



**Personal Healthcare
Empowerment**

Deliverable 1.2b

MARKET ANALYSIS & BUSINESS PLAN SPECIFICATION 2ND
VERSION

WP 1 – Use Cases
T1.2 Market and Business Models

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Glossary

Acronym	Meaning
%	per cent
\$	dollars
&	and
£	pounds
€	Euros
3D	Three Dimensional
5G	5th generation (mobile networks or wireless systems)
app	application
CAGR	Compound Annual Growth Rate
CARG	Compound Annual Growth Rate
CE	Communauté Européenne (French: European Community)
COPD	Chronic Obstructive Pulmonary Diseases
CORD	Chronic Obstructive Respiratory Diseases
D	Deliverable
etc	Et Cetera (Latin: And So Forth)
EU	European Union
GSM	Global System for Mobile communication
ILO	International Labour Organisation
iOS	iPhone Operating System
IoT	Internet of Things
IT	Information Technology
mHealth	Mobile Health
PHE	Personal Health Empowerment
US	United States
version	version
WHO	World Health Organisation
WP	Work Package

EXECUTIVE SUMMARY

This document is deliverable D1.2 from Personal Health Empowerment (PHE), “Market Analysis & Business Plan Specification”. D1.2 is the second deliverable of the WP1 of PHE project. This report describes the process by which market analysis has been performed (section 2 and 3) and business plan specifications have been derived (section 5).

The deliverable D1.2 studies the complete market for the PHE project, covering the perspectives of all the involved stakeholders and identifying the exploitable results. This will allow defining; identifying and proposing innovative business models. As a result, people will be empowered to monitor and improve their health using personal data and technology assisted coaching. In addition, other potential markets will be identified and analysed, and possible business models for them will be defined.

Deliverable D1.2 complements the content of five other Personal Health Empowerment (PHE), tasks:

- T1.1 Use cases and Requirements analysis
- T1.3 Ethical and privacy issues
- T2.1 Requirement Analysis
- T2.2 Monitoring
- T2.3 Analytics

These actions and their associated outputs will be gathered in D1.2 and will then act as input to the work package 2 activity, allowing to select the top use cases for detailed analysis, and then deliver worked examples of business model based on them.

1 Introduction

This introduction describes the overview to deliverable D1.2, the background to its work, and a description of the tasks at hand.

The Personal Health Empowerment project aims to achieve significant cost reductions for preventive solutions to help the person adopt a healthy lifestyle and providing the person with tools to actively participate in the treatment when diseases do arise by empowering people to monitor and improve their health using personal data and digital coaching. The solution will post notices based on the working hours of employees and the types of their jobs and the means of that solution working places will be healthier and workable. As a result, these will be causing to reduce the number of patients and decrease the burden on care personnel.

The main goal of this proposal is to empower people to monitor and improve their health using personal data and technology assisted coaching.

In this project, innovations that are expected to achieve specified at the below;

1. analytics on heterogeneous personal health sources to provide insight in the relation between behaviour and health,
2. methodologies to develop interactive, dynamic and personalised coaching programmes,
3. for healthier individuals, more fruitful workplaces
4. innovative motivating approaches for long-term adherence,

The results of the project include:

- Innovative technologies for vital signs, activity and behaviour monitoring
- Personal health analytics and visualisation tools
- Methodology and tools for the development of interactive and dynamic coaching programs (content & functionality)
- A modular reference framework for coaching application development and deployment
- Motivating self-care applications
- Healthy Workplaces
- Validated pilot with users in the target groups for lifestyle management
- Exploitation plans for partners including go-to-market plans with disruptive business models

The project innovations will have a large impact on healthcare provision in the future, providing both evidence and means to realise people-centric and preventive healthcare, and allow for cost-saving self-solutions with increased patient involvement. It will address societal challenges including ageing, rising dependency ratio, lifestyle-related diseases, and healthcare efficiency to provide care in a more personalised and efficient way.

1.1 Deliverable Scope and Objectives

This deliverable, D1.2, is prepared within the Work Packaged 1 scope which addresses user and business factors for the specification and exploitation of the solutions for PHE project. WP1 provides requirements and specifications to the technical WP2 and WP3 where monitoring and

analysis solutions and the coaching framework are developed. The use-case specific results are then piloted in WP4, and evaluation is fed back to the requirements specification and exploitation in WP1. WP5 manages the project and takes care of general dissemination. The dependencies between the work packages is shown in the figure below.

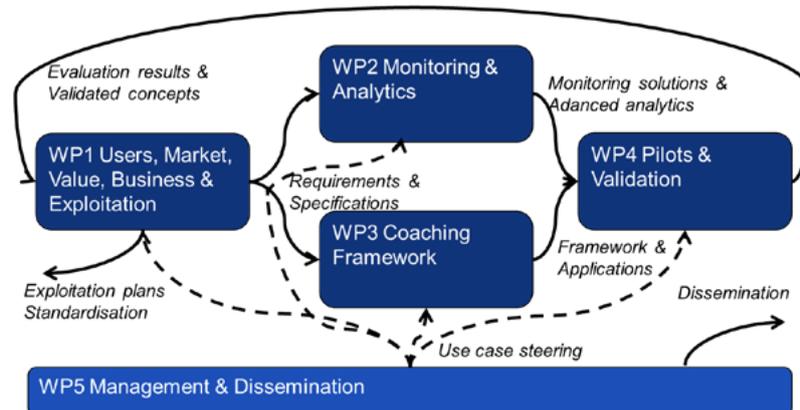


Figure 1: PHE WP interactions

Deliverable 1.2 covers the perspectives of all the involved stakeholders and identifies the exploitable results. This will allow defining; identifying and proposing adequate and innovative business models to smoothly introduce our solution into the market. As with the previous task, other potential markets will be identified and analysed, and possible business models for them will be defined.

Main objectives in this deliverable are:

- collaborate to come up with specific requirement analysis from the all uses cases and market perspective into a common framework.
 - the current market situation and business models will be reviewed
 - initial business models will be drafted to guide the development of the use-case driven solutions
- open new business opportunities using its Medical and Government reach to secure endorsement particularly for Healthy Workplaces and Lifestyle and Nutrition
- innovative mHealth technologies will be improve and validate for the CORD use case
- business models will be in adaptation to Turkey but in conjunction with the European approaches

2 State of the Art

The market for health applications continues to grow, however, these applications still have shortcomings and limits. Sometimes, user interactions can require considerable effort, causing the user to drop out. The assessment may not be in line with the expectations or the lifestyle of the users. In addition, not all the content can benefit all users, and getting users to download and engage with mobile applications is very complicated¹. Many smartphone applications are not based on behavioural change theories or guidelines (where these could have made a significant and positive difference, if applied)^{2 3}.

PHE has a competitive advantage in this respect, we have worked hard on the development of a personalized application (T3.2 is exclusively dedicated to the profiling of the user in order to provide him with personalized advice), as well as the recommendations provided by the coaching plans are oriented towards changing the user's behaviour. With the emergence of pandemic outbreaks, the market of health applications has received much attention in recent years, and people are willing to use such applications for controlling their health status. One of the major benefits of these applications is to reduce the presence of low-risk patients in hospitals and healthcare providers. The size of this market in Europe was worth 2.68 Billion USD in 2020 and is estimated to reach 8.68 Billion USD by the end of 2025 with a growth rate of 26.52% during the forecast period. One of the main reasons for this rapid growth is the use of the IT healthcare sector and health IoT devices over the past years. The impact of this market can be assessed from the following points of view:

- With digitized health records, patient behaviours and histories can be detected more effectively. Predictive analytics will separate patients at risk of crisis from chronic health conditions, providing doctors with the ability to have corrective action plans that minimize hospital visits, thus further decreasing the total cost of resources.
- HIMSS (Healthcare information and Management Systems Society) in Europe provides tailor-made services, related to the digitization of healthcare delivery, based on the individual needs of healthcare providers and health authorities, to interpret data and translate it into actionable outcomes.
- The market is powered by rising evidence-based operations and the transition from volume to value-based commissioning. As health budgets fall under pressure, states, payers, and other providers shift their approach from volume-based to value-based as treatment becomes more patient-centred. Therefore, value-based treatment moves the focus of the health system towards a more holistic outlook on patient health, linking departments to promote overall well-being.
- The availability of Big Data relating to health can have a positive effect on health and medical functions in Europe. Life expectancy is expected to rise further by 2025, according to the EU, and this could lead to more people living longer, but not necessarily

¹ Heron KE, Smyth JM. 2010. Ecological momentary interventions: incorporating mobile technology into psychosocial and health behaviour treatments.

² McTavish FM, Chih MY, Shah D, Gustafson DH. 2012. How Patients Recovering From Alcoholism Use a Smartphone Intervention. *J Dual Diagn.* 8(4), 294-304.

³ Riley WT, Rivera DE, Atienza AA, Nilsen W, Allison SM, et al. 2011. Health behavior models in the age of mobile interventions: are our theories up to the task? *Transl Behav Med.* 1(1), 53-71.

in a safe and active condition. This will place further pressure on the cost of healthcare and economic productivity in Europe.

- The market growth is supported by the effects of COVID-19. In response to the pandemic, health infrastructure involves free access to platforms, emerging tools for digital assistants, dissemination, and exchange of critical resources, and more. Telemedicine and other emerging methods to provide treatment are increasingly being embraced by patients and physicians.

This market is extremely competitive in nature, with many large and emerging players, mainly from the U.S., such as IBM, McKesson, Oracle, MedAnalytics, Cerner, OPTUM, Health Catalyst, SCIO Health Analytics, Wipro Limited, and VitreosHealth.

Regarding COR, great number of existing proposals already combine different machine learning techniques in order to monitor the health condition of the patient⁴⁵ [34-39]. In this sense, we have seen systems using techniques such as fuzzy classifiers and artificial neural networks⁶⁷⁸. However, these monitorization is mainly performed with the goal to analyse patient data and detect respiratory diseases or respiratory complications such as exacerbations⁹¹⁰ rather than understanding the profile (and associated behaviours) of the patient and anticipating further complications. This means that in some way most existing systems are less proactive and more reactive to the current health condition of the patient. Another issue which may compromise the usability of this kind of systems is that it often requires the use of multiple devices such as a smartphone solution combined with a digital spirometer to analyse respiratory function, which bring additional costs to the average user. With these points in mind, PHE project was designed to provide a solution which relies only upon the use of a smartphone and its embedded sensors to correctly monitor and capture patient data through the application of innovative monitoring algorithms.

Finally, there are relatively few studies on the efficacy (from a clinical and cost perspective) of smartphone applications and more research is needed to adequately address this issue. Evaluating some aspects of particular applications or types of applications may require a full clinical trial or evaluation study and the resources needed to conduct it, which goes far beyond what a single person or a few people can evaluate using a list of search criteria.

⁴ Labaki, W.W., Han, M.K.: Improving detection of early chronic obstructive pulmonary disease. *Annals of the American Thoracic Society* 15, S243-S248 (2018)

⁵ Spathis, D., Vlamos, P.: Diagnosing asthma and chronic obstructive pulmonary disease with machine learning. *Health informatics journal* 25, 811-827 (2019)

⁶ Agusti, A., Faner, R.: When Harry Met Sally, or When Machine Learning Met Chronic Obstructive Pulmonary Disease. *American Thoracic Society* (2020)

⁷ Badnjevic, A., Gurbeta, L., Custovic, E.: An expert diagnostic system to automatically identify asthma and chronic obstructive pulmonary disease in clinical settings. *Scientific reports* 8, 1-9 (2018)

⁸ Zarrin, P.S., Roekendorf, N., Wenger, C.: In-vitro classification of saliva samples of COPD patients and healthy controls using machine learning tools. *IEEE Access* 8, 168053-168060 (2020)

⁹ Gurbeta, L., Badnjevic, A., Maksimovic, M., Omanovic-Miklicanin, E., Sejdic, E.: A telehealth system for automated diagnosis of asthma and chronic obstructive pulmonary disease. *Journal of the American Medical Informatics Association* 25, 1213-1217 (2018)

¹⁰ Badnjevic, A., Cifrek, M., Koruga, D., Osmankovic, D.: Neuro-fuzzy classification of asthma and chronic obstructive pulmonary disease. *BMC medical informatics and decision making* 15, S1 (2015)

Within the PHE project we intend to contribute in this respect thanks to the pilots included in WP4.

3 Market Characterization

3.1 Key Trends

The market of mobile health apps is about to turn 10-years old. Although there were various digital health solutions prior, it was in 2008 that Apple enabled what is now a mass market for mobile health apps by launching its Apple App Store. Pending the perspective, 10-years can be considered a long or short period of time. In the traditional healthcare industry, 10-years is merely the time span for a product development cycle.¹¹ In the digital arena, 10-years is close to prehistoric. The two environments are very different, and yet, the fast-paced digital industry and the slow-paced healthcare industry have been colliding to produce digital health – bringing disruptive change to the market. After 10-years of market development, it is fair to say that some of the dust of early disruption has settled, and that some of the market leaders and lagers can be segregated by, for example, business models, monetization and marketing.



Figure 2: Timeline 2007-2017 of Google searches globally for the keyword “digital health” comparing users from the internet/telco industry and from the healthcare industry

In 2018 there were 325,000 health apps (health & fitness and medical apps) available on all major app stores and 78,000 new health apps have been added to major app stores¹².

The market for mobile health has been growing steadily over the last years and continues to do so. The mobile health (mHealth) market is forecasted to reach USD 115.61 billion by 2025 from USD 25.17 billion in 2020, showcasing a vibrant CAGR 35.65% during the forecast period¹³.

The app growth is fuelled mostly by an increase of Android apps. Android has seen a growth rate of 50% from 2016 to 2017¹⁴. In comparison, iOS health apps have increased by 20% within the

¹¹ The average time to develop a new drug is 10 years, Biopharmaceutical Research & Development, 2016

¹² Research2Guidance 2017 – mHealth Economics 2017/2018

¹³ <https://www.marketdataforecast.com/market-reports/mobile-health-market>

¹⁴ Research2Guidance 2017 – mHealth Economics 2017/2018

last year. Android has now overtaken iOS as the number one platform for health apps and has the greatest number of mobile health apps of any app store.



Figure 3: Number of mHealth apps displayed in App Stores

The aforementioned 325,000 mHealth apps equates to an expected 3.7 billion app downloads in 2017 (estimated). Compared to last year, this is an increase of 16%. The growth rate has picked up speed again when compared to the previous year, where the growth rate of app downloads was only 7%. The growth of download numbers is driven mainly by downloads from Android and iOS. Android contributes the highest share of mHealth app downloads in 2017 (estimation). Apart from Android and iOS all other platforms only play a marginal role.

3.7 billion mHealth apps represent the supply side of the mobile health app market. The demand for mobile health apps is fuelling the supply. The health industry is experiencing the same phenomenon as other industries before: The demand for apps fuels supply growth.

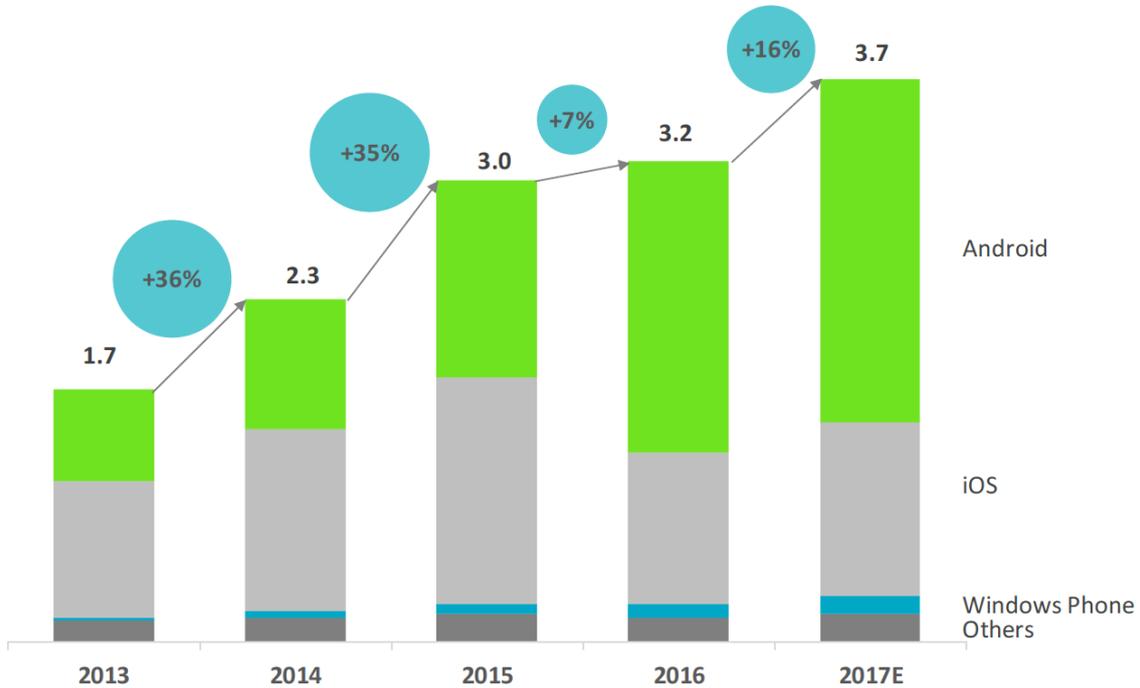


Figure 4: Estimated total downloads of mHealth apps (billions)

Growth rates of downloads have slowed compared to some years ago. App usage is still high but getting new downloads is a tough sell. The use of mobile apps is concentrated on 20 or fewer apps for the majority of app users. On the supply side, the number of app publishers continues to grow. The growing number of apps is fuelled by a growing number of app publishers. This year more than 84,000 app publishers are developing apps for the medical and health & fitness market.

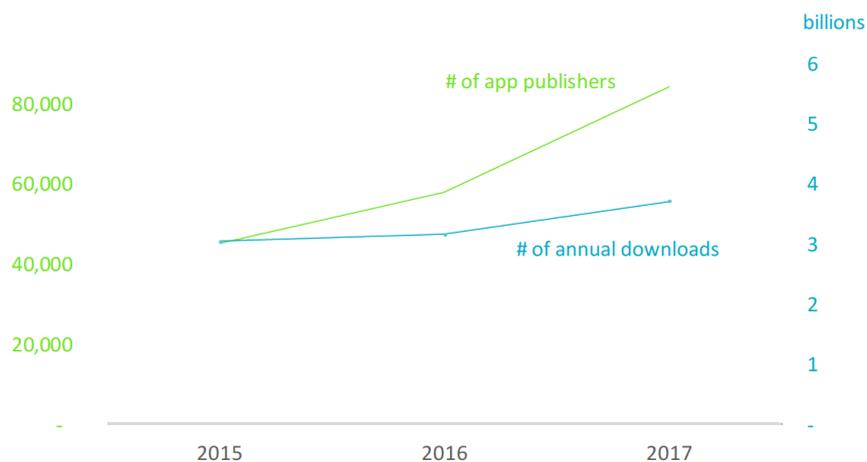


Figure 5: Number of downloads of health apps; number of health app publishers 2015-2017¹⁵

¹⁵ Research2Guidance - mHealth App Developer Economics study 2017 - n = 2,400

With the introduction of new digital technologies, new markets can emerge, and entire industries can be reshaped. Artificial Intelligence, Blockchain, Internet of Things, 3D printing are the technology buzzwords floating around in 2017, and their impact on nearly every industry are currently, and set to further disrupt the healthcare industry.

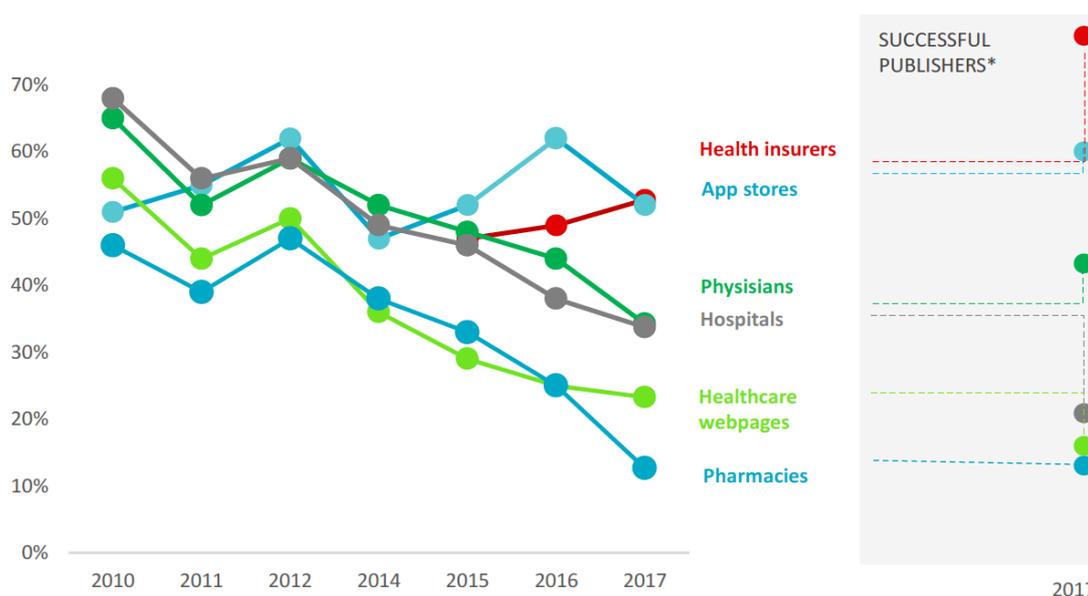


Figure 6: Distribution channels with best market potential in the next 5 years

The technologies with the perceived most disruptive potential in the next 5 years is artificial intelligence and remote monitoring. Wearables, IoT (Internet of things) Virtual reality, 3D printing and Blockchain are next in the ranking, leaving 5G as the least disruptive.

Successful mHealth publishers are more bullish about new technologies than the average mHealth publisher. They bet on nearly all technologies to a higher percentage. Especially remote monitoring, IoT and virtual reality. However, they are less optimistic about wearables.

Whilst the market for digital health is still young and quickly changing, a number of digital health stakeholders have established themselves by developing products and services with a strong concept and business model. Since most mHealth publishers are rather new to the market, these established and successful stakeholders can serve as best-in-class or role models and pave the way for the new breed of digital intruders.

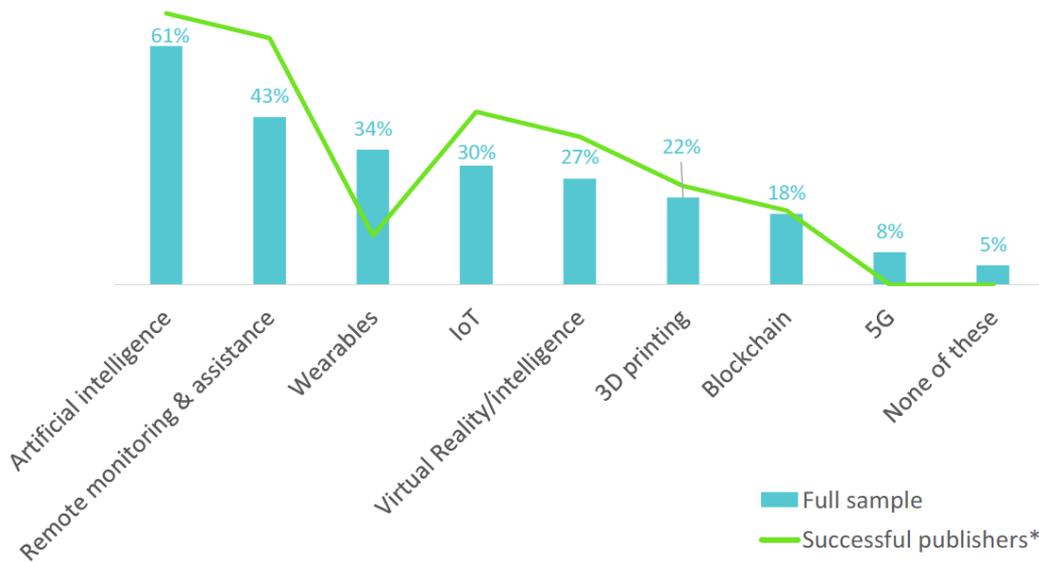


Figure 7: Most disruptive (Trend) technologies to the data health sector within the next five years

Medical applications have achieved an important place in the world with personal assistance. People's supply of digital health apps keeps the market strong and up to date. It is estimated that the rate of demand for applications in the market will increase rapidly. This assumption is supported by the graph below.

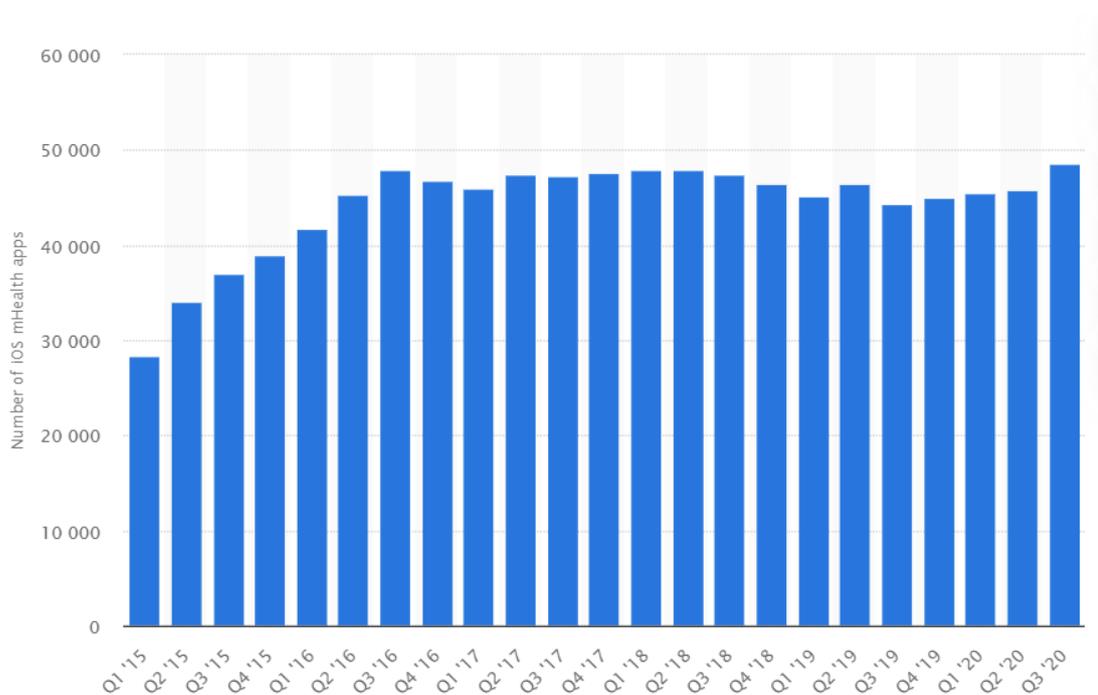


Figure 8: mHealth in the App Store from the first quarter of 2015 to the third quarter of 2020

This statistic displays the number medical apps available in the Apple App Store worldwide from the first quarter of 2015 to the third quarter of 2020. During the last measured period, there were 48,608 iOS healthcare apps available, representing 6.15 percent increase over the previous quarter¹⁶.

3.1.1 Impact of Covid-19 on the Market

The COVID-19 pandemic has affected the number of smartphone sales worldwide. According to Gartner, a decline of 20.4% in the number of sales to end users has been observed in the second quarter of 2020. The same source refers to these numbers as a result of “Travel restrictions, retail closures and more prudent spending on nonessential products during the pandemic led to the second consecutive quarterly decline in smartphone sales this year.”. The detailed numbers among the Top 5 smartphone brands are shown below:

Vendor	2Q20 Units	2Q20 Market Share (%)	2Q19 Units	2Q19 Market Share (%)	2Q20-2Q19 Market Growth (%)
Samsung	54,759.4	18.6	75,111.8	20.3	-27.1
Huawei	54,125.0	18.4	58,055.7	15.7	-6.8
Apple	38,386.1	13.0	38,522.9	10.4	-0.4
Xiaomi	26,095.2	8.9	33,250.7	9.0	-21.5
OPPO	23,612.1	8.0	28,070.2	7.6	-15.9
Others	97,692.1	33.2	137,282.5	37.1	-28.8
Total	294,669.9	100.0	370,293.9	100.0	-20.4

Figure 9: Top 5 Smartphone Brand Sales between 2019 and 2020

Although the number of smartphone sales has decreased during 2020, the interest for mHealth technologies and applications has increased significantly. In fact, Market Research has published a recent study¹⁷ analysing the global Digital Health Market size affected by COVID-19 and concluded that the pandemic could hasten the adoption of many digital health technologies for the upcoming years. In this sense, it is noticeable how the pandemic contributes to digital healthcare awareness improving stakeholder credibility and driving favourable factors for market growth. The numbers stated in this study refer that the global market of digital healthcare would considerably rise at a rate of 26.30% and would expect to gain revenue of USD 3, 28,887.8 million by 2025. Therefore, the impact of digital technology in the healthcare industry has contributed significantly for end-user to become used and rely on digital health applications. As major areas of application within the healthcare sector, these applications are being progressively implemented to perform remote monitoring for chronic disease and access electronic medical and personal health records through broadband and mobile. PHE should play close attention to these numbers as there is an evident increase of interest to use Digital Health technologies, especially in the context of chronic disease intervention. Several studies confirm a sudden increase in the number of mHealth applications developed for respiratory

¹⁶ <https://www.statista.com/statistics/779910/health-apps-available-ios-worldwide/>

¹⁷ <https://www.marketresearchfuture.com/reports/digital-healthcare-market-7636>

monitorization that have been released in the market over the last year¹⁸ which could become potential competitors of PHE CORD Management Use Case.

The escalating number of Covid-19 cases across the world is also demanding the increase of mHealth market. Social distancing is requesting the adaptation of digital health services during the Covid-19 pandemic and the mHealth market is likely to increase. The 48% of healthcare consumers are using mHealth apps and the number is expected to increase disruptively due to Covid-19.

With the spread of the COVID 19 epidemic worldwide, people have shown great interest in mobile health applications. Due to the high transmission rate of the epidemic, they preferred mobile health applications by receiving remote support instead of going to the hospital for health services and a healthy life. While digital assistants are used for the new normal with social distance, they also play an active role in improving the quality of life with health practices. As a global range of applications while supporting Turkey's process, "Hayat Eve Siğar" app aims to fill this gap.

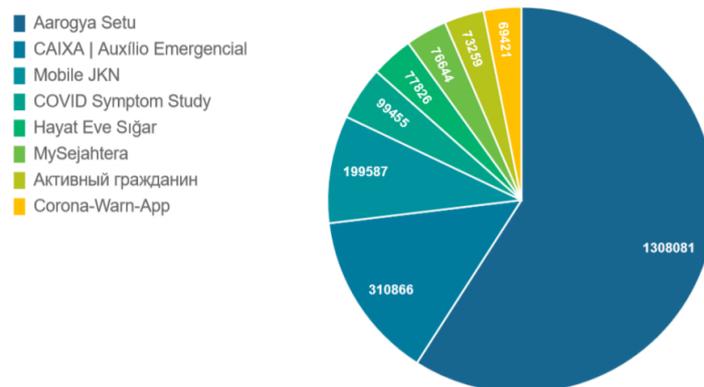


Figure 10: Top 8 most rated COVID-19 related in Google Play

¹⁸ Ming, L.C., Untong, N., Aliudin, N.A., Osili, N., Kifli, N., Tan, C.S., Goh, K.W., Ng, P.W., Al-Worafi, Y.M., Lee, K.S.: Mobile health apps on COVID-19 launched in the early days of the pandemic: content analysis and review. JMIR mHealth and uHealth 8, e19796 (2020)

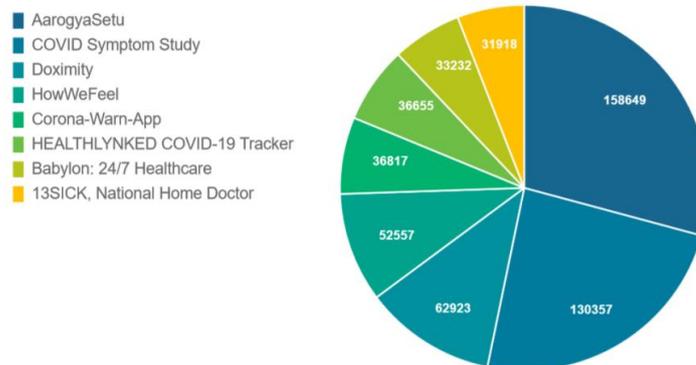


Figure 11: Top 8 most rated COVID-19 related in App Store

Statistics with an indication of the apps that attracted much interest are as below. The number of user ratings each app received, and the results are shown in Figure 10 and Figure 11, with the top 8 most rated COVID-19 related apps in Google Play and App Store, respectively (notice that “most rated” does not mean “best rated” - rating often comes out because of bad user experience).¹⁹

3.2 Stakeholders

In this section we tried to identify different customers, groups and institutions that may be interested in PHE project results. It is important to have a clear view of all potential stakeholders and understand their goals, interest and influences to identify proper communication channel and marketing strategies.

PHE potential stakeholder have been classified into the following types:

- Potential adopter / Client / End user: Clients and or end users of PHE technologies and tools
- Significant Promoter: Promoter o supporter with considerable influence towards other stakeholders. Helpful to increase visibility, be trusted by clients, etc.
- Interested Party: Any entity or organisation interested in PHE solution and technology (competitor and/or adjacent solutions provider, governmental bodies, other projects...)

For each PHE use case a specific analysis is being performed.

3.2.1 Use Case 1: Workplace

As known, Experis IT belongs to the multinational corporation ManpowerGroup and therefore has a great commercial capacity behind it.

As potential adopters/clients/end users: Experis IT will be the first adopter, thus the closest stakeholder is Manpower’s Occupational Health Department, which has been involved in the process since the beginning of the project. Moreover, Manpower has significant clients of continuity in the IT sector (IBM, Microsoft, HP, CSC or Cisco) and in other sectors (Iberdrola,

¹⁹ https://ec.europa.eu/jrc/communities/sites/jrccties/files/covid-19_techncial_report_-_final.pdf

Endesa, Repsol, Bankia, BBVA, Santander Mapfre, Fugitsu, Siemens, Roche or Telefonica), that are potential customers for the PHE Healthy Workplace solution.

Manpower also has a strong communication potential that will be used to arouse the interest of other promoters (mHealth gurus, specialised media, etc.), as well as other interested parties.

3.2.2 Use Case 2: CORD

CINTESIS and ISEP-GECAD are research centres working closely to a diversity of companies and associations. CINTESIS has established partnerships with 17 health units (for example, Centro Hospitalar São João, IPO-Porto, CUF-Porto). MEDIDA has licenced products to Portuguese and European companies in the past (mostly from the pharmaceutical industry) and, in Portugal, it has access to end users such as patient (APA and RESPIRA) and professional (SPAIC, GRESP, SPPN and SPP) associations and the leading private healthcare provider group (CUF).

3.2.3 Use Case 3: Pain and Infection

Turkey is a transcontinental Eurasian country, located at the crossroads of Europe and Asia which makes it a country of significant geostrategic importance. The Turkish consortium is formed by leading firm (ARD GROUP) in Medical Process Tracking and Infection Control Systems and leading firm (MANTIS) in redesigning the ontology platform to handle different sources. ARD GROUP is the first Turkish Software Company to collaborate with 3M Infection Control Solutions and they developed software branded and sold by 3M Global offering complete management of sterilization process for hospitals of all sizes with full instrument tracking integration. ARD GROUP's customer base and MANTIS' s successful Industry 4.0, deep learning, big data analysis and analytics, ontology experience will play an important role in the development and dissemination of the project together.

3.3 Target Markets

3.3.1 Healthy Workplace

Worldwide, there are 3.2 billion workers who spend one-third or one-half of their waking hours at work. Many are often stressed, at risk and facing economic insecurities. The Global Wellness Institute in its report (2017) states that “unwellness at work is a global epidemic suffered by billions of workers and costing the world’s economy 10-15% in output”²⁰.

In addition, companies are also facing the “silver tsunami” that started in 2011 and will continue until 2030. Workforce is ageing due to demographic change and the proportion of elderly employees is significantly increasing. The European Labour Force Survey data indicated in 2017 that workers over 55 represented 16% of the total labour force in the European Union²¹.

²⁰ Global Wellness Economy Monitor - January 2017 (Global Wellness Institute)

²¹ Employment and unemployment (LFS), (Eurostat, 2017)



Figure 12: World Workforce Increasingly Unwell. Source: Global Wellness Institute Information

European citizens are living and working longer. However, ageing is accompanied by an increased risk of developing health conditions, which means that chronic diseases are increasingly common in the workplace. Currently, in Europe, chronic diseases such as cardiovascular disease, mental health disorders or depression affect around 33% of older workers²² and the majority can be prevented or controlled by simple changes in lifestyle or living conditions.

In summary, the biggest challenges faced by organisations these days include work-related injuries or illnesses, chronic illnesses, absenteeism y. The strong impact this has on employers' medical expenses and employee productivity is forcing European organisations to improve the management of their companies' health and well-being.

According to Health and safety statistics from the UK Government 1.3 million working people suffer from a work-related illness (2016/17). The cost of injuries and ill health from current working conditions is estimated to be £14.9 billion (2015/16)²³. Hence, building a healthy workspace is not only of worker's interest but also beneficial for their companies. Research shows every Euro invested in Work Health Promotion leads to Returns on Investment (ROI) between €2.5 and €4.8 due to reduced absenteeism costs²⁴.

Workplace wellbeing programmes or interventions are intended to improve employee's health status and encourage them to adopt a healthier lifestyle. At the same time, wellbeing coaching services can help companies to augment their productivity while reducing operational costs.

²² Rehabilitation and return to work after cancer – instruments and practices – May 2018 (EU-OSHA)

²³ Health and Safety Executive Statistics: <http://www.hse.gov.uk/statistics/>

²⁴ Workplace Health Promotion for Employers – 2013 (European Agency for Safety and Health at Work)

There are already references to several success stories, examples of good practice already in place^{25,26}.

There is a clear market opportunity on health and wellbeing in the occupational sector. In recent market research, the global workplace wellbeing market size was valued at \$50.2 billion for 2017 and expected to grow at a CARG of 6.8% from 2018 to 2025²⁷. Currently, there is a widespread commitment to health and wellbeing at workplace, both on a personal and business level, which in turn is generating significant market growth²⁸. Numerous businesses and companies in various industry sectors have started to implement wellbeing programs for their employees that will also drive market demand.

At present (2017) the US and EU are dominating the market (Figure 13) and they will likely receive the highest revenue, due to their government policies and high health care expenditure. In the US there are more than 550 organizations who offer wellbeing programmes to their employees and the EU is following the lead.

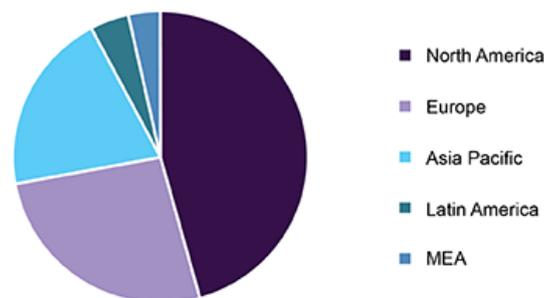


Figure 13: Global corporate wellness market share, % by region (2017)

Source: Grand View Research.

According to CDR Foundation⁶ workers in the U.S. face the following serious health challenges:

1. Stress is the first workplace health issue and major occupational riskⁱⁱ.
2. Sleep disorders may lead to low productivity and/or safety incidents that can ultimately affect the company's profitability²⁹.
3. Costs of lost productivity because of chronic pain range from \$11.6 to \$12.8 billion annually³⁰.
4. Diabetes: Medical costs for people with diabetes are twice as high as for people without costs for people without. This could lead to economic stress.

²⁵ European Agency for Safety and Health at Work (March, 2016): Northumbrian Water Group 'Wellbeing Programme'.

²⁶ European Agency for Safety and Health at Work (December, 2015): Assisting companies in taking better account of chronic diseases in workplace: France.

²⁷ Corporate Wellness Market Size, Share & Trends Analysis Report 2018-2025 - July 2018 (Grand View Research).

²⁸ 10 Workplace Trends You'll See In 2018 (Forbes, November 2017)

²⁹ Moore-Ede, 2011; Rosekind et al. 2010; Sirois, 2007

³⁰ NIH, 2008



5. Obesity: Growing urban populations and sedentary lifestyles increase the risk of obesity in the population and among workers. Full-time workers in the United States who are overweight or obese and have other chronic health problems lose about 450 million more days of work than healthy workers, costing them more than \$1 billion³¹.
6. Heart disease & Stroke: Heart disease and stroke are among the most widespread and costly health problems facing our nation today. Treatment of these diseases accounts for up to \$1 of every \$6 spent on U.S. health care⁸.
7. Tobacco use: Smoking is the leading cause of preventable death in the United States, accounting for one in five deaths every year³²

All over the world, many corporations have implemented different welfare initiatives for disease prevention in order to improve productivity. They offer specific services targeted at the major health risk factors identified (Figure 14).

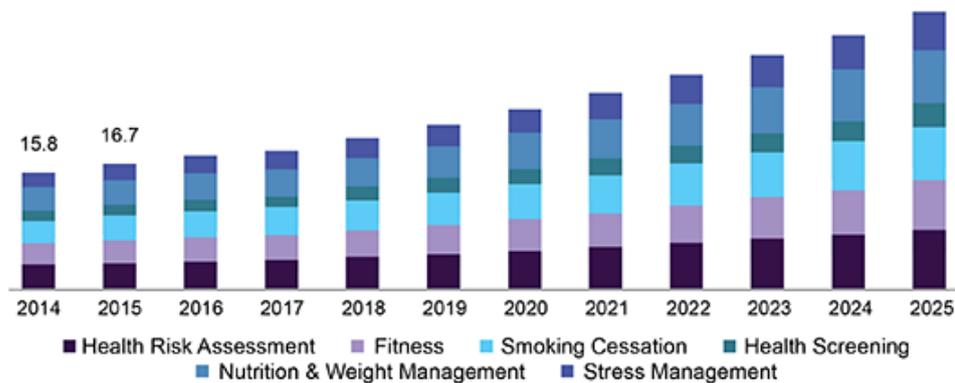


Figure 14: US corporate wellness market size by service in USD billion (2014-2025).
Source: Grand View Research.

Workplace wellbeing is no longer reduced to health scanners and gym membership reimbursement. According to the USC, current major trends in workplace wellbeing are driven by technology. Offering workers a wearable or a similar tool, without proper coaching, does not solve the problem either.

Experis has detected a significant business opportunity here and it is aiming at exploiting the results obtained in this project both internally and as a provider to other corporation who are current clients.

IDewe can also improve its services concerning supervision and monitoring employees' health and wellbeing (especially those services focusing on employees with (ongoing) musculoskeletal complaints and pain). The services of IDEWE are strongly focused on prevention and based on a multidisciplinary approach and they are continuously adjusted to new evolutions and developments in the field. That will have a positive impact on IDEWE's customers (employers

³¹ Gallup-Healthways Wellness Index, 2011

³² Centers for Disease Control and Prevention (accessed 2018 Oct), *Smoking & Tobacco Use*.

and their employees) and probably results in an increased company turnover. It will ultimately lift health and safety prevention at work to a higher level. Therefore, this project will be of added value for IDEWE as well as for Flanders/Belgium, and even has the potential to become an example of good practices in Occupational Health and Safety (OHS) prevention worldwide.

3.3.2 CORD management

Worldwide, more than 1 billion people suffer from chronic respiratory diseases³³ and, in Europe, the total annual cost of respiratory diseases amounts to more than €380 billion³⁴. CORD are high-burden chronic diseases throughout the life cycle - asthma starting from early life and COPD from the middle-age onwards. CORD is already the 3rd leading cause of death and the 5th cause of hospitalisations due to disease both worldwide³⁵. The joint market and global COPD and Asthma was placed in 2016, according to the market analysis company Visiongain, in \$32,900 million, with a compound growth rate forecast of 5.6% per year for the next 5 years. According to GlobalData, for 2015, the volume of the 8 largest markets (United States, France, Germany, Italy, Spain, United Kingdom, Japan and Australia) for COPD was \$9,900 million. Research & Markets estimates that in 2016 for those 8 indicated markets could there are up to 109.3 million people with COPD or asthma.

This poses CORD as a public health problem with increasing demands on healthcare systems and thus there is a growing market demand for solutions which can help to reduce costs, while maintaining quality of care.

Patients with CORD are continuously at risk of deterioration of health, requiring regular medical check-ups and monitoring of their health status. Traditionally health care is delivered through clinicians' face-to-face interaction. With the growing prevalence of CORD and continuous pressure from healthcare authority's/insurance companies, an increasing number of patients is being managed at home in their own environment and most of the time being left alone with traditional self-management materials (books, leaflets, videos, and web-based technology). Coaching solutions appear to be an ideal platform to deliver both simple and effective self-management interventions, while maintaining/improving quality of care and reducing costs. mHealth technologies for CORD should involve monitoring and managing signs and symptoms of the disease, empowering patients to recognize the early signs of exacerbations and to develop skills to better manage their disease.

mHealth can help to address this societal challenge. The market trends support this hypothesis. According to P&S Market Research, in 2015, the global mHealth market represented US\$13,674.3 million, and it is expected to grow at a CAGR of 34% until 2022, with the mHealth application segment experiencing the fastest growth.

³³ Forum of International Respiratory Societies. (2013). Respiratory diseases in the world: Realities of Today – Opportunities for Tomorrow (pp. 1-34). Sheffield: European Respiratory Society.

³⁴ European Respiratory Society. (2013). The economic burden of lung disease In G. Gibson, R. Loddenkemper, Y. Sibille & B. Lundbäck (Eds.), The European Lung White Book (pp. 16-27). Sheffield: European Respiratory Society.

³⁵ Observatório Nacional das Doenças Respiratórias. 11º relatório do observatório nacional das doenças respiratórias: Prevenir as doenças respiratórias acompanhar e reabilitar os doentes, 2016. Available from: www.ondr.pt.

The Research2guidance expects that mHealth app market reach US\$31 billion in 2020, 2.6 billion app users downloading an mHealth app at least once and 551 million of these app users being active users. Moreover, according to PricewaterhouseCoopers and the GSM Association, Europe will be the largest mHealth market in 2017, *with revenues of US\$6.9 billion. This is mainly related to growing aging population, increasing prevalence of chronic diseases, and increasing healthcare cost in Europe.*

Smartphones remain the leading device for app development. Smartphone sales from 2013 to 2016 represented US\$53.6 billion in Western Europe and US\$16 billion in Central and Eastern Europe. In fact, in Europe, a median of 60% of adults now own a smartphone³⁶ and in line with the trends observed in Americans, ownership is rising among older adults (27%)³⁷. Patients with COPD follow the trend observed in the general population. In a sample of 103 patients with COPD, 41% reported owning a smartphone and 49% preferred to report their daily symptoms using app on their personal smartphone³⁸. Also, in a sample of 46 adults with asthma, more than 80% were willing to use mobile technologies to self-monitor and self-manage³⁹. These results show that patients with COPD are willing to use mobile phones and apps to manage their disease.

There is a growth potential market for COPD mobile applications. According to a 2015 study on the most widely used mHealth apps by consumers, it was observed that disease and treatment management comprises only 1/4 of mHealth apps, with only a small share being specific to a particular disease⁴⁰. In addition, a review comparing mobile apps for the leading causes of death among different income zones, found that those referring to COPD represented less than 10% of apps in middle-income and high-income countries⁴¹. Moreover, the majority of COPD apps were informative and guides for healthcare professionals and some COPD trackers and apps for learning to use inhalers. Regarding asthma, the proportion of apps in line with international guidelines is low (about 25%), and the majority only provide basic information on asthma (50%) or diary functions (24%)⁴². The feature to send data for the health professional is also not available in most apps for COPD and asthma. But this feature may enhance disease control by allowing the health professional to have access to up-to-date and accurate data regarding its patients and to make treatment plan adjustments.

³⁶ Pew Research Center, February, 2016, "Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies"

³⁷ Pew Research Center, February, 2016, "Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies"

³⁸ Laura Khurana, Ellen M. Durand, Sarah Tressel Gary, Antonio V. Otero, Chris Hall, Kelsey Berry, Christopher J. Evans, Susan M. Dallabrida, Valdo Arnera (2016) Patient preference for using computers, smartphones, and internet to participate in COPD clinical trials. *European Respiratory Journal*, 48:PA2899.

³⁹ Fonseca, JA et al, 2006. Asthma patients are willing to use mobile and web technologies to support self-management, *Allergy*, 61(3), pp. 389–390.

⁴⁰ Mevvy, June 2015; IMS Health, AppScript, June 2015; IMS Institute for Healthcare Informatics, August 2015.

⁴¹ Martínez-Pérez B, Torre-Díez I, López-Coronado M, Sainz-De-Abajo B (2014) Comparison of Mobile Apps for the Leading Causes of Death Among Different Income Zones: A Review of the Literature and App Stores. *JMIR Mhealth Uhealth*, 2(1):e1.

⁴² Huckvale, K et al, 2015. The evolution of mobile apps for asthma: an updated systematic assessment of content and tools., *BMC Medicine*, 13, p. 58.

There is, therefore, much room for the development of personalised, mHealth solutions for objective self-monitoring and self-management of CORD. Indeed, citing research2guidance “remote monitoring is the app category offering the greatest market potential over the next 5 years”. Another aspect that was clear from this review was that there is more work done in the commercial field (38 apps) than in the research field (23 papers), showing that a number of mobile solutions have been developed poorly grounded in research and detached from clinical practice. However, an important element to create a successful and useful applications, is to conduct research engaging end users on the design, usability and reliability of the system. Rigorous research to test apps effectiveness and acceptability in the CORD market are still lacking and this use case can give an important contribution in this field.

3.3.3 PHE Customer Segments

3.3.3.0 Use Case 1: Workplace

From 2016 to 2017, health care costs increased for 79% of organizations⁴³. Thus, it is no surprising that employers are seeking for possible ways to reduce costs. One of the most effective strategies to lower health spend is by implementing a corporate wellness program.

In the United States, employee wellness is already a big business and it is growing in Europe too. More than nine in ten organizations offer at least one wellness initiative. More than three in five (63%) have budget devoted to wellness and over half of them (51%) expect this budget to increase in the next two years. In addition, one in nine organizations without wellness budget, expects to adopt one in the next two years⁴⁴.

More than half of employers who are already offering and measuring their wellness efforts have reported a decrease in absenteeism, 66% experienced an increase of their productivity and the 67% indicated their workers are more satisfied⁴⁴.

Corporate welfare is a thriving market and large corporations play a key role in the dissemination or real improvement of wellness programs. This is reasonable as it is large corporations that have ample human and financial resources to identify and implement welfare strategies.

PHE Healthy Workplace is aiming at developing and testing a Personalised Virtual Coach that will help to improve the health and well-being status of its users (employees) while avoiding future development of further affections. This particular use case is led by Experis(ManpowerGroup) and at first it will be customized and tested for its internal usage as an in-house improved and more innovative ManpowerGroup wellness program. Secondly, it is planned to license the SW developed for other interested companies to implement the PHE Healthy Workplace in their organisation.

ManpowerGroup has a great commercial capacity. It has a strong global presence, operating in 75 countries with 3,100 offices worldwide (more than 120 just in Spain) and over 400,000 customers. Focusing on Experis IT, it is present in 54 countries with 400 offices all over the world.

⁴³ SHRM (2017) Employee Benefits Report.

⁴⁴ International Foundation of Employee Benefit Plan (2018) Workplace Wellness Trends: 2017 Survey Results Report.

Experis IT group has significant clients of continuity in the IT sector (IBM, Microsoft, HP, CSC or Cisco) and in other sectors (Iberdrola, Endesa, Repsol, Bankia, BBVA, Santander Mapfre, Fugitsu, Siemens, Roche or Telefonica), that are potential customers for the PHE Healthy Workplace solution.

It is expected that PHE Healthy Workplace main clients will be large enterprises that are looking to implement a wellness program for the first time or wishing to improve their existing program. (As mentioned above, large companies have greater resources to undertake this type of programmes). However, recent studies highlight that the development of wellness in small and medium-sized companies is the future⁴⁵ and therefore they will also be considered as potential target customers in the future.

3.3.3.1 Use Case 2: CORD

The main objective of the CORD use case is to develop and validate innovative mHealth technologies for objective self-monitoring of lung function parameters and computerized respiratory auscultation. The main market goal and economic valuation is the licensing of these developed technologies to be used in products of other companies. This licensing market includes not only other mHealth companies, but mainly pharmaceutical and medical device companies and companies of other healthcare technologies that are investing significantly in solutions that increase the amount and quality of data available to demonstrate efficacy (clinical trials) and effectiveness (real-life and post-release studies) of their products. This market goal, which is based in agreements between pharmaceutical companies and mHealth companies, is a reality in today's market, where we find several examples of successful partnerships such as Pond Healthcare Innovation and Novartis (MedCityNews (a)); Propeller Health and GlaxoSmithKline (MedCityNews (b)); the company Welby and Johnson & Johnson (MobiHealthNews (a)), among others. The developed technologies have high potential of transforming CORD health care and may be of high value to a set of stakeholders in the health care system - funders, health care providers and health technology providers. The remote monitoring technologies and strategies to promote behaviour sustained changes will promote a better control of CORD, with potential to reduce exacerbations and the unscheduled visits to health services (emergency, hospitalizations) and avoid unnecessary escalation of the level of treatment, with consequent reduction of costs and increase of clinical quality. Based on this impact on health care, it is expected that health care providers will have a direct and immediate interest in the developed solutions given the need to use the respiratory function laboratories for the initial evaluation (and then during the usual follow-up process of the patient). In fact, it is expected that the advanced signal processing algorithms will be considerably more accurate when there is an initial comparison between the values of the respiratory parameters obtained with a spirometer and the mHealth solution. Thus, in addition to health technology companies (in particular the pharmaceutical and medical device companies), funders (e.g. health insurers) and health care providers are also potential direct customers. The increased potential of these monitoring technologies when combined with the coaching component will allow the project to deliver a validated prototype to be used by the patient. So, patients will also be possible clients.

⁴⁵ Merrill RM. Small Business Worksite Wellness. *JOEM*. 2012.

4 Competitive Analysis

4.1 Competing products/services

Analysis of the existing products / services that are offered in the market at present for each use case.

4.1.1 Use Case 1: Workplace

Nowadays in the market, there are different approaches to Corporate Wellness solutions, all of them sharing the same final aim - to promote or maintain employees' health status-.

Originally this type of service was only focused on monitoring users' activity through wearables. Today we are aware this is not enough, and more comprehensive tools are being developed.

Currently most of the solutions developed to improve or manage the health of workers focus on reactive solutions. They are usually associated with insurance companies and allow the management of appointments, prescription of medicines, etc. (for example Health Assure-Health Pass; zinkware, Chiron Prevention, etc.). Others also have a greater focus on the prevention of occupational risks, allowing for the formalization of parts, etc.

Anyhow, none of them has a personalized and preventive approach with the aim of preventing employees from developing future illnesses thanks to the improvement of their current health.

The most innovative market players are focusing on the development of platforms/apps that provide personalized information about users' health status and establishing and monitoring goals linked to their health status.

The inclusion of digital portals helps data collection, online reporting, faster delivery of results and provision of tools such as articles and videos is driving the growth of Corporate Wellness. Previously this work was only possible through e-mails, posters, newsletters or face-to-face interactions.

In particular, **PHE Healthy Workplace** will provide the following functionalities:

1. Obtain a personal analysis of the user (employee) health status, helping to identify their strengths and weaknesses, as well as the most deficient well-being areas or those that require special attention.
2. Provide personalised health recommendations in line with users' health deficits.
3. Set of personalised goals based on specific challenges.
4. Behaviour / Activity monitorisation for performance tracking.
5. Customised education and recommendations for each user as his/hers needs transform.

In the international market there are similar solutions to PHE currently being introduced, such as sprout in the Canadian market. Sprout, like PHE, focuses on reducing absenteeism through the strengthening of well-being and the acquisition of healthy habits. However, sprout emphasizes the social aspect and gamification rather than personalized recommendation and the accomplishment of challenging health goals.

Other solutions such as Limeade or Healthain are also focused on improving employee welfare, but not so much in a personalized way but as a vehicle for employees to get involved in the company.

There is also a wide variety of non-integral applications focusing on a particular aspect, for instance, Unit4 is specialised in identifying the major causes of absenteeism in a company.

Company and Location	Product	Price	Strengths	Weaknesses
Virgin Pulse , UK/Ireland	Cloud, SaaS, Web / Mobile: Android & iOS	Not available (pay for all employees / pay for users)	Quite complete and simple to use	Some Programmes only functional on the portal / many bugs reported.
sprout , Canada	platform / app / wearable compatible	Not available	Centred in engagement	Lack of personalisation
Limeade , USA	Cloud, SaaS, Web / Mobile iOS	Not available	Based on employee engagement offering Health & Wellbeing programs	Poorly focused on health and wellness issues
Healthain , USA / EU(Germany)	SAP Cloud Platform / HCP App services	Not available	Quite complete and customizable	Lack of personalisation; only available on the SAP HANA App Centre
CoreHealth , Canada	Cloud, SaaS, Web / Mobile: Android & iOS	Not available	Quite Complete & Good level of customization for the company	Lack of personalization in recommendations to the user
Biwel , Spain	Web platform / Mobile Android / wearable compatible	Not available	Quite Complete and customizable for company convenience	It seems to give a lot of information but forgets employees' engagement
Inithealth , Spain	Web platform / Mobile: Android & iOS/ wearable compatible	Not available	Good level of customization for the company	Lack of personalization in recommendations to the user

Table 1: Healthy Workplace use case main competitors

Actual prices charged by our competitors are difficult to find. They usually offer subscription plans (98% according to GetApp) and their estimated price is around \$120 per month.

4.1.2 Use Case 2: CORD

Companies that are launching potentially competing CORD monitoring solutions rely mostly on devices connected to mobile phones and not on the use of mobile phones' embedded sensors for data collection. Thus, the developed technologies in the CORD use case has significant potential competitiveness given the rapid spread it allows and the low costs associated with software-only solutions. The demonstration of this reality is visible in the review of the National

Institute for Health Research Horizon Scanning Research and Intelligence Center Work Program (Dixon et al., 2016), where they evaluated the latest technologies of respiratory function monitoring. Three portable spirometers with connection to the smartphone were identified (MySpiroo - Poland, MIR Smart One - Italy, Smartphone spirometer - USA). These spirometers were considered promising technologies due to the high degree of innovation, the potential impact and adoption by the National Health Service of the United Kingdom and because they were considered acceptable by patients. A number of competing solutions for automatic respiratory function analysis using smartphones have also emerged outside Europe, such as SpiroSmart (USA) (Larson et al., 2012) and the BKSpiro (Vietnam) (Tran et al., 2015). However, as far as we can see, these solutions are being developed in academic context and none are commercially available. SpiroSmart is the solution that is in a more mature phase of development, with a database of 4000 patients and is currently in the process of approval of the Food and Drug Administration (Comstock n.d.). However, it lacks the ability to analyze data in real time and the models implemented are generic, not customizable to the characteristics of the patient. Regarding computerized respiratory auscultation, some potentially competing solutions have emerged that integrate the connection of a stethoscope to a smartphone, such as CliniCloud Stethoscope (CliniCloud) (USA and Australia) and the solution proposed by Chamberlain et al., 2015 (USA and India). However, we did not find solutions that use only the built-in smartphone sensors. MEDIDA is in a privileged position because it was one of the first companies in the world develop a solution based solely on software using the smartphone embedded sensors, avoiding what has been the strategy of mHealth companies to use additional connected equipment to mobile devices. This market represents a valuable opportunity, in which there is plenty of room for the development of mobile health solutions, customized and allowing self-monitoring and self-management. We do not know marketing solutions that are similar to those proposed in the CORD use case.

Company and Location	Product	Price (€)	Strengths	Weaknesses
HealthUp - Poland ⁴⁶	MySpiroo+app	400	Complete spirometer test; Device bluetooth connected	External device needed
Medical International Research - Italy ⁴⁷	Smart One+app	150	Record Peak Flow and FEV1; Device bluetooth connected	External device needed
Resp.io - USA ⁴⁸	Respio's smartphone spirometer	-	uses smartphone's sensors to ensure proper body posture	Smartphone mounted, handheld device

⁴⁶ <http://aiocare.com/#About>

⁴⁷ <https://www.spirometry.com/ENG/Products/smartone.asp>

⁴⁸ <http://www.resp.io/>

		during the spirometry		
Research team from the University of Washington - USA ⁴⁹	SpiroSmart (Larson et al., 2012)	-	Uses smartphone microphone	- Lacks the ability to analyze data in real time - Models implemented are generic
Research team from Hanoi University of Science and Technology - Vietnam ⁵⁰	BKSpiro (Tran et al., 2015)	-	Uses smartphone microphone	Low accuracy of lung function parameters
CliniCloud - USA and Australia ⁵¹	CliniCloud Stethoscope	150	Records lung sounds at medical diagnostic quality (44.1kHz, 16 bit)	Do not include automatic lung sound analysis
Research team from Massachusetts Institute of Technology-USA and Chest Research Foundation - India ⁵²	Solution proposed by Chamberlain et al., 2015	-	Algorithm capable of automatic detection of wheeze sounds	External device needed - low-cost stethoscope

Table 2: *CORD Management main competitors*

⁴⁹ <https://ubicomplab.cs.washington.edu/pdfs/spirosmart.pdf>

⁵⁰ <https://dl.acm.org/citation.cfm?id=2833289>

⁵¹ <https://clinicloud.com/store/stethoscope/>

⁵² <https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=7344001>

4.1.3 Features Analysis

	Competitors	Functionalities							
	Company name (country)	User Profiling	Monitor Health Parameters	Data Analytics	Coaching Plan	Medical Recommendation	Mobile Sensors	Personalised Recommendation	Health/Wellbeing Status Analysis
Use Case HW	Virgin Pulse (UK/Ireland)		X	X	X		X	X	X
	Sprout (Canada)		X	X	X		X		X
	Limeade (USA)			X	X				
	WellNow (LLC)		X	X	X	X			X
	Biwel (Spain)	X	X	X	X	X		X	X
	Inithealth (Spain)		X	X	X	X			X
	Oncoshare (Belgium) https://www.oncoshare.com/	X		X			X	X	X
	Nexuzhealth (Belgium)			X			X		X
	HealthUp (Poland)		X	X					X
	Medical International Research (Italy)		X	X					X
Use Case CORD	Resp.io (USA)		X	X			X		X
	Washington University Research Team (USA)		X	X			X		X
	Hanoi University Research Team (Vietnam)		X	X			X		X
	CliniCloud (USA/Australia)		X						X
	Massachusetts Univeristy Research Team (USA)		X	X					X
	Radboud University Research Team (USA)		X	X			X		X
	PHE	X	X	X	X	X	X	X	X

Table 3: PHE Feature Analysis

Overall, among the identified competitors, there is a clear interest to develop solutions based on Health Parameters monitoring combined with data analytics and perform health/wellbeing status analysis. In the context of Healthy Workplaces Use case there is a greater interest to develop solutions combining User Profiling techniques with personalized and medical recommendation features. On the other hand, for the CORD Management use case, most competing solutions combine the use of mobile sensors to monitor different health parameters along with other external devices to correctly measure the health state of the patient.

5 Legal Aspects

Regarding the regulation applicable to mHealth apps, there is a diffuse and unclear field, although FDA and the European authorities are determined to clarify it.

The REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, that will be applied on 26 May 2020, clarifies when a software can be considered a medical device: “It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.”

If the develop solutions (e.g., apps) are a software (it has instructions to solve tasks, is not only a set of digital documents or repository), if it acts on the data or information that it handles (that is, interacts with the data to make a diagnosis or recommend a treatment), if it is intended for the benefit of subjects and designed to be used as a medical device (among others, "diagnosis,

prevention, follow-up, treatment or relief of a diseases"), would theoretically be a Class I Device, and would require the CE Marking.

In the case of the developed solutions the differential fact will be in the level of action/coaching on the data collected. But for now, it is a confusing field and subject to nuances as for any decision could be valid and justifiable.

In addition, of course, our solutions are intended to comply with the data protection legislation of each country.

Subjects' personal data obtained with the developed solutions will be treated according to the European Regulation on Data Protection (UE) 2016/679.

6 SWOT Analysis

Strengths	Weaknesses
<ul style="list-style-type: none"> - Well defined scope and core of the project - Partners expertise in parallel to the project scope - Access to different markets - Specific use-cases defined for different needs and markets 	<ul style="list-style-type: none"> - Partners all work on different areas which may cause loss of focus - Exploitation and business models may differ in different markets for different stakeholders. - Distance between stakeholders.
Opportunities	Threats
<ul style="list-style-type: none"> - PHE focuses on a trending technology and aims to close a big gap where there is no standard solution. - Innovation and development within project scope and core is always possible. - PHE results will have direct effect on the booming area of personal health. - No real legislation right now, we may bring standards by the end of the PHE. 	<ul style="list-style-type: none"> - Fast evolving technologies not only as hardware but also for software solutions. - Hot topic encourages many companies and research to bring competition. - Regulatory issues in legislation and data share, personal data protection related issues.

Table 4: PHE SWOT Analysis

7 Assessing Risks and Contingency Plans

In this section we described risks. Potential risks are defined with details below table.

WP/Task related	Risk Identification	Risk Description	Potential Impact	Avoidance action	Mitigation Plan	Severity	Probability
WP 5	Risk 1	Project Delay due to consortium reorganization	failure of the project on time	All partners have to organize their programmes	set meeting regularly	Medium	Possible
WP 1	Risk 2	Data Privacy	The law on the protection of personal data problem	Focus more on achieving effective solutions to the scalability problem of big data privacy and security in the era of healthcare	if it is occurred, it will be decided with other partners	High	Likely
WP 5	Risk 3	Coherence problem in customer – potential market	Inability to obtain commercial profits	cooperate with appropriate sectors	Set meeting regularly with appropriate sectors	High	Likely
WP2	Risk 4	Data Collection	Inability to provide genuine piece of hardware unit	Cooperate with existing data providers or with every single individual on specific terms	Will be decided when recognized	High	Likely



WP 2	Risk 5	Structural Data Decomposition	Inability to provide algorithms to distinguish different activities provided by low level structured/unstructured activity data	Cooperate with existing data providers and existing algorithms (preferably open source solutions)	Will be decided when recognized	Medium	Likely
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Table 5: PHE Business Related Risks identified