenced mainly by impaction. They are less flexible and can only hardly change their direction. However, they already hit the walls in the upper respiratory tract so that the active substance is lost in the mouth and throat and even causes harmful side effects (P. Haidl 2018). Sedimentation is the most crucial effect of inhalation. It works best for trim but not too fast particles (P. Haidl 2018). They sink into the airways, and the lung disposition is most successful. It can be further promoted by slow inhalation and breathing pauses. Sedimentation also acts on particles that have not been deposited by impaction (Ingelbo and Wildhaber 2013). Diffusion affects tiny particles that even reach the pulmonary alveoli in the airways. These particles are so small that they can either be extracted again or directed to the wall by collisions with gas molecules (air) (Th. Voshaar et al. 2001). In this case, slow inhalation and lengthy breathing pause support the lung deposition in the peripheral airways (Ingelbo and Wildhaber 2013). Lastly, the patient has a massive impact on medication effectiveness. However, the patient cannot influence their airway anatomy and morphology of the upper and lower airways (including throat and larynx), which may impede the flow and deposition of particles depending on their form (e.g., airway obstruction) if the airways are obstructed (narrowed), the deposition shifts to the upper airways because the particles can hardly pass through the bronchial tree (P. Haidl 2018). The patient's breathing behavior is most relevant, which can significantly influence lung deposition. Patients regulate their patterns, including inspiratory flow, inspiratory volume, inspiratory time, and breathing pause after inhalation (Voshaar 2018).

On the one hand, if the patient inhales slowly and deeply, deposition in the peripheral airways increases. On the other hand, if the patient inhales quickly, the deposit in the oropharynx and the central airways increases (Clarke and Pavia 1984). Depending on the inhalation system, different requirements of breathing behavior apply to enable effective therapy (Voshaar 2018).

4.4 Inhalation device types and their requirements

A wide range of inhalation therapy models differs in application, dosage, medication, and design. Each device has advantages and disadvantages (Ingelbo and Wildhaber 2013; Stein and Thiel 2017). After explaining the benefits of inhalation therapy and its mechanisms, the different inhalation types are presented in the following. Inhalers can be distinguished based on their medication delivery. There are three different types: metered-dose inhalers (MDIs), dry powder inhalers (DPIs), and soft mist inhalers (SMIs). Each class has advantages and disadvantages (Sparks 2021). When choosing an inhaler, the expert should take the following aspects into consideration, medication, age, cognitive ability, manual dexterity, ability to coordinate inhalation (Sparks 2021; P. Haidl 2018). Each device has different requirements and applications, making it even more difficult for patients to apply the necessary technique to ensure a successful lung disposition. SMIs are easy to use because the patient only needs to inhale and exhale deeply through the mouthpiece. However, these devices are inconvenient for daily use due to their size, the energy required, and regular cleaning (Traini, Colombo, and Buttini 2013). DPIs do not use a propellant for inhalation. The patient's inspiratory flow generates the energy necessary to create the powder's respirable particles (the aerosol). A threshold needs to be reached so the powder can transform into aerosols. Unless the patient can provide the necessary respiratory flow, no or only large respiratory particles are generated, reducing the effect of medication (Byron 2004; Peter Haidl et al. 2016). Accordingly, DPIs are unsuitable for children, the elderly, and patients with exacerbations because they cannot provide the necessary respiratory flow.

MDIs are very convenient and famous due to their size and robustness (Ingelbo and Wildhaber 2013). The propellant pushes the medication out of the device and the propellant gas at high velocity. The propellant evaporates shortly after, creating small, respirable aerosol particles (Voshaar 2018). MDIs have several advantages, such as high and constant dosage release, robustness, convenience for daily use, low cost, independence of the patient's inspiratory flow, and short application time (Haidl et al. 2016; Ingelbo and Wildhaber 2013). However, patients have to inhale deeply and slowly during the inhalation to avoid deposition in the oropharynx and transport the small particles deep into the lungs. In addition, a breathing pause is necessary to promote sedimentation (Laube et al., 2011).

The most critical patient-specific problem posed by MDIs is the requirement for coordinated inhalation and actuation of medication delivery. Hand-breath coordination is the most common failure during inhalation. Here, the spray stroke must be made at the beginning of the inhalation. Otherwise, a large part of the dosage ends up in the mouth and smoke chamber (Traini, Colombo, and Buttini 2013).In addition, common mistakes during use are not shaking the device, not exhaling strongly before inhalation, inspiration not being deep enough, lack of a breathing pause (Laube et al. 2011).

5 History of transition towards health apps

As in any other industry, the health and well-being sector saw the development of multiple online applications and services in these past years that use innovative technologies to provide new services to consumers. However, few sectors saw an increase as significant as health and well-being during the COVID-19 Pandemic. As in any other industry, the health and well-being sector saw the development of multiple online applications and services in these past years that use innovative technologies to provide new services to consumers. However, few sectors increased as large as health and well-being during the COVID-19 Pandemic. Since March 2020, the number of apps has jumped, and users have increased drastically to combat pandemic fatigue and diagnose medical issues without going to the hospital. Health and well-being services are also provided to large corporations as an employee benefit to serve as a retention tool and increase employee morale. It can be offered with other services as part of a more extensive offer by corporations, governments, or family offices (Wortham 2021).

The terms health and well-being apps are usually used together. However, there is a difference between them. Health apps can be considered application programs that offer smartphones, tablets, or PC health-related services. Health apps have a key part role for the movement towards mobile health programs in healthcare. There are many different varieties of health apps available for purchase from the market. Some are designed to help customers make healthier choices in their everyday life by offering advice about fitness or nutrition. Others assist doctors and patients in communicating (e.g., apps for people with diabetes that automatically send glucose readings to their main physicians). Some apps target physicians themselves with many apps providing and using information from electronic medical records, allowing doctors to keep accurate records (GlobeNewswire 2021).

In contrast, well-being apps can be considered applications that promote healthy practices and proactively assist the user in maintaining a healthy lifestyle. Individuals use them to access their health and keep it, focusing more on the daily aspects of health and well-being (e.g., fitness, sleep cycle, diet) rather than on severe medical conditions issues (Broek 2017). The European market for health and well-being apps has been growing, with new innovative technologies being developed in multiple countries across the EU. The European Commission (2008) has indicated more than a decade ago in 2008 that:

"eHealth can help improve the lives of EU citizens, both in terms of patients and health professionals. However, as the Commission has put it, integrating healthcare services systems such as teleradiology (the transmission of radiological patient images, x-rays, CTs, and MRIs, from one location to another) and teleconsultation (consultations where the healthcare provider and the patient are not at the exact location) is a challenging task. The main issues concern:

Building confidence in and acceptance of telemedicine services.

Bringing legal clarity, particularly concerning the relevant regulatory regime.

Solving technical issues and facilitating market development."

So, the development of health and well-being apps has been happening for quite some time, even though only in the past few years has the growth accelerated with the development of new apps and services using new technologies (Peeyush Singh 2021).

5.1 Value added by using health care apps following the COVID-19 Pandemic

The COVID-19 Pandemic has also helped health and well-being services providers by shining a light on respiratory issues, increasing the concerns that people direct towards respiratory diseases and health issues in general.

Companies like Kata®, whose mission is to improve inhalation and thus the quality of life of patients with respiratory diseases, have seen the market opportunity to provide an app that shows users how to inhale correctly in an understandable way while simultaneously reminding customers to inhale and assessing whether they have completed the critical individual steps of the inhalation process in a way that the active substance is released into the lungs in the best way. (VisionHealth 2021)

5.2 Well-being services for the workforce

Some companies on the insurance and benefits market have developed an offering with different apps for every need and medical issue, offering multiple services on one location, mitigating the need to research for an app for every single medical problem, and to develop an ecosystem where customers find solutions for minor health problems or if they want to increase their health (Rachel Suff 2021). For instance, Swiss Life Global Solutions and employee benefits providers offer access to multiple health & well-being services to complement their international employee offering and provide companies a way to support their workforce by providing direct access to them. These apps offer companies a tool to increase the motivation of their employees, to improve the competitiveness of the company, and to minimize sickness and absenteeism, quoting their official website (Swiss Life Global Solutions 2020):

"While a productive workforce is always the key to a company's success, the increasing workplace challenges mean that employees are expected to work under greater performance pressure. Our health and well-being offering complement and strengthen our existing global employee benefits solutions and ensure a healthier and more productive workforce, adding yet another way to help companies manage their talent strategy and individuals work towards their own aspirations."

The benefits of investing in employees' health and well-being have been scientifically proved. Investing in the well-being of employees can present a 6 to 1 return on investment on health care costs and absenteeism. Hence, an asset on the workforce's health is vital to sustaining a valuable workforce when retention is a significant issue for many corporations. This investment is critical in economies where health care costs and needs are expected to rise because of COVID-19 related problems and the increase of concern by both the companies and employees on the health and well-being of the workforce, as can be seen in Figure 1(Katherine Baicker, David Cutler, and Zirui Song 2010).

Financial wellness is one of the most recent concepts and markets branching out from the wellness industry. The concept of financial wellness is financial security and freedom of choice by effectively managing one's economic life and the absence of money-related stress. Similarly, like other forms of wellness, it improves clients' life, in this specific service, the main goal is to stress employees less with their financial life and increase their loyalty towards their employer (PubMed Central 2014).

Companies like Ayco, from the Goldman Sachs Group, focus on providing financial wellness to the employee in large corporations as a form of employee benefit by teaching basic economic concepts, providing investment planning, investing in retirement funds and insurance for teams, departments, and managers, adjusting the level of complexity with the seniority and financial complexity of the employee (Ayco 2021).

5.3 Medical vs. well-being usage

The apps' value cannot be denied, both on an ecosystem with multiple other apps or used individually. However, apps target different users, either people concerned about their health or users who check the seriousness of their medical condition. The target groups differ not only because of needs and characteristics but also the development and legal compliance of the app (Crossley Simon 2016). According to the Global Wellness Institute, the well-being market offers a broader and more diverse range of customers. The well-being market is the more extensive and more valuable of the two, priced at $4.5 trillion in 2019, with revenues increasing by $1299.84 billion between 2020 and 2024. However, this value has already been boosted by the increase in app development during the pandemic lockdowns (Global Wellness Institute 2019). The well-being market offers various apps and services, which might threaten smaller companies establishing in the market and aggravate customers searching for something specific for their needs.

In contrast, mHealth apps require more regulation, prescribed that those apps are up to standards to be rescripted and used by doctors and medical professionals. Countries and regions have regulatory agencies to prevent those negative impacts, and a specific legal framework applies (European Commission 2014). To be successful, the European Union needs to use the existing General Data Protection Regulation GDPR (in force since May 2018), but according to the paper "mHealth and telemedicine apps: in search of a common regulation 2018" the existing European legal framework is not yet sufficiently adapted to the vast regulatory needs from mHealth. It is still necessary for each country to decide (PubMed Central). The market dimension was considerably valued at approximately $10 billion in 2019.

Further, with the potential to grow more than tenfold over the following years, with a market forecast for 2026 of $105.4 billion, so the opportunity exists for both markets (GlobeNewswire 2021). Companies could also target both markets by offering both services in one app. However, customer evidence and impact should be assessed. It is also essential that medical experts use health apps that focus on one specific medical field (e.g., cardiology, dermatology, psychiatry) that would not value the added value by an integrated app offering health and well-being benefits. The market potential needs to be carefully assessed depending on customer needs.

6 Innovative Technologies used in diverse medical fields and specialties

New technologies have been developed and applied to multiple apps and services to improve the healthcare of numerous people around the world. However, implementing these technologies is not straightforward and readily accepted in every situation and every medical field. One specific medical area where the implementation of apps and medical devices has been challenging is cardiology. Mhealth apps have contributed to healthcare in many ways, for example, providing information, instructing patients, displaying data, and communicating vital patient information to medical professionals. Even though the benefits of these apps are clear, some barriers need to be crossed. For example, the usage of smartphones and smart devices decreases sharply with increasing age, from 59% in those aged 65–69 years to 31% of those old 75–79 years. This is important for 17% of people aged >80 years since cardiovascular risks tend to increase with age (CFR 2020). Obtaining the proper regulations and permits to enter the market has the debate for rules is far from ending. In 2017 the new European Medical Devices Regulation was published (entering into force in May 2020), ensuring the smooth functioning of the internal European market regarding medical devices, taking as a base a high level of protection of health for patients and users. Although regulations ensure consumer safety, they also make it harder for innovation to occur, especially in areas as delicate as the cardiovascular diseases field, where a small mistake can prove to be fatal (The European Parliament 2018). A technological advancement contributing to the creation of multiple apps and services in the healthcare field, providing billions of dollars in value by saving costs and reducing waiting costs, is AI (Artificial Intelligence). AI usage in healthcare is already a well-established reality, and it is getting increasingly sophisticated at doing what humans do, but more efficiently, quickly, and at a lower cost. Together with robotics and other technologies and apps, the possible uses of AI are vast. Its use is seen in all the different processes and areas of the medical field, from diagnosis and medical education and research to treatment and even end-of-life care (Wilson 2017).

An excellent example of the benefits of AI usage is the early detection of multiple diseases, including cancer. According to the American Cancer Society, a high proportion of mammograms yield false-positive results, leading to medical professionals informing one in every two women that they have cancer. The use of AI enables the review and translation of mammograms multiple times faster with approximately 99% accuracy, reducing unnecessary patient biopsies and reducing the time required to check every mammography since manual reviews of 50 charts took two clinicians around 60 hours. In contrast, AI software reviewed 500 charts in a few hours, saving the human doctors 500 hours of their time. (Wired 2016).

Other than breast cancer, AI has been used in combination with medical devices (wearable and not wearable gadgets) to oversee the early stages of other diseases, for example, heart diseases, allowing medical professionals to better monitor and detect life-threatening diseases at an earlier, more treatable stages, potentially saving the lives of patients (PWC 2017).

6.1 The drivers of digitalization in healthcare

The digitalization of healthcare is applied to several processes and areas in the healthcare system. Digitalization fosters efficiency due to increasing medical quality, knowledge management, and patient safety (Eiff et al. 2020). The phenomenon of digitalization attracts new players revolutionizing business models such as health insurance companies, medical care organizations, and the dynamic between doctors and patients.

Digital technologies allow the development of innovative solution-oriented processes and the optimization and delivery of preventative, clinical, and rehabilitative healthcare services. The advancements with the most significant impact on diagnosis, treatment, care services, and the relationship between physician and patient are digital health, 3D printing technology, Artificial Intelligence, Big Data, and POCT (Point-of-care-testing) (Chawla 2020 and Kraus et al. 2021). It is challenging to quantify digitalization, but factors such as the acceptance of telehealth, development of Electronic Monitoring Devices (EMDs), and usage of web-based and mobile applications are relevant to draw general considerations about the adoption of new technologies that promote higher-quality care (Blakey JD et al. 2018).

Telemedicine is the broad term used to describe technology to deliver remote clinical services. The healthcare industry has experienced an unprecedented rise because of the Pandemic. In numbers, 69% of all ambulatory consultations were teleconsultations in the U.S. in April 2020

(Negreiro 2021). Other medical practices also shifted to digital, with access to prescriptions, digital health records, and online booking for appointments, either with a doctor or exams (Charleson 2021). According to the Eurostat ICT household survey in 2020, 55% of people between the ages of 16 to 74 searched for health-related information online in the first quarter of 2020, the main related activity to access personal health records (Figure 2).

Studies have shown that the adoption of telemedicine is correlated to certain medical specialties. In September 2020, Doximity – the largest community of healthcare professionals in the U.S. - listed the ten things that most frequently use telemedicine. The results revealed an evident overlap between the higher usage of telemedicine and the treatment of chronic conditions that require routine care and frequent patient visits that do not necessarily have to be in-person. Pulmonology comes up in the tenth position in this list that goes up to 50 specialties (Doximity 2020). Chronic diseases are also served with a broader portfolio of Remote Patient Monitoring (RPM) devices that allow more timely, meaningful, and effective disease management.

6.2 Digital Health Tools and Respiratory Applications

The WHO defines the group of predominant respiratory diseases as "the big five." This comprises the most common causes of severe illness and death worldwide related to respiratory conditions, including COPD, Asthma, acute lower respiratory tract infection, tuberculosis, and lung cancer (WHO 2016).

The opportunity for digital developments in the respiratory field is extensive. From prevention, diagnosis, and monitoring to treatment, respiratory diseases are a bit behind compared to other medical conditions. Most of the new technologies in healthcare are developed before assessing the problem they are meant to address. This solution-problem methodology generates two immediate flaws. The first is that the technology may not be optimal for the resolution. The second is that the health problems currently being addressed do not represent high-priority problems for healthcare systems. Home Respiratory Care (HRC) designates the services to solve the needs resulting from COPD, respiratory infections, and sleep and breathing disorders. HRC includes aerosol, oxygen, and ventilation therapies prescribed for many conditions and diseases. The growing prevalence of chronic respiratory diseases is driving organizational changes and technological developments to improve accessibility and quality of respiratory care and pulmonary rehabilitation.

Diagnosis is, across all medical fields, the stage where the acceptance of websites or mobile apps is low, and the respiratory area is no different. Pulmonary, respiratory, breathing apps have been mainly developed for monitoring and treatment. Breathing apps are widely used for anxiety management and combine AI with the microphone and camera to assure optimal breathing exercises. Respiratory apps are commonly developed to address chronic conditions such as Asthma and help track symptoms, manage medication, and provide essential information in an emergency. More recent apps use AI to assess the correct use of medical devices, such as inhalators, flowmeter devices, and ventilators. Pulmonary monitoring is becoming more accessible with new apps and devices that detect lung sounds substituting the standard stethoscopes or lung function testing that evaluates the user's breathing capacity or tracks coughing activity throughout the day (Kaplan et al. 2021).

COVID-19 has also raised awareness for the prevalence of respiratory conditions, respiratory etiquette to reduce exposure and infection of respiratory viruses and led discussions on the available methodologies and mechanisms in respiratory care (Negreiro, 2021). Most countries dealt with a critical shortage of ventilators, oxygenators, staff, and hospital beds during a global pandemic revealing that the healthcare industry, particularly respiratory treatments, has a long journey of digital integration to allow self-management, distant treatment, and quality screening.

6.3 The Role of Digital Technology in Pulmonary Rehabilitation

According to WHO, 67 million people are diagnosed with moderate to severe chronic obstructive pulmonary disease. It is predicted that many more are undiagnosed. With no cure, the treatment for COPD is expensive and continuous, and it is a global healthcare challenge to provide these patients with more autonomy in managing their condition. Most of these patients suffer exacerbations or lung attacks that deteriorate their clinical condition and can be life-threatening, requiring hospitalization (Health Europa, 2020). To this day, the only way to reduce the severity of these episodes is to provide continual and closer monitoring of patients and treatment management tools. According to WHO, 67 million people are diagnosed with moderate to severe chronic obstructive pulmonary disease. It is predicted that many more are undiagnosed. With no cure, the treatment for COPD is expensive and continuous, and it is a global healthcare challenge to provide these patients with more autonomy in managing their condition. Most of these patients suffer exacerbations or lung attacks that deteriorate their clinical condition and can be life-threatening, requiring hospitalization (Health Europa, 2020). To this day, the only way to reduce the severity of these episodes is to provide continual and closer monitoring of patients and treatment management tools.

An essential aspect of digital health in the respiratory field is that there isn't one type of user. Instead, there are millions of patients with unique needs that vary over time, meaning that all technologies and devices need to be designed in a way to deliver the best results for a particular patient, condition, and situation (The Lancet 2017). Monitoring apps target COPD patients and combine AI with clinical profiling to determine trends and behaviors that lead to exacerbations. These apps typically combine input, sensor collected, and log-in activity to generate datasets of symptoms, exercise, oxygen levels, medication, and lung capacity. Prediction algorithms are applied to the users' data and give timely alerts of possible exacerbations. With exacerbation, the patient has higher chances of timely intervention, avoiding clinical deterioration, and preventing unnecessary hospitalization (Spiteri and Phillips 2020).

In both Asthma and COPD, inhalation therapy is the primary treatment, offering higher efficacy with lower side effects. Inhalation devices have a high rate of misuse, which leads to worsening of symptoms, lower efficiency of the medication, and overall higher costs for the patient. This is where the ample opportunity of digital technologies relies on the respiratory field with an addressable market of 235 million asthma patients combined with 67 million people who suffer from COPD. Inhalation therapy is expected to innovate in three areas: medical devices, new formulations and medications, and digital technology related to monitorization and quality assessment of the inhalation treatment (Fekete, et al., 2021).

6.4 Acceptance and Results of Digital Technologies in Respiratory Conditions

The offer of apps and devices to support self-management from patients with chronic diseases is increasing at an unseen pace. Smart devices are revolutionizing the treatment of respiratory diseases, and innovative sensors combined with individual datasets can evaluate potential triggers or symptom worsening factors that lead to severe episodes. Symptoms can be detected through wearable biomedical sensors such as smartwatches, activity trackers, smart implants, or patches that monitor oxygen level, heart rate, arterial oxygen saturation, and physical activity. New technologies allied with global internet availability create the opportunity to rehabilitate patients at a distance, improve respiratory function, optimize medicine administration, real-time communication between doctor and patient, and storage and transmission of healthcare data. The availability of self-management solutions has a clear advantage of increasing treatment accessibility, but both patients and physicians are still hesitant to adopt these solutions. The diversity of digital healthcare apps and devices can also be a barrier to broader adoption. The typical user doesn't have the necessary knowledge to assess accuracy and efficiency for medical devices, which means that if digital products targeting similar conditions are not standardized, users and doctors will feel demotivated to test all available options.

6.5 The Digital Future of Respiratory Conditions

The WHO predicts that respiratory diseases are expected to become more common as the quality of air decreases due to pollution. The Pandemic has also increased the population's concerns regarding pulmonary health. These factors lead to a higher necessity for air quality monitoring, higher appointment demand, and better telerehabilitation solutions. In other words, the need for new technology to assist doctors in the diagnostic and treatment of respiratory diseases has never been so high (HITC, 13). All stages of the medical process will have better technologies - diagnostic algorithms that lead to a more precise diagnosis that can be determinant for a quick and efficient detection which in some conditions, such as lung cancer, are significant factors for a jump start of the treatment phase and probability of success, smart inhalers, and wearable devices for monitoring patients' conditions, improve treatment and rehabilitation. To understand the complexity and impact of health digitalization, in figure 1, it is possible to visualize possible applications in the various concepts that integrate digital health.

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The technological revolution of healthcare, particularly the respiratory field, brings advantages to all involved stakeholders. Regarding patients, closer monitoring avoids condition worsening, telehealth increases accessibility to HCPs, and more accessible and safer data collection that is shareable between physicians and institutions raises the potential of precision therapy (Eiff & Eiff 2020). For practitioners, the availability of continuous monitoring datasets reduces inefficiencies and costs, decreases diagnostic time, and improves individual patient care with a better understanding of each patient's needs (Bernstein 2021). The access to up-to-date and accurate data regarding the population's health status would provide central governments essential information to improve planning and resource allocation in national healthcare systems. It improves their value chains and ultimately ensures that patients have access to clinically and cost-effective care (Pinnock and McKinstry 2016). Insurance companies also gain a more profound knowledge of the population's activity based on accurate data and general health conditions. This helps to develop a business model adjusted to the concomitant health conditions of a given population (Dundon et al. 2020). Similarly, to insurance companies, pharmaceutical companies also gain a significant advantage in knowing the habits and prevailing conditions that affect a population, generating real-time medical adherence data, and allowing design by data to increase the success of new medicine through predictive algorithms and tools for performance measurement. To develop and execute digital health strategies, these companies will have to adapt their competencies to cope with the accelerated speed that comes with digital solutions (Little 2016). Considering all medical, social, operational, and financial aspects of the industry's transformation, it is expected that digitalization will impact the roles and importance of this industry's stakeholders and allow new players to enter the market, including devices, software, and technology companies.

The many healthcare ecosystem players who share the common objective of improving healthcare practices and outcomes have different gains, barriers, and incentives for the digitalization of the healthcare system. Nevertheless, a collaborative approach must be developed, allowing information sharing and understanding of the different perspectives and contributions that each may bring to the discussion to help set priorities for future developments of digital tools for diagnosing and managing respiratory conditions (Dundon et al. 2020).

6.6 Incorrect application of inhalation devices

There is no cure for COPD, but early diagnosis and treatment can help slow the condition's progression and control the symptoms. Inhalation therapy forms the basis for treating chronic respiratory diseases such as Asthma or COPD. Through correct inhalation, beneficial active ingredients can reach the diseased airways directly to exert their healing effect. A widespread problem with this form of therapy is that many patients do not know how to use their inhalation devices correctly (Bonds, Asawa, and Ghazi 2015). The institute for safe medication practices claims in their article that up to 94% of patients with Asthma and COPD misuse their inhalers (Smetzer 2016). Different problems lead to incorrect application, such as the wrong angle at which the inhaler is held, or the burst of spray triggered at the wrong time, meaning not directly after the start of inhalation (Fernandes 2017). Each inhaler requires adapted training. The healthcare system faces high costs due to crucial errors made by patients using inhalers, leading to a confusing market for patients, caregivers, and physicians. According to Pearl and Madvig (2020), the costs for chronic patients are likely to arise. When it comes to discussing how to decrease costs of the U.S health care system, it's mainly about "the sickest 5% of the population consume 50% of health care spending ".

7 Solution Kata® App

Kata®'s mission is to use inhalation assistants to improve inhalation significantly and thus the quality of life of patients with respiratory diseases. Kata® offers comprehensive support in inhalation therapy, which – as previously shown - is urgently needed to train patients in the use of their devices and to increase adherence. According to the start-up VH, patients should take their therapy into their own hands and check their inhalation technique between visits to the doctor. After all, the better disease and its therapy are managed, the greater the chance of stable condition with minor decline. Kata® is a digital and artificially intelligent solution to improve inhalation therapy for chronic respiratory diseases. The inhalation app trains patients to correctly use their inhalers, review them and provide instant feedback after each inhalation procedure. Compared to other inhalation apps, Kata® works with an algorithm to differentiate and evaluate different breathing maneuvers. This way, it can determine whether the patient is exhaling heavily before inhalation when using the inhaler or if he holds their breath long enough after inhaling and whether the timing of the medication delivery (e.g., spray burst) was correct. Just by the smartphone's sensor technology alone, Kata® can detect critical handling errors and eliminate them over time by training the inhalation process.

No other hardware or technical tool is needed. In addition to training and feedback, the app has additional features to promote patient adherence, such as a reminder function. As Kata® reminds patients to take their medication on time and a diary, to maintain an overview of the course of the disease, patients can record therapy-relevant values (peak flow values, SpO2, pulse, and daily condition) in the app. Kata® will also offer a library for patients to learn more about their condition and get helpful tips. By using Kata®, significant improvements in inhalation can be achieved by detecting handling errors through AI feedback. In addition, the disease progression can be better monitored. The patients' self-efficacy can be strengthened, and an overall improvement in treatment adherence can be achieved through individual reminders. Kata® was developed by VH in Munich in early 2018 and launched in March 2019. Although numerous solutions are available in the health field to improve inhalation technique and adherence in patients with chronic diseases, no digital product can measure and evaluate the complete inhalation process using a smartphone and has functions to promote compliance.

7.1 The market for VisionHealth

Worldwide, Kata® could support the therapy of about 250 million patients with chronic respiratory diseases, including about 8.9 million cases in Germany (VisionHealth 2018). Eighty million asthma patients are severely and poorly controlled (Peters et al. 2006). Furthermore, 125 million COPD patients face exacerbations (Raluy-Callado et al. 2016). Currently, the Kata® app is a complete product that can be used on all iOS and Android devices. An ongoing selective contract has been signed with the public insurance company AOK Bayern as a pilot project, covering 500 asthma and 500 COPD patients over 24 months. In addition, the Kata® app is certified as a class 1 medical device. The patent application is going into the national phase. According to Statista, there are currently 103 public health insurance companies in Germany. Around 73.4 million insured or members and family members are covered by these, representing about 90% of the German population (Statista 2021). The primary source of revenue for Kata® will be medical prescriptions, where physicians prescribe Kata® to their patients under inhalation medication. After the prescription, previously mentioned public health insurers reimburse Kata®.

7.2 Digital Health Apps in Germany

Since October 2020, selected health apps have been eligible for prescription coverage in Germany so that the statutory health insurers will refund the costs under certain conditions. These reimbursable apps are called *Digitale Gesundheitsanwendungen* (DiGA), meaning digital health applications. The German Federal Institute for Drugs and Medical Devices maintains a list of DiGA that have already been approved based on the Digital Health Care Act. There are currently 24 DIGAs on the market, of which 18 applications have been provisionally accepted. The evaluation period lasts three months from receiving the complete application. DiGAs open a wide range of possibilities for supporting the detection and treatment of diseases and on the path to a self-determined, health-promoting lifestyle to a McKinsey report. In recent years, global sales of all health apps have doubled (BfArM 2021). The extreme simplification of processes through the Digital Care Act will revolutionize the market for health apps (Hedwig et al. 2020). Kata® is one of the first health apps to obtain the Europe-wide CE mark as a digital medical device. It is, therefore, qualified for the approval procedure (Kata 2021). Once the app is registered as DiGA product, it can be prescribed by the attending doctor or physiotherapist and can then be activated via a prescription code within the app. The anonymity of personal data and the DSGVO-compliant data structure are guaranteed. So far, there is no direct competition for the Kata® app.

7.3 Challenges for Apps

However, a seamless integration process of DiGA has not yet been accomplished. Challenges such as the integration of insurance companies and the acceptance and trustworthiness of the inspection of DiGA remain. Nevertheless, the biggest challenge for good integration into the German healthcare system is the unwillingness of doctors to prescribe DiGAs actively. According to IQVIA's study, 40% of general practitioners are unwilling to prescribe health apps, and insufficient medical benefits and privacy concerns are frequently cited for this (IQVIA 2020). In addition, the user experience of DiGA must take into account the different levels of knowledge users have in using the technology. Even though 59% of the participants in the bitkom research study can imagine using apps on prescription, there is a significant age gap that should not be ignored. While 67% of 16–29-year-olds can certainly envision using them, almost only one in two of the over-65s (48%) say the same (Bitkom 2020).

Furthermore, Urban claims that older people develop negative emotions from health apps. Accordingly, elders suffering from severe chronic diseases feel uncomfortable integrating these technologies into their daily lives because the apps constantly remind them of their illness (Urban 2017). Another significant difficulty is the prerequisites that a company must meet before starting the Fast-Track DiGA process. When an app is proposed as a DiGA product, several resources, effort, and time must be invested. This is not always easy to manage, especially for start-ups. Topics such as security, functionality, quality, data protection, and safety are reviewed (BfArM 2021).

7.4 Competition of the Kata® App

From the distribution of DiGA applications by application area, there is no significant competition in respiratory diseases. Most DiGA applications are offered in the mental health section, closely followed by the muscle, bone and joint, and nervous system sections (BfArM 2021). When comparing the Kata® app with direct competitors that offer similar products, with or without hardware, it becomes apparent that the Kata® app has several advantages over its competition. The Kata® App is about a unique combination of training content techniques and improving therapy adherence. Kata® is a software-only solution, no hardware is required. In addition, patients can get feedback in real-time and rely on high flexibility as there is maximum adaptability to content devices and care concepts. All relevant features were compared with the competition. Finally, it can be stated that there is no app like Kata® that offers all the essential features and has applied for DiGA at the same time.

7.5 Challenges for Kata®

Although DiGA and the rise of health apps like Kata® have welcomed many, it faces several challenges and unresolved issues. The inhalation aid Kata® promises to make the daily therapy routine of a patient with chronic lung disease easier by showing him how to inhale correctly and imparting relevant knowledge about inhalation. The inhalation technique is to be improved by a checking algorithm, and adherence is to be increased by additional functions (Visionhealth 2019). Nevertheless, Huckman and Stern (2018) are claiming that even if a constant revenue stream can be guaranteed for apps for managing chronic disease, it must be ensured that customers are willing to use this app on a sustained basis. This is the only way to achieve real treatment success and guarantee cost savings in the treatment process (Huckman and Stern 2018). Even if the DiGA approval can ensure a regular flow of payments, customers must be convinced of Kata® in the long term to determine success in the treatment. Therefore, patients must use the app continuously to save costs sustainably. There are also further challenges for Kata® in the negotiation of prices. The standardized reimbursement price depends on how the negotiations between Kata® and the National Association of statutory health insurance will proceed. Since DiGAs are prescribed by physicians, they must first be convinced of the DiGA's benefits. They also need to find the price reasonable and integrate it into their daily practice. Otherwise, they will not prescribe it. For Kata®, this implies demonstrating the app's benefits, creating and gathering relevant data on positive patient outcomes to negotiate the price with insurance firms, and finally integrating it into the doctor's daily routine.

Furthermore, the results of a survey that asked eHealth experts from Germany to rate essential eHealth challenges for healthcare providers in 2021 are revealing. Forty-three percent of respondents believe IT security and data protection are the biggest challenges (Stewart 2021). Gerke, Yeung, and Cohen (2020) claim the risk of re-identification. In the world of Artificial Intelligence and Big Data, requested data can be re-identified by algorithms combined with other available data from a beneficiary. Kata® lists in its privacy policy the possibility to keep the user account under a pseudonym or to enter another email address only for Kata®. However, the goal is to protect hackers' sensitive information such as insurance numbers, prescriptions, and treatment records.

7.6 Vision and Outlook

Most doctors have a positive attitude towards apps on prescription. According to a survey conducted from March 2020 to May 2020 of 1,000 doctors, 42% said they found the DiGA prescription very good or good, while 48% found it partially good. Nevertheless, when asked how well prepared they felt to prescribe such apps, 41% said they felt poorly prepared, and 15% said they felt very poorly trained (BARMER 2020). The extent to which doctors and patients will accept DiGA in the future will only become apparent in the next few years when good study results and application observations are available. Preparations for the DiGA registration are currently in progress for the Kata® App as well as all requirements have been handed into BfArM, the Federal Institute for Drugs and Medical Devices. VH's roadmap in terms of app users assumes 10,000 users in 2022, 40,000 users in 2023, and up to 80,000 users in 2024. About 250 million patients with chronic respiratory diseases worldwide can be supported in their therapy by Kata®. The current plight of patients with respiratory infections due to the COVID-19 Pandemic highlights the importance of treating vulnerable patients with innovative technologies (VisionHealth 2018).

8 Transition to Individual Parts

The first two individual parts are dedicated mainly to the market of VH and their main product, the Kata® App. The first part deals with improving the collaboration between sub-teams of VH and external stakeholders to improve the software development process. For this purpose, interviews were conducted with various decision-makers of VH, also to elaborate on the company structure. The second individual part focuses more on the product itself, the Kata® App. The usability study tested 33 patients with chronic respiratory diseases to address to what extent Kata®'s algorithm can improve patients' inhalation technique.

Germany's digital healthcare network provides a unique regulatory, health provider, and insurance network for applications like Kata® to leverage historical records and new streams of health data on patients across health providers efficiently and trustfully. New patient monitoring, health data management, and clinical decision-making approach at an HCP and Healthcare System-level must be implemented as homogeneously as possible within the EU. This individual section aims to introduce a framework for leveraging Blockchain's trust-building capabilities in achieving a homogeneous and agile integration of emerging technologies across EU health networks. Trust in digital healthcare applications is paramount for their effectiveness in enhancing patients' adherence to treatments and smooth integration into clinical practice across EU's health providers.

The last two individual sections focus both on healthcare systems in Portugal. First, it examines how much Portugal lags the most advanced countries in healthcare technology and how it can keep track of digital advances in a rapidly evolving technological world. A significant problem in Portugal is the lack of patient trust in digital healthcare solutions. The last single section focuses on High-Net-Worth Individuals moving to Portugal. The country of Portugal is mainly looking to attract high net worth individuals in Europe to take advantage of their wealth and assets. Special attention is paid to the healthcare system in Portugal.

9 Discussion

9.1 Apps on-prescription in Europe

The COVID-19 pandemic has accelerated the digitization of healthcare. In response, the European Commission has launched several initiatives to promote the adoption of digital solutions (European Commission 2021). The results of a European countries survey conducted in 2020 to analyze the willingness to use a mobile app to manage prescriptions in Europe are revealing. Serbia has the highest acceptance rate to use a mobile app to manage medications at 86 percent, with Poland and Italy following. In contrast, only 60 percent of Germans use apps to manage medications (Statista 2020). Although Germany was the first country to mandate digital apps, it remains the top country, followed by the rest of the EU region, Italy and Belgium. In 2018, *mHealthBelgium* was launched by the Belgian government. *mHealthBelgium,* also known as mobile health Belgium, is a Belgian platform for mobile apps that are CE marked as medical devices. As of January 2021, medical apps can now be submitted for reimbursement in Belgium for the first time (mHealthBelgium 2021). Belgium has also devised a digital approach in which physicians are compensated for caring for COVID-19 patients, particularly patients who cannot see their physician (WHO 2020). However, challenges, such as regulations, vary from country to country. The development of digital health solutions is proceeding at different speeds in the various European markets. Germany, Sweden, and the United Kingdom promote innovation and programs to digitize healthcare and have standardized reimbursement options. The reimbursement models are not clearly defined (Brinkmann-Sass et al. 2020). The different nature of healthcare system structures, as well as increased scrutiny by governments and physicians, means that companies will have to invest a lot of time and effort if they want to have any chance at all of being reimbursed, which will lead to a complex and likely slowed implementation, despite the accelerated process due to COVID-19. Therefore, it is fundamental that EU institutions and member states work together to reduce regulatory barriers for innovators in digital health and simplify and standardize the process.

9.2 The opportunities of digitalization in medical diagnosis, treatment, and education

The digital transformation impacts several areas from diagnosis to education of following physicians. The healthcare sector is experiencing unprecedented attention and investment, starting with telemedicine. Patients' interest increased from 11% prior to COVID-19, to 76% post-pandemic, with 17% of the appointments held remotely in the U.S., regulators and investors see the potential and are willing to take risks because increasing efficiency in healthcare is more important than ever. They collaborate to lower restrictions and open the virtual market. In addition, investments doubled from 2018 to 2020 to $14.5 billion, depicting the high perceived market potential (Bestsennyy 2021).

Most important, COVID-19 caused several technologies and research breakthroughs. The big winners here are in-vitro diagnostics, robotics/automatization, and sensory (Spectaris and Roland Berger 2020). Particularly respiratory care and treatment make use of these innovations. For instance, StethoMe® improves telemedicine with AI and sensory diagnosis to identify respiratory diseases with an intelligent stethoscope directly connected to an app, which will revolutionize pneumology (Stethome 2021). AI improves diagnosis through analysis of breathing noise, depth, and length. These findings can be expanded to other areas like sleeping disorders.

Moreover, smart inhalers directly transfer vital information from patients to doctors, share information about patients' conditions, environmental triggers, and even remind them to take their medication. One step further, patients can even track their conditions with smart shirts and stickers to be fully surveilled (HITC Staff 2020). The generated data is used to support patients' conditions and improve treatments.

The advantages of integrating technology in medical training are innumerous. Students can learn and work with real-time data and know more about diseases, progressions, and treatments than any other generation before. Their learning experience will completely change, eventually adding value to the health system. Moreover, new technology and insights provide information for educational purposes. Hence, universities and medical institutions must invest in technological learning tools to support interactive real-time procedures that combine analog and digital learning formats (Kuhn et al. 2018).

Another factor that drives digital adoption is changing societal expectations preventing students from learning at real-life patients to protect their lives. The preparation of students suffers, so realistic experiences that facilitate knowledge acquisition, improve skills, and create a safe and controlled practice environment that complies with the new rules, eliminating risks to patients is necessary. These realistic experiences combine virtual reality, AR, AI, and real-time streaming of procedures, so that medical students enroll in a more engaging, personalized, and flexible way (Phyllis 2015). For instance, methods and tools can be computer-aided instruction, allowing students to assist complex procedures; AR enables students to see an actual patient and acquire clinical information while operations are performed. And simulations are performed on mannequins with high anatomic accuracy due to 3D printing technology (Park et al. 2021). Further, online learning is a resource-efficient method for training and medical education that allows students to prepare for real-life scenarios at a distance and at their own pace (Alkhowailed et al. 2020).

However, the new technologies create highly accurate simulations, imitating actual patients, precise anatomically representations, and real-life mirror circumstances. They cannot replace field learning and only work complementary (Konstantinidis et al. 2021).

These opportunities would be accessible for the most affected and poorest regions globally. Patient data could be generated that improves algorithms and can be shared across disciplines.

Digitalization fosters a global exchange of knowledge, diagnosis, and treatments, which eventually will improve patients' conditions, save resources and costs, and invest in prevention strategies to prolong life expectancy finally.

9.3 Obstacles for mHealth Implementation & AI value

mHealth apps have contributed to healthcare in many ways, for example, providing information, instructing patients, displaying data, and communicating vital patient information to medical professionals. However, implementing these technologies is not straightforward and readily accepted in every situation and every medical field. One specific medical area where the implementation of apps and medical devices has been challenging is cardiology. Even though the benefits of these apps are clear, some barriers need to be crossed. For example, the usage of smartphones and smart devices decreases sharply with increasing age, from 59% in those aged 65–69 years to 31% of those old 75–79 years. This is important for 17% of people aged >80 years since cardiovascular risks increase with age (CFR 2020).

Obtaining the proper regulations and permits to enter the market, the debate for restrictions is far from ending. In 2017 the new European Medical Devices Regulation was published (entering into force in May 2020), ensuring the smooth functioning of the internal European market regarding medical devices, taking as a base a high level of protection of health for patients and users. Although regulations ensure consumer safety, they also make it harder for innovation to occur, especially in areas as delicate as the cardiovascular diseases field, where a small mistake can prove to be fatal (European Parliament 2018).

AI is a technological advancement contributing to the creation of multiple apps and services in the healthcare field, providing billions of dollars in value by saving costs and reducing waiting costs. AI usage in healthcare is already a well-established reality. It is getting increasingly sophisticated at doing what humans do, but more efficiently, quickly, and at lower costs.

Together with robotics and other technologies and apps, the possible uses of AI are vast. Its use is seen in all the different processes and areas of the medical field, from diagnosis and medical education and research to treatment and even end-of-life care (PWC 2017).

An excellent example of the benefits of AI usage is the early detection of multiple diseases, including cancer. According to the American Cancer Society, a high proportion of mammograms yield false-positive results, leading to medical professionals informing one in every two women that they have cancer. The use of AI enables the review and translation of mammograms 30 times faster with approximately 99% accuracy, reducing the need for unnecessary patient biopsies and reducing the time required to check every mammography since manual reviews of 50 charts took two clinicians between 50 to 70 hours (or about three days). In contrast, AI software reviewed 500 charts in a few hours, saving the human doctors 500 hours (or about three weeks) of their time (Wired 2016).

Other than breast cancer, AI has been used in combination with medical devices (wearable and not wearable gadgets) to oversee the early stages of other diseases, for example, heart diseases, allowing medical professionals to better monitor and detect life-threatening diseases at an earlier, more treatable stages, potentially saving the lives of patients (PWC 2017).

9.4 Revisiting patient trust in AI digital healthcare applications

Both HCPs and patients would prefer if the clinician oversaw any final decision-making processes rather than machine learning algorithms. By design, the entire value-chain created from health systems IT infrastructure, inter and intra-organizational health data networks, to specialized digital healthcare applications only generates value by solving HCPs recognizable and avoidable daily problems, not replacing them (Spear 2005). HCPs are a crucial agent in any likely scenario for digitalized health networks in the EU, notably in the co-development of digital applications (Castell et al. 2018).

Less than half of current AI-enabled applications for healthcare are in-use in European Health organizations, with around 55% of them still in development or pilot phases. Of those in-use, over 90% are reported to be actively used within health organizations (European Commission, PWC 2021). The majority of AI in healthcare developers have acknowledged that active co-development with healthcare organizations is necessary for translating AI-related research into value-generating healthcare applications. The patient sentiment is crucial in understanding the impact of AI-based technologies and applications in healthcare systems. Patients are critical stakeholders in the healthcare sector, and their perceptions regarding AI can trickle-down effect on society. A common theme that emerges from literature relates to trust and whether patients can trust AI-powered medicine and healthcare services. Patients tend to question whether AI will harm human engagement, empathy, and involvement in healthcare services.

This resistance to AI stems from the idea that no technology alone can understand and process patients' unique characteristics, provide personalized outcomes, and that health outcomes would be on-par with fully human healthcare services (Longoni et al. 2021). Contingencies for negative patient perceptions of AI-enabled healthcare applications should be considered before their deployment, as a negative public opinion and lack of trust in these applications severely hinder their effectiveness, more than half of which is still being proved (White et al. 2003). EU's focus on achieving a solid link between AI and trust is highly relevant in the healthcare sector. However, current literature indicates that patients and other stakeholders are not convinced that they can foster a relationship of trust with AI-powered tools (Tran et al. 2019). Patient monitoring AI applications used for aiding clinical decision-making show greater overall trust levels from recent consumer data, proving the less risky field for developing trust in these transformative technologies (1). Inpatient monitoring for aided clinical decision-making and treatment, secure and effective digital infrastructures, and healthcare data management are paramount for developing and integrating these technologies into the healthcare sector in a trustful environment.

Framing European AI in healthcare R&D contributions, the scientific output in AI in healthcare is primarily correlated with the size of healthcare networks. More extensive national healthcare networks show higher collaboration between each other and with smaller networks. More specifically, healthcare network collaborations tend to be stronger between countries that share borders or have solid cultural ties or smaller EU healthcare systems that benefit from partnerships with larger ones, like Portugal's outlier case (2). The start-up ecosystem varies across EU healthcare systems and is mainly driven by private initiatives and support networks.

Lastly, regarding awareness and strategic communication of these technologies, social media should be utilized by the European Commission along with EU Healthcare systems as channels similar to local or national news in increasing awareness of AI and other emergent technologies in the healthcare sector. Effective communication strategies would enhance citizens' understanding and build the necessary trust that will support the generalized adoption of critical emergent technologies in healthcare (European Commission PWC 2021)

10 Conclusion

The EU Health Network is an ideal environment for promoting emerging digital applications. Digital applications will continue to impact patients' lives and health outcomes, and digital technologies can also support healthcare professionals in their daily tasks. At the same time, digital transformation will accelerate science by using real-time, real-world data to multilaterally inform clinical decision-making, drug and medical device manufacturing, and relevant health authorities at national and EU levels. At the same time, the COVID-19 pandemic has lowered the barriers to entry into the digital health market through the urgent need for digital health innovation while highlighting the integral inequalities between health systems that hinder these opportunities in the EU.

However, the challenge of co-developing digital health applications needs to be addressed across different medical specialties and healthcare systems to take advantage of new technological opportunities in healthcare in the EU. Artificial intelligence in healthcare requires the general trust of patients and healthcare professionals. However, this trust must first be built. Therefore, it is best to provide patients with tools, such as apps, to check their health status. Therefore, chronic disease monitoring and management, similar to Kata®'s value proposition addressing respiratory disease burden, is the right way to build patient trust. However, concerns about using technology, as described previously, also represent challenges for further technology development and adoption. In this context, knowledge transfer and quality assurance are of particular importance. Confidence still needs to be built up here concerning specific clinical application areas and opportunities for mHealth.

11 Individual Part

11.1 Introduction

"A change in vision is crucial – from a provision and hospital-centered system to a new, prevention-oriented and citizen-centered one, supported by a restructuring of the health system based on an intelligent and rational use of technology." Lord Crisp on the Future for Health in Portugal

There is a global need for an innovative healthcare system, and Portugal is still on the path to become a pioneer in digital health. Portugal is a medium-sized country widely recognized in 2011 when the government had to restore the National Health Service (NHS) while facing one of the worst financial crises the country has suffered.

The Portuguese eHealth developments linked all public hospitals and primary care centers with a new Health Data Platform that allowed national access to medical records. The first patient portal was launched in the following year with e-booking for online appointments and a platform where citizens could document and consult their data. In 2015, the NHS launched ePrescription, an alternative for paper prescriptions later banned in 2020. Also, in 2015, the first telehealth platform was established, and throughout the following years, many more digital solutions were developed and implemented in the National Health System (Martins 2020).

Although Portugal has come a long way in the process of digitalization, it is far from having a fully Digital Healthcare System, and it has been falling behind other European examples such as Sweden, Denmark, Estonia, Germany, and the Netherland that are a few of the countries that are considered prime markets in digital health evolution.

This thesis investigates the characteristics that negatively impact the scale-up of Portuguese digitalization of the healthcare system, intending to develop strategies based on other countries' examples to overcome those obstacles.

11.2 Research Questions

The focus of the following segment is to assess the Portuguese stage in the digitalization of healthcare and define the main factors that impede the implementation of modern technologies in digital health strategies, allowing the development of a roadmap that pairs Portugal with the most digital countries in the medical field. To comprehend the implications of digitalization in healthcare and identify the most recent trends in this field, the definitions and analysis of digital innovation in healthcare were defined previously in this document. Furthermore, the most current and impacting event, the COVID-19 pandemic, was analyzed in the EU. It was crucial to understand the state members' capacity to rapidly innovate and adopt new technologies to strengthen their healthcare system. The goal of this section of the thesis is to answer the following questions:

1. How does Portugal compare to the most developed countries in digital health?

2. Which factors are most preeminent in delaying the Portuguese healthcare system's adoption of new technologies?

3. The Digital Roadmap. How can Portugal become a powerful player in digital health?

11.3 Theoretical Framework

The evaluation of a country's stage of digitalization of the healthcare system is not consensual across the globe. Multiple institutions have developed indexes and systems that comprise several factors to assess a country's phase of digitalization and predict the evolution of the process. This segment provides the theoretical foundation for the conducted research, focusing on existing frameworks that classify and rank countries' digital transformation.

11.3.1 The World Health Organization Framework

World Health Organization defines Digital Health Interventions (DHIs) as "the way in which digital and mobile technologies are being used to support health system needs" (WHO 2018). This classification of DHIs is only relevant when paired with the Health System Challenge (HSCs). It addresses and with the System Category, which represents the field in which DHIs are delivering results (WHO 2018). This framework identifies eight categories of challenges that health systems face – information, availability, quality, acceptability, utilization, efficiency, cost, and accountability – 25 system categories that include electronic medical records, health finance, insurance information system, and telemedicine. It divides the DHIs based on the addressed digital functionality, comprising clients, healthcare providers, health system managers, and data services.

11.3.2 The Global Digital Index

Based on the WHO's National eHealth strategy toolkit, another index was developed in 2016, with an official launch in 2018, the Global Digital Health Index (GDHI) offers an innovative digital resource that tracks and monitors the use of technology across the 22 participating countries represented in an interactive world map (GDHI 2019). The theory that led to the development of the index is that "*if countries can measure and monitor their progress and maturity in digital health, then they can identify the key gaps to inform the development of policies, scale up and integration of systems, and investment in human and financial capital*" (GDHI 2019). The information gathered and analyzed to create the index is mainly directed to governments, NGOs, and private companies. Six components are measured in the interactive world map, and an overall digital health maturity phase is quantified. The dimensions are leadership and governance, strategy and investment, services and applications, standards and interoperability, infrastructure, legislation, policy and compliance, and workforce. In the first data collection, Portugal was the only European country participating in the study, which makes this helpful tool to collect data for the Portuguese digital health stage but doesn't provide enough information to compare it to some of the most evolved examples in the world.

11.3.3 The Digital Intelligence Index

The Fletcher School of Tufts University developed a Digital Intelligence Index (DII) that evaluated the level of digitalization in a country and applied it to the healthcare capacity of 46 countries, originating a matrix to assess the digital state of healthcare (The Fetcher School 2021).

The two variables are a simplistic way of comparing countries, but with the Digital Intelligence Index, conclusions regarding the capacity for innovation can be drawn. The DII assesses the competitiveness of a country's digital economy as a function of two main factors: the current state of digitalization and the pace of digitalization over time, measured by the growth rate of its digitalization score over twelve years. Using the digital evolution state on the vertical axis and the digital evolution momentum on the horizontal axis, the Digital Evolution Chart (DEC) is created, classifying economies into four trajectory zones: Stall Out, Stand Out, Watch Out and Break Out (Chakravorti et al. 2020).

The Digital Intelligence Index is developed based on five main dimensions applied to each country's reality, scored, and ranked. The dimensions comprise Digital Evolution, Digital Trust, Remote Work Readiness, New GDP, and AI readiness. The 2020 report focused primarily on the Digital Evolution and Digital Trust. Digital Evolution has four main drivers: supply conditions that consider the existing infrastructure to facilitate and host digital interactions. Demand conditions quantify the consumers' willingness and ability to engage in the digital economy, institutional environment analyses the government's participation in supporting businesses that develop and make digital innovations available to the public, and innovation and change that can be broken down into the availability of talent and capital, as well as educational institutions' involvement in R&D as well as new digital products and services created. Digital Trust is one of the main obstacles to implementing and promoting the adoption of new technologies.

The evaluation and ranking of digitalization of healthcare are slightly different among the institutions mentioned above. However, the goal is shared: to understand countries' digital health capacities and increase their potential to create value through digital medicine.

11.4 Methodology

11.4.4 Academic Research

11.4.4.1 European Countries to Look Up To

Healthcare systems are transforming methods and operations at different paces. Some countries are marching towards digital health innovation, and it is expected that by 2025, digital health will account for 8% of the overall healthcare market (Roland Berger 2020).

Estonia started the journey 12 years ago. It currently has 99% of data generated by doctors and hospitals online, automating processes that connect the healthcare system with the citizens' jobs, tax offices, and population registry (Illiv 2021). All citizens have a digital health record that retrieves data from different providers (private and public). This country is considered the number one example of digital health worldwide (e-Estonia 2021). The e-health solutions use KSI Blockchain technology to mitigate threats and ensure data integrity. The previous section of this thesis has a deeper analysis of the usage of Blockchain to build trust.

Denmark has a Digital Health Strategy for the period between 2018 until 2022 to ensure that the country continues to lead the way to incorporate new technologies in the healthcare system (Jensen 2018). The Danish healthcare system is publicly funded and primarily free at the point of use with two different insurance schemes. It is extensively digitalized, and currently, an innovative portfolio of telemedical services is being tested for chronic obstructive pulmonary disease (COPD) patients. One single platform has been established for all national telemedicine services (Deloitte 2020). This paper has a brief analysis in the introductory part to learn more about COPD and what innovations are being implemented in healthcare for this specific condition.

Sweden and Germany are two additional European countries leading the path towards digital healthcare with the development and prescription of apps, such as the DiGA apps in Germany, analyzed in the introductory part of this paper. In Sweden, the NHS offers various apps to track conditions, such as Coala Life, a smartphone-based ECG that can detect cardiac irregularities, or Actiste monitors blood sugar values and insulin intake specially designed for diabetic patients (Allard et al. 2021).

11.4.4.2 The Main Dimensions of the Portuguese Health Digitalization

The barriers to digital transformation are mainly nontechnological. This indicates that it is not in the technology itself that the difficulties of adoption and implementation rely on, but on social, economic, governance and mindset factors (Jones et al. 2019).

Socially, the willingness to change heavily depends on the governments' approach and incentive to digital innovations (Jones et al. 2019). In Portugal, the regulatory schemes applied to digital health and health care IT are highly bureaucratic and time-consuming, creating barriers to health innovations. Although there are two health "subsystems", public and private, the private subsystem can only adopt specific methodologies and technologies with the approval of the Ministry of Health. This reduces the disparity between public and private solutions and stops the digital path of a health subsystem that may have the resources to test and adopt new technologies.

The population's mindset plays a big part in digitalization. Integrating new technologies, equipment, operations in the healthcare system is extremely expensive, and a phased path is necessary to test the public's reaction. During the COVID-19 pandemic, numerous countries worldwide created tracing apps to control the spread of the virus and notify in case of possible infection. In Portugal, the StayAway COVID was downloaded on approximately 3 million devices which translates to one-third of the population. For these contact-tracing apps to become relevant and effective, at least 60% of the people must use them (Pequenino 2021).

Digital evolution in Portugal is highly dependent on the government's policies, and digital adoption is highly dependent on the population's trust, two obstacles that will be deeply analyzed further in this thesis.

11.4.4.3 Overview of the Portuguese Digital Health Offers

In Portugal, private healthcare exists alongside the public NHS provision. The NHS covers all the residents in the country, and it is almost free of charge, while private hospitals and clinics are more expensive, although not as expensive as in many of the European countries. There is a digital gap between private and public health institutions, as the private usually have a wider availability of solutions and digital offerings to its patients. This thesis will focus on the public health sector and the digital services portfolio it offers.

11.4.4.3.1. Telemedicine

Portugal has been involved in telehealth since 1990, and this has always been a priority for digital health (Health Europa 2020). There is a lot of disparity regarding accessibility to medical care, and some regions in Portugal lack medical institutions such as hospitals or primary care clinics to attenuate this dissimilarity. The country faces an urgent need for a reliable and robust digital infrastructure to provide medical appointments nationally. Although it offers a twenty-four service for telephone appointments (NHS-24), a significant part of public health facilities still lacks the necessary equipment to provide virtual appointments, which creates a gap between the demand and offer, particularly enhanced during the COVID-19 pandemic.

11.4.4.3.2. Medical Records

Patients' data is stored in an Electronic Health Record that is available nationally and has been used since 2015. This is a nationally available record that can be accessed by medical professionals working in the public healthcare system. This lack of data interoperability between the public and private sectors is due to regulations that create an increased constraint for patients that engage with both spheres of the Portuguese health system (Martins 2020).

11.4.4.3.3. Telemonitoring

Various digital tools are available for patients' empowerment through monitoring at a distance. Hospitals provide the patients with the equipment, and the patient updates the platforms with the registered data. For the time being, telemonitoring mainly occurs for patients with undiagnosed conditions requiring specific and accurate data throughout a certain period and patients with chronic diseases (Canhão 2020).

11.4.4.3.4. Apps

The Portuguese Ministry of Health offers six different mobile applications with other functionalities:

Telemonit SNS 24 is an app that allows patients currently in prescribed monitoring programs to register their biometric parameters and self-evaluations, contributing to better management and more profound knowledge from their healthcare providers.

PEM is the ePrescription platform where all prescriptions are automatically updated and linked to each user. The app lists the pathologies related to the medication and the respective medication guide.

SICO is an information system that links all entities involved in emission death certificates. The app allows users to access the documentation, and in 2014, this system became mandatory for all death certifications in Portugal.

CEC Mobile is a platform for suppliers and medical institutions to sell and purchase medical equipment and access all relevant documentation regarding the specifications of the equipment.

SNS 24 is the most downloaded app as it is the most complete and relevant app in day-to-day life. In this app, citizens can access an extensive portfolio of health information and documentation: vaccination records and future dates, prescriptions, pathologies, appointments, and exam results. Besides the information, it is also a portal for prescription renovation, appointment booking, and urgent medical care, where it automatically connects the user to a 24-hour line.

MySNS is a platform with the latest news and communications from the Ministry of Health, and a list of all public medical institutions and MySNS Tempos is an app that allows the user to consult the average waiting time of the NHS's facilities, with integrated GPS and data regarding the clinics and hospitals, such as address and contacts.

The Portuguese healthcare system has a reasonable number of apps, but that information is still manually generated by physicians through the traditional channels and is not linked to automated data generated by health apps.

11.4.4.4 The present and future of digitalization of Portuguese NHS

To gain insights into the current difficulties in adopting recent technologies in medical practices, an analysis of a board discussion was conducted that included António Lourenço, José Luís Biscaia, Rita Nortadas, Armando Alcobia, and Bruno Trigo. This panel contains two hospital directors, one doctor, a pharmacist, and the IT director for the Ministry of Health. During this two-hour session held in November 2020, several aspects of the Ministry of Health's advancements were highlighted. The central pain points were present as obstacles for the Portuguese digital future. António Lourenço, director of the significant Lisbon university hospital center, started by stating a current goal *"a strong investment in the information technology area, to improve the efficacy/efficiency in attending to the populations' needs,"* reinforcing the need to deliver patient-centered care. With the COVID-19 pandemic, the urge for doctors to work remotely highlighted the lack of equipment such as computers and, consequently, some physicians' lack of computational skills to integrate this tool into their standard practice. Some of the significant shifts included video consultations, phone consultations, and the creation of a call center with pharmacists to deliver and provide assistance with prescribed medicine.

Regarding technological challenges, seven main difficulties were highlighted: articulating new technologies with outdated systems, inoperability between digital systems, finding the balance between reports and improved productivity, lack of defined norms, transitioning from an individual approach to a populational policy, managing the permanent change and finding the balance between the users' needs and the bureaucratic needs. From these challenges, Bruno Trigo, IT director for the Ministry of Health, developed some learnings for the Portuguese healthcare system: software performs functions to a specific problem; working in teams is critical, whether between the same organization or across departments (physicians and IT specialists); software is an intervention, it is not just about dematerialization but also improving results; the success of software doesn't rely just on the software, it also includes hardware, *peopleware* (collaboration), *integraware* (key data) and *localware* (national vs. regional politics), and finally the importance of feedback and constant search for better alternatives.

During this session, the focus was mainly on the technical difficulties of adapting to new technologies and the urge to update the infrastructure to allow a more interoperable system that provides a seamless experience for patients and practitioners.

11.5 Research Results

Portugal is, in various aspects, a country that has been developing and implementing strategies to improve the NHS through innovation. With 9.5% of GDP in health expenditure, the Portuguese healthcare system is an example of good eHealth practices, such as access to patients' data, legislation, telemedicine, and other measures (SNS 2021).

The Global Digital Health Index classifies the Portuguese overall Digital Health Phase in a four out of five. As previously stated, this ranking is not helpful compared to other countries due to a low number of participants. Still, it provides a classification for Portuguese performance based on seven indicators. Standards and interoperability are classified as phase two, mainly due to the absence of a national digital health architecture and information exchange (GDHI 2019). With two subsystems – private and public – the registered users in EHR portals vary because, at the time, no system allowed data sharing between ecosystems (Tomásio 2018). It is estimated that between one-fifth and one-quarter of the population uses private health services, representing up to 35% of total health expenditure as private. This interoperability between systems leaves these patients with incomplete health records that interfere with the goal of accurate and accessible health records at the point of care (Simões et al. 2017).

Regarding infrastructure – equipment, computers, phones, software, devices, etc. – the public healthcare service sector is estimated to have between 25% and 50% of the necessary health infrastructure available and in use (Simões et al. 2017).

As for digital trust, the results show that the quality of interaction between Portuguese citizens and health institutions still has a long way to go. The digital environment is strongly correlated with the population's perspective on privacy and security, and Portugal classifies in the 13th position with a score of 61.5%. Due to experience and behavior indicators for digital Trust, Portugal has started to fall behind other European countries. Experience measures the quality of the user experience regarding infrastructure, access, and interaction. The multiple portals and segmentation between private and public subsystems create friction in adopting new patient technologies.

11.6 Discussion

Portugal has shown solid signs towards a more digitalized healthcare system in the past years. In 2019, the Shared Services of the Ministry of Health (SPMS), co-created in 2010 by the Ministry of Finance and the Ministry of health to create solutions for the future of health, took part in an international project, "Digital Health Europe" that aims to create a Digital Single Market as a collaboration platform where parties from all over Europe can analyze challenges and develop joint strategies and solutions for a future European eHealth ecosystem. For this project, SPS is a task leader for two assignments: Task 4.1 – Collaboration of national and regional initiatives on citizens access and management of their health data, and Task 6.1 – Data collected from citizens, relevant to their health and wellbeing, feedback from healthcare providers (SNS 2019).

Compared to other European countries, the Portuguese healthcare system is seen as innovative and, on the path, to becoming digital-driven, but there are still significant discrepancies inside borders. The conditions for digital transformation are radically different between private and public healthcare organizations, mainly due to investment capabilities that lead to modern and robust infrastructures in the private subsystem and outdated and incompatible with newer technologies in public (Nabeto 2020).

For the digital transformation to occur and improve the Portuguese performance in the digital path, some conditions are required internally to the healthcare sector and at a political and social level. At a societal level, political and social motivation must shift towards a more acceptive approach, paired with initiatives to increase citizens' eSkills and digital knowledge and CyberSecurity as a service. Regarding internal changes in the NHS, healthcare providers also need to develop eSkills and technical competencies and the spirit for collaboration between the different agents in the healthcare system (startups, medical devices producers, physicians, and politicians). Finally, to overcome the challenge of interoperability across systems, both existing infrastructures and bureaucracies must be evaluated to achieve the ultimate goal of a uniform digital healthcare system across different institutions to serve the Portuguese citizens best.

11.7 Limitations

This study had some limitations within the scope of available data and stakeholders' participation. The unlimited number of indexes and studies that assess the level of digitalization allows creating an overview of factors that play a part in digital health. Still, it leads to multiple interpretations and different results. Most of the studies are also conducted by private organizations that can have some sort of partiality and single-sidedness when it comes to the analyzed dimensions.

Although there are limitations to what the private subsystem can or cannot incorporate, there are still some significant differences that were not explained in detail. There is not much information available online. Additionally, comparisons across countries required that the system in the analysis would be the National Healthcare System. Initially, the goal was to complement the academic research with interviews with public and private health organizations' board members. Still, due to time constraints, the study was completed with a recorded discussion analyzed in part 13.6. This study should complement interviews with Ministry of Health officials, app developers, and doctors and a questionnaire made available to the public to assess digital trust in Portuguese patients to overcome these limitations.

11.8 Conclusion

"Digital" in healthcare is available, and it is possible to achieve. The bases for a digital-based health system are the transformation of processes, professionals, and patients. New ways of collaboration between institutions and individuals must be created to restructure a healthcare system. New technology requires financial investment and re-evaluation of resource allocation. New challenges arise with digital tools, such as data security, data privacy, and interoperability which are the foundations for building the trust necessary for the new social construct (Martins 2020). This requires that countries have the motivation to adapt to change. Digital health value lies not in the technology itself but its application and benefits to society. The results show that Portugal has mainly infrastructure and digital trust obstacles. Synergies must form between public and private healthcare subsystems, and citizens are offered the privacy and security requirements to trust in the digitalization of their health information and services.

To further understand the main concerns from the patients, this study should be complemented with a public survey and interviews with government officials and relevant stakeholders in healthcare institutions to plan the best measures to increase digital trust in Portuguese society.

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13 Appendix

13.1 Table of Abbreviations

AI	Artificial Intelligence
BD	Backend development team
CEO	Chief Executive Officer
CTO	Chief Technical Officer
COPD	Chronic obstructive pulmonary disease
CRD	Chronic respiratory disease
DALYs	Disability-adjusted life-years
DiGA	Digital Health Applications
DPIs	Dry powder inhalers
DS	Data Scientist
EHRs	Electronic Health Records
EU	European Union
FCTC	Framework Convention on Tobacco Control
FD	Frontend development team
HNWI	High Net Worth Individuals
LMIC	Low- and middle income countries
MDIs	Metered dose inhalers
MHMD	MyHealthMyData
MS	Microsoft

MVP	Minimal Viable Product
NHR	Non-Habitual Resident
PM	Project management team
PO	Product Owner
QA	Quality Assurance
ROI	Return on Investment
SDG	Sustainable Development Goals
SMIs	Soft mist inhalers
SNS	Serviço Nacional de Saúde
TB	Tuberculosis
UHNWI	Ultra-High Net Worth Individuals
UX	User Experience
VC	Venture Capital
VH	VisionHealth
WHO	World Health Organization

13.2 Table of Figures

Summary Of Employee Wellness Studies Analyzed

Study focus	Number of studies	Average sample size: Treatment	Average sample size: Comparison	Average duration (years)	Average savings[a]	Average costs[a]	Average ROI[b]
Health care costs	22	3,201	4,547	3.0	$358	$144	3.27
Absenteeism	22	2,683	4,782	2.0	$294	$132	2.73

SOURCE Authors' calculations based on studies described in Appendix Table 1, available online at http://content.healthaffairs.org/cgi/content/full/29/2/hlthaff.2009.0626/DC2 [a]Per employee per year, costs in 2009 dollars. [b]Average of the individual return-on-investment (ROI) figures for each study.

Figure 1: Results on the effects of providing Employee Wellness

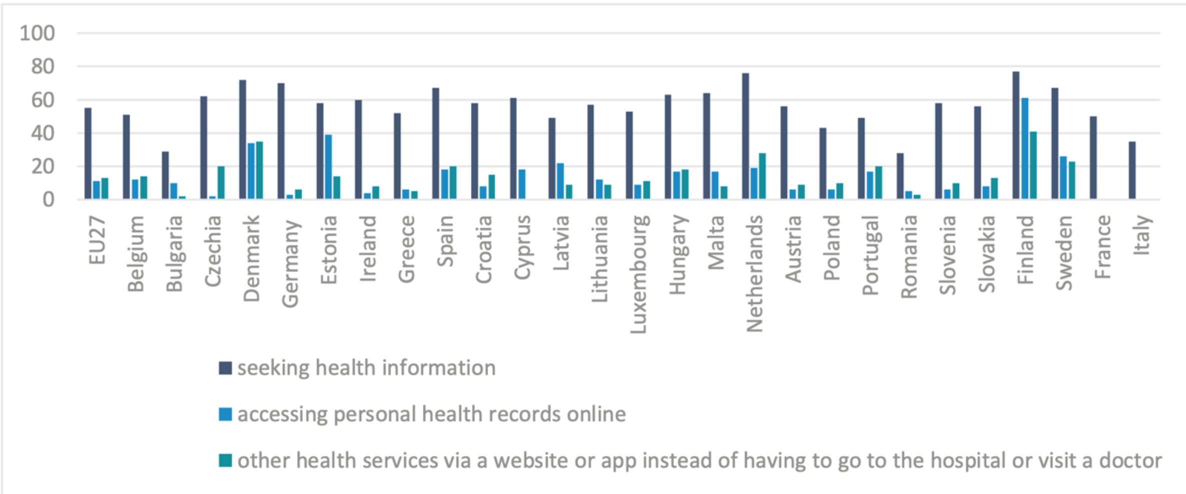

Figure 2: Percentage of users, ages 16 to 76, using the internet for health-related activities.

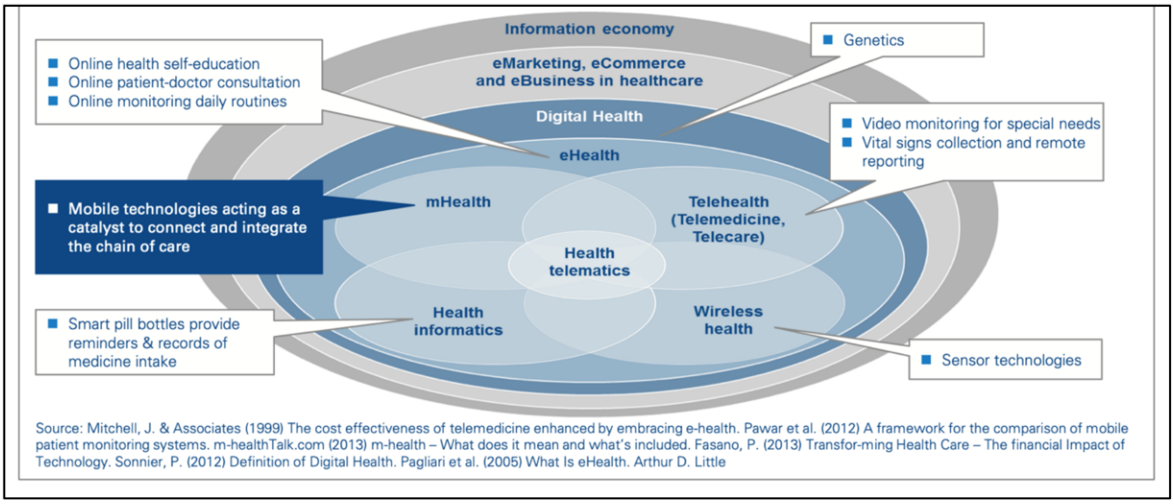

Figure 3. Digital Health related concepts and applications– mobile technologies act as a catalyst

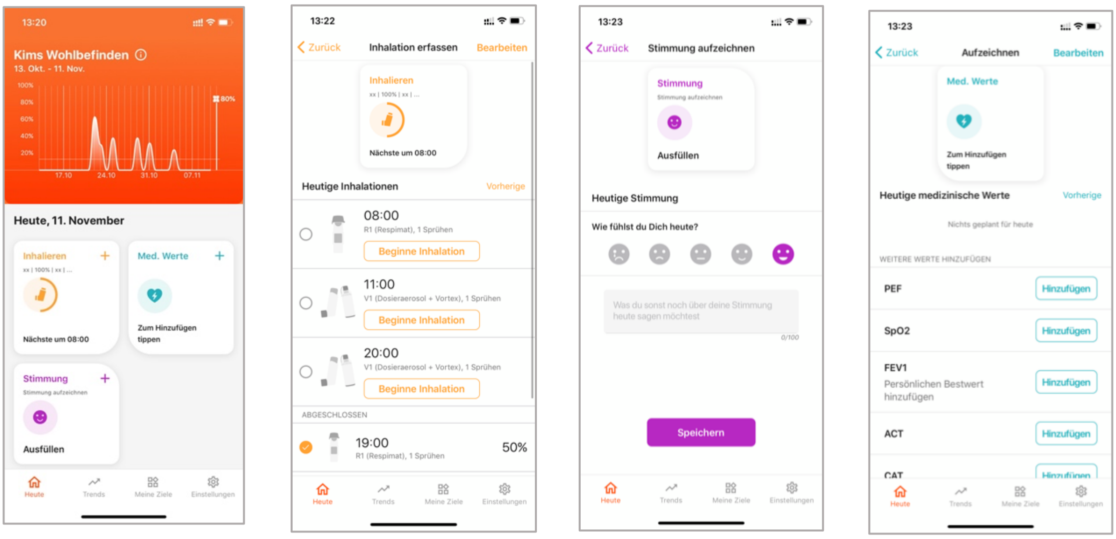

Figure 4: Screenshots of the Kata App

	Kata	Propeller Health	Adherium	Cohero	AsthmaMD & others	AssistMe	Widzy Pets	Trainhaler Buddy
What	Digital Solution	Hardware &App	Hardware &App	Hardware &App	App	App	App	App & Hardware
Training	✓	-	-	✓	-	✓	✓	✓
Feedback	✓	-	-	-	-	-	-	✓
Adherence	✓	✓	✓	✓	-	✓	-	-
Diary	✓	✓	✓	-	✓	-	-	-
Information	✓	✓	✓	✓	-	-	✓	-
Stats	✓	✓	✓	✓	✓	-	✓	-
Companion App	✓	-	-	-	-	-	-	-

Figure 5: Overview of Katas Competition

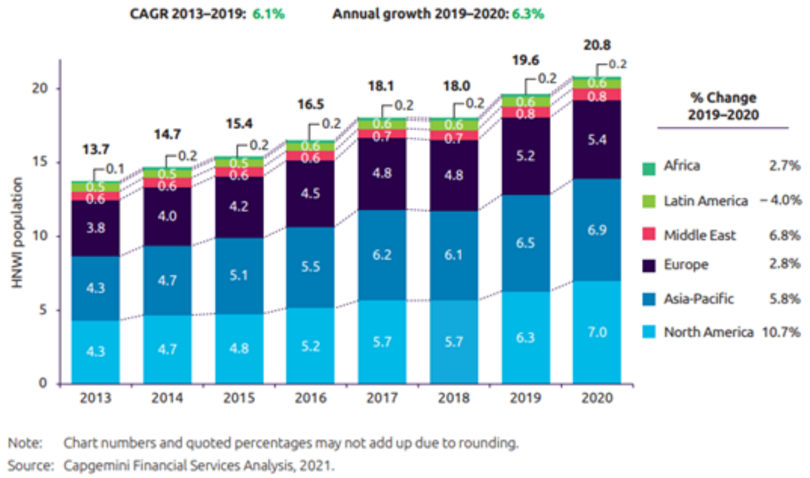

Figure 6: Number of HNWIs by region in millions between 2013 and 2020

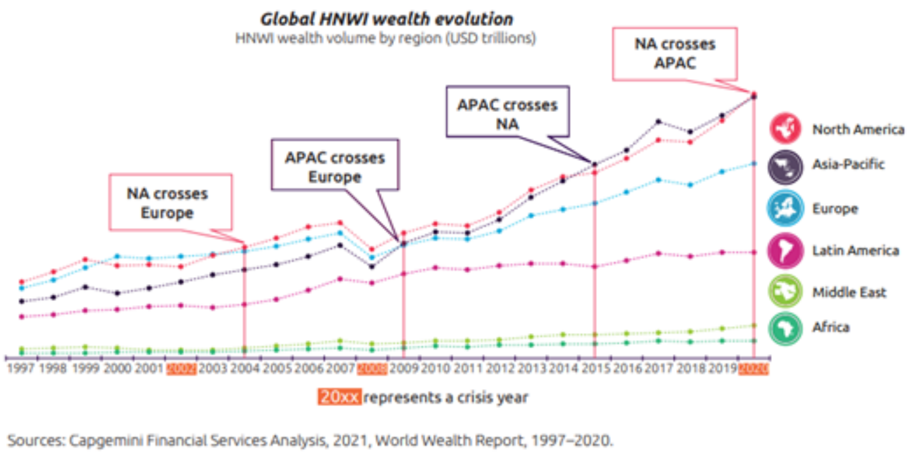

Figure 7: HNWI wealth evolution by regions from 1997 until 2020