A Demonstration of 4D Digital Avatar Infrastructure for Access of Complete Patient Information

Project acronym: MyHealthAvatar

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PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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ABSTRACT:
The business plan provides a blueprint for exploitation activities after the official end of the project. Examining the external market environment including industry, customer and competitor analysis, and link it to internal resources and capabilities, the business plan summarizes all relevant experience and knowledge to provide assistance in the utilization of all direct and indirect project results.

KEYWORD LIST:
MyHealthAvatar (MHA), business plan, exploitation, digital health, EHR, PHR, VPH

[1] **R**=Report, **P**=Prototype, **D**=Demonstrator, **O**=Other

[2] **PU**=Public, **PP**=Restricted to other programme participants (including the Commission Services), **RE**=Restricted to a group specified by the consortium (including the Commission Services), **CO**=Confidential, only for members of the consortium (including the Commission Services)

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Content

1 Executive summary

This deliverable presents the final version of the MyHealthAvatar (MHA) Business Plan. The word MHA in this context means the outcomes of the project, consisting of tangible assets (the MHA core platform and the related modules) and intangible assets (services, knowledge). The document discusses our approach taken, describes the market around the MHA proof of concept and charts progress and plans towards exploitation for the period after the end of the project. The document includes several different exploitation aspects including a commercial dimension.

Successful exploitation and sustainability of MHA results is a major objective of the project. As a tool to enable exploitation, this plan includes all the important aspects: (1) results to be exploited; (2) stakeholders; (3) possible models of exploitations and (4) an analysis of the fit between these results.

2 Introduction

2.1 Project Background

Owing to the highly fragmented health systems in European countries, gaining access to a consistent record of individual citizens that involves cross-border activities is very difficult. MyHealthAvatar is an attempt at a proof of concept for the digital representation of patient health status. It is designed as a lifetime companion for individual citizens that will facilitate the collection of, and access to, long-term health-status information. This will be extremely valuable for clinical decisions and offer a promising approach to acquire population data to support clinical research, leading to strengthened multidisciplinary research excellence in supporting innovative medical care.

MyHealthAvatar will be built on the latest ICT technology with an aim of engaging public interest to achieve its targeted outcomes. In addition to data access, it is also an interface to access integrative models and analysis tools, utilizing resources already created by the VPH community. Overall, it will contribute to individualized disease prediction and prevention and support healthy lifestyles and independent living. It is expected to exert a major influence on the reshaping of future healthcare in the handling of increased life expectancy and the ageing population in Europe. This complies with the priority and strategy of FP7 ICT for healthcare, and constitutes a preparatory action aiming at the grand challenge on a "Digital Patient", which is currently the subject of a roadmap in the VPH community.[3]

MyHealthAvatar can be described as a personal bag carried by individual citizens throughout their lifetime. It is a companion that will continually follow the citizen and will empower them to look after their own health records. This fits very well into the recent trend of developing patient-centred healthcare systems.

2.2 Structure of the document

The business plan is structured as follows:

1. A market analysis was performed in order to position MHA. The market analysis provides an insight of the digital health market landscape including trends, the multitude of different stakeholders and competing solutions.

2. The strategic direction is given by performing a thorough SWOT analysis, describing the chosen business model and providing detailed information about the open source strategy that the consortium decided to follow.

3. The final results of the project – the core solution as well as the auxiliary modules – are examined from a commercial perspective. We analyse MHA features from a customer standpoint, measure its innovation and business potential.

[3] MyHealthAvatar project, Description of Work (DoW) document p. 4

4. Academic exploitation activities are examined from another perspective, the individual project partners' activities and roles in the exploitation process. In this section we also consider possible cooperation with related European projects.

2.3 Scope of the document

The objective of this document is to present the various exploitation possibilities for the MHA project and also describe activities that are linked to these possibilities. Exploitation activities should spread the results among the internal and external communities to ensure sustainability after the official end of the project.

In order to ensure a successful project cycle, careful dissemination and exploitation strategies are essential. Dissemination activities have been performed from the start of the MHA project, the exploitation strategy concentrates on the project's results during the later stages and afterward to reach sustainability after the project ends.

The term sustainability means the following:

- the developed products are used as the basis for further research activities by (1) the partners; (2) new projects; (3) business entities; (4) public institutions;
- these products/services are used in real world contexts.

To enable the transition from an R&D setting to commercial use, important stability and ease of adaptation requirements should be met. During validation, specific activities will be undertaken to create a complete picture of all these requirements. The results should clarify the best way to exploit each result, including any need for further R&D.

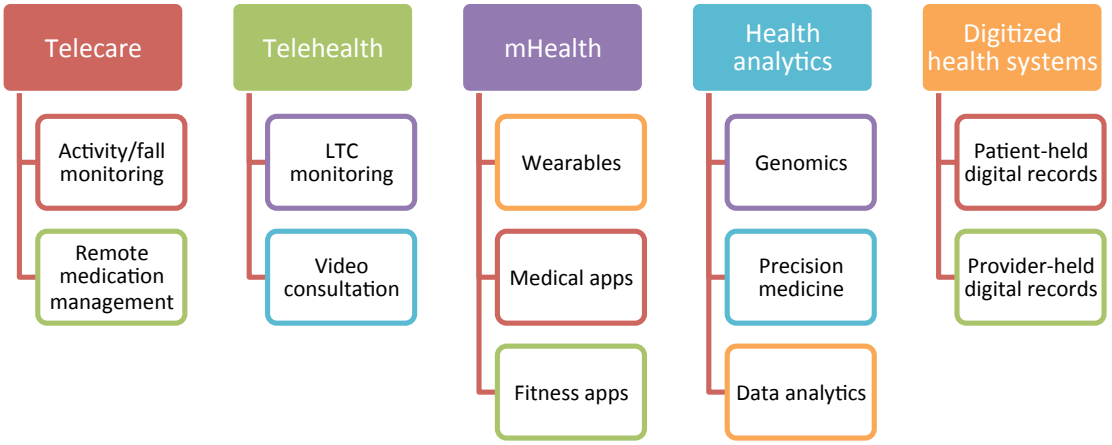
Finally, this document aims to create a common view for all MHA partners of these exploitation activities. It states how the outcomes should be promoted to support the adoption and use of the product in different academic, educational, and commercial environments.

3 Business environment

3.1 Industry overview

Broadly speaking, MHA is part of the Digital Health (DH) ecosystem. DH is an emerging industry arising from the intersection of healthcare services, information technology and mobile technology. Digital health innovations are only just starting to be more widely accepted as necessary for the future of efficient healthcare service delivery. As we address the behaviour, social, legal and technical challenges, over time, digital health advances have the potential to help increase access, decrease healthcare system costs and improve health outcomes.

The emerging digital health industry encompasses digital products that can monitor, analyse, educate or improve health. The industry can be segmented in a number of ways: in this document we have chosen to segment the industry into telecare, Telehealth, mHealth, health analytics and digitised health systems as described below[4]:



These sub-sectors are highly interrelated. For example, telehealth is supposed to be the fixed line version of specific, emerging parts of mHealth; however we expect the line between them to become increasingly blurred. Digital health systems are the primary care and hospital information systems and are essential for collecting data required for health analytics. These sectors face many similar drivers and challenges.

[4] Monitor Deloitte report on Digital Health: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/461479/BIS-15-544-digital-health-in-the-uk-an-industry-study-for-the-Office-of-Life-Sciences.pdf

Where does the MyHealthAvatar platform fit in this space of digital health? The core system clearly falls in the category of 'Patient-held digital records'. It has however strong links to the following elements: all items in mHealth (wearables, medical and fitness apps); and data analytics. With the assistance of additional modules connections could be established with Telecare and Telehealth thus providing a complex and complete, but still customizable, solution. VPH can be linked to the Health analytics sector with a special emphasis on genomics and of course general data analytics, further strengthening the tie with these sub-sectors.

3.1.1 IT and Healthcare

Technology is transforming every aspect of the way we live. Today no area is more important or more profound than the innovations we are seeing in healthcare. As the industry looks to leverage technology to increase access to information, drive better patient outcomes and unlock mysteries hidden in plain sight, it is facing the enormous challenges of privacy and security that are perhaps more worrisome in healthcare than in any other industry[5].

The adoption of IT in healthcare systems has, in general, followed the same pattern as other industries. It has been clear for a long time that healthcare reform needs important support from information technology. However, the evidence of successes in healthcare IT is decidedly mixed[6]. Players in the healthcare industry were relatively successful at—and benefited from—the first wave of IT adoption; but they struggled to successfully manage the myriad stakeholders, regulations, and privacy concerns required to build a fully integrated healthcare IT system. There is some evidence of the significant value of healthcare IT (e.g. within primary care medicine and across a number of hospital institutions) in (1) improving the quality of care e.g. with adherence to guidelines; (2) reducing the risks of care e.g. by reducing medication errors.

On the other hand though, there is much less evidence of related savings of time or money. Proof of widespread benefit across healthcare systems is limited and points to the challenges of scaling and maintaining information technologies amidst the complexity of healthcare. Yet while there has been a myriad of stories of suboptimal health IT deployments, the appetite and drive towards greater and wider use of healthcare information technologies continue apace. What can explain this puzzle and gap between aspiration and reality?

One important reason for the low IT penetration is in the structure of the health care system. It has a fragmented set of stakeholders: providers, payers and patients. As a result it may be difficult to understand the return on investment of a HIT investment when it creates costs for some stakeholders and provides benefits for others[7].

[5] https://www.hpematter.com/content/10-big-technology-trends-healthcare

[6] http://frectal.com/book/healthcare-change-the-way-forward/healthcare-needs-better-information-technology/

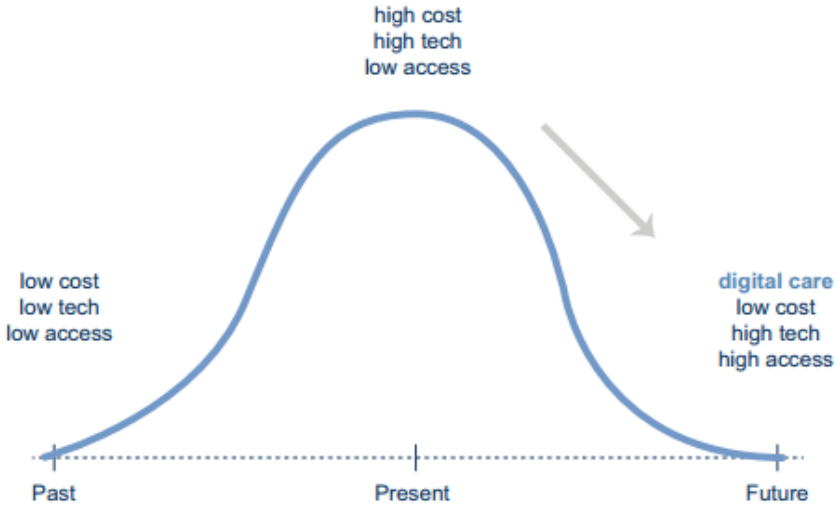
[7] http://www.vencore.com/health-analytics/vencore-health-blog/2015/10/28/why-has-health-care-been-so-slow-to-implement-information-technology

Another important aspect is the changing economical and societal environment. The first wave of IT adoption focused more on processes and less on patient needs[8]. Now that patients around the world have grown more comfortable using digital networks and services, even for complex and sensitive issues such as healthcare (successful websites DrEd, PatientsLikeMe, and ZocDoc are just three examples of this trend), it is widely believed the time has come for healthcare systems, payors, and providers to take the next leap in digital strategies.

While developments in clinical technology have had a revolutionary impact on healthcare over the last 30 years, the same cannot be said for the use of technology and data to improve heath and the way health and social care services are delivered. The consumer experience of care services remains much as it was before the mobile phone and the internet became commonplace. For care professionals, from social workers to doctors and nurses, the arrival of the digital age has often been experienced not as a force for good but rather as an intrusive additional burden in an already pressured existence. At the same time the technology industry is investing massively in consumer health products but these are not comprehensively linked to the formal health and care sector[9].

3.1.2 Trends in healthcare

Digital healthcare, though still in early stages of development, has the potential to revolutionize the healthcare industry by making diagnosis, treatment, and prevention widely accessible at a fraction of current costs. While a host of challenges surround the development of digital health, changes in the healthcare reimbursement paradigm (shift to value based care from fee for service) alongside advancement in wireless technology have set the stage for significant industry disruption as depicted on the below figure.



Disruptive innovation in healthcare[10]

[8] http://www.mckinsey.com/insights/health_systems_and_services/healthcares_digital_future

[9] Personalised Health and Care 2020 - by NHS

[10] Goldman Sachs Global Investment Research

Let us examine the five main trends affecting the future of healthcare with their impact on the industry. The following table contains these in an easily understandable format.

Emerging trend	Impact on Healthcare
Demographic shifts and societal changes are intensifying pressures on health systems and demanding new directions in the delivery of healthcare. We are getting older. Ageing populations in both emerging and developed nations are driving up the demand for healthcare.	Driven in part by demographic changes, a new paradigm of public and private sector collaboration is developing to transform healthcare financing and delivery. Partnerships with new market participants from industries such as retail, telecommunications, technology, wellness and fitness are expanding and reshaping the health system.
Chronic diseases and conditions are on the rise worldwide. An ageing population and changes in societal behaviour are contributing to a steady increase in these common and costly long-term health problems.	New delivery models are emerging to address growing chronic care demands. Technology has a key role to play. Advancements in precise detection and diagnoses of disease will go far to minimise the cost of treating chronic conditions.
Healthcare systems around the world are dealing with depleting resources at a time when demand for healthcare is rapidly rising.	Governments are looking for low-cost, efficient solutions to reform healthcare and address their depleting resource issues. They are adopting process-driven advances and standardised procedures, and optimising human resources with an eye to continual quality improvement and cost cutting.
Consumers are demonstrating a lack of trust in traditional health systems; they are increasingly willing to entrust their health services to non-health sectors; and ubiquitous technology is giving them the tools to do so.	New entrants have several advantages within the healthcare space: global reach, customer insights, commitment to transparency and trusted brands. They regard their unique perspective as an asset to capture and dominate the fragmented sector. Technology and the rise of mobile health (mHealth) have blurred the borders for healthcare products and services.
Consumers are taking advantage of unprecedented access to information to become more diligent and informed about their health. The growing power of the patient as discerning consumer is creating new global markets and informing new models for care.	More engaged and discerning consumers are exerting greater influence on health systems and driving new business models. This trend is opening the door for new entrants from industries such as retail, telecommunications, technology, and wellness and fitness. At the same time, new products, services and delivery systems are helping to democratise and decentralise healthcare.

The digital health revolution will obviously not happen in just a few years. There are a few factors however that can push digital health beyond infancy in the next five to ten years. While there are a host of novel technologies that address a vast array of disease states, we can pinpoint some verticals that appear most viable in the near-term. In other words, at this point in time, only a select few

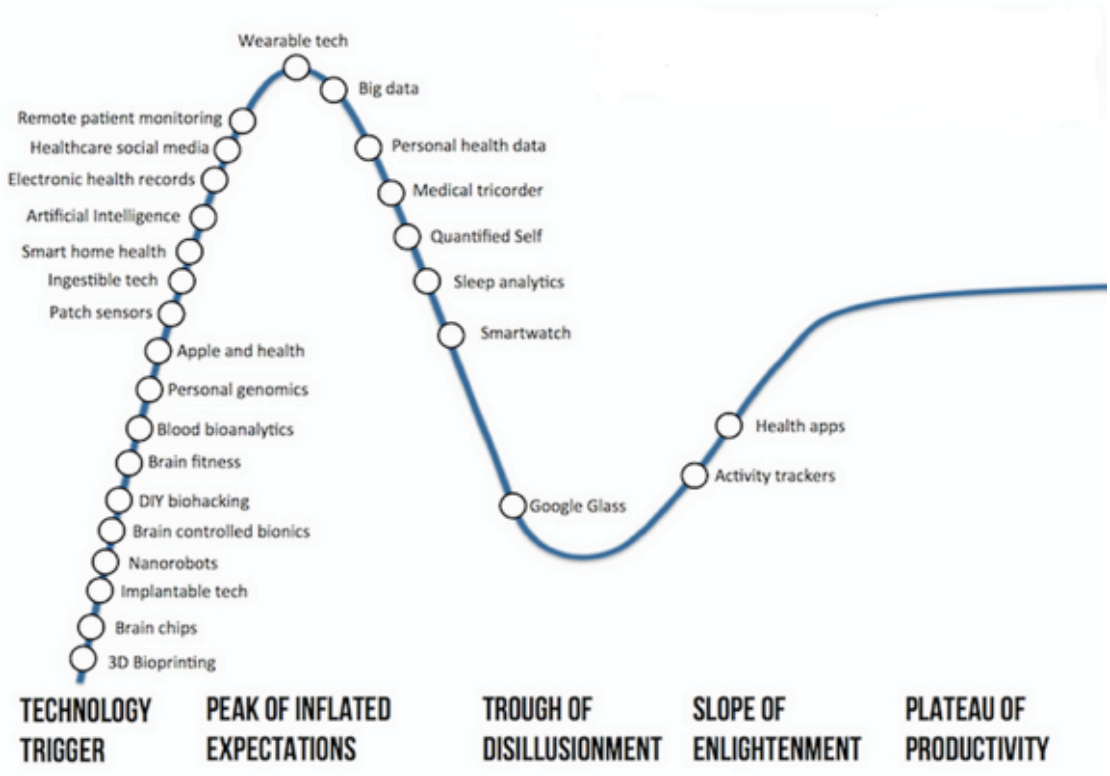
markets have the critical mass (high addressable patient populations) to produce substantial commercial revenues:

a. Remote patient diagnostics and monitoring: Technology to monitor changes in patients' health status outside of conventional clinical settings.

b. Telehealth: Doctor access and advice, from outside the confines of an office visit.

c. Behaviour modification: Platforms that help patients change their habits and adopt healthier lifestyles, with the primary aim of preventing illness and a clinically validated methodology of doing so (note that this excludes "general wellness/fitness applications").

Given the wide range of new technological developments, predicting how the market will evolve and which technologies will have the most impact on healthcare delivery is challenging. The following cycle might help us position where we are in the framework of technologies.



The Digital Health Hype Cycle[11]

Many of the emerging digital health technologies are at the beginning of the hype cycle which is not surprising given digital health is still in its infancy. As the market continues to develop however, not only will these technologies move further around the cycle but new innovations in health that are currently unknown or have yet to be invented will come in to the fold too.

[11] http://bionic.ly/digital-health-hype-cycle/

Another key development is the growth in wearable technology, and in particular, bio-sensing wearables. These devices include fitness bands, digital hearing aids, blood pressure monitors and smart pills. The global movement in digital health is the catalyst for the development of wearables[12].

Patients also increasingly use mobile technology to research information online, share experiences, identify treatment options, rate providers and help diagnose illnesses. Healthcare commissionaires and providers have acknowledged that current and emerging technologies offer opportunities to transform the way people engage with their own health.

How to use digital health technology to help people who do not care for themselves but do not yet show symptoms of chronic disease is a huge unsolved problem. Consumers are interested, but want measurable impact, not just data. They want to control their data, know who is looking at it, and decide who should see. And, they want a tangible and immediate benefit or reward for behaviour that cultivates health[13].

3.1.3 Patient empowerment

Connecting patients to information, advice and support can help move from the patient as a passive recipient of care to one where they are actively engaged in their own care.

Traditional paternalistic model of care

- Patient completely reliant on HCP to receive information, diagnosis and referral
- Difficult for patients to navigate within and between health and social care
- Interventions usually in response to physical evidence from patient
- Fragmented commissioning and little or no financial incentives for commissioning TEC

Empowered patient sharing ownership

- Patients informed whenever and wherever, using their interoperable patient record
- Co-creation of care packages, proactive prevention and rapid access to services
- Technology enabled supported discharge/self management
- New business models for commissioning TEC at scale

[12] Connected health - How digital technology is transforming health and social care. - Deloitte Centre for Health Solutions

[13] http://www.forbes.com/sites/toddhixon/2015/05/28/why-doctors-are-frustrated-with-digital-healthcare/2/

Patients are demanding more sophisticated, convenient, transparent, affordable and personalised service. As a result, an agile private sector has gained a strong foothold in the delivery and financing of healthcare. In a recent PwC consumer survey, almost half of respondents said they would consider having procedures like wound treatment, stitches or staples removed at a retail clinic or pharmacy[14]. The underlying message is that patients are accepting greater accountability for their health. Patients are also welcoming the flexibility that technology brings to their care. Increasingly, they are willing to be monitored wirelessly for their conditions. Leveraging available health information, new technology, and mobile health (mHealth), the empowered consumer knows more, wants more and is able to do more for themselves.

Patient Empowerment has also gained traction on a European level. The European Patients' Forum (an umbrella organisation that works with patients' groups in public health and health advocacy) officially launched a major one-year campaign on Patient Empowerment on 20-21 May 2015. They work in concert with the health community to promote understanding of what patient empowerment means from the patient perspective among political decision-makers and health stakeholders.

3.1.4 Market size

The global mHealth market reached $2.4 billion in 2013 and $21.5 billion in 2018 with a compound annual growth rate (CAGR) of 54.9% over the five-year period from 2013 to 2018[15].

The number of mHealth apps that are published on the two leading platforms, iOS and Android, has more than doubled in only 2.5 years to reach more than 100,000 apps (Q1 2014).

Today's mHealth app publishers and Wannabes predominantly target chronically ill patients (31%) and health and fitness-interested people (28%). As primary users, physicians are targeted by 14% of app developers.

The vast majority of mHealth app publishers (82%) generated less than 50,000 downloads with their mHealth app portfolio last year, whereas the top 5% reached more than 500,000 downloads.

68% of mHealth app publishers make less than USD 10,000 or no revenue[16].

[14] http://www.pwc.com/gx/en/industries/healthcare/emerging-trends-pwc-healthcare/new-entrants-healthcare-provision.html

[15] http://www.bccresearch.com/market-research/healthcare/mobile-health-hlc162a.html

[16] http://research2guidance.com/r2g/research2guidance-mHealth-App-Developer-Economics-2014.pdf

The wearables market maintained its upward trajectory in the first quarter of 2015. A new forecast estimates that 72.1 million wearable devices will be shipped in 2015, up a strong 173.3% from the 26.4 million units shipped in 2014. Shipment volumes are expected to experience a compound annual growth rate (CAGR) of 42.6% over the five-year forecast period, reaching 155.7 million units shipped in 2019[17].

3.1.5 Healthcare across borders

A number of factors are making health policies and health systems across the European Union increasingly interconnected[18]:

- Patients getting healthcare across the EU
- Health professionals working in different EU countries
- Higher expectations for healthcare
- New developments in health technologies.

Health-care provision is increasingly subject to policy decisions and is managed more than ever before. Health care is also becoming more international and collaboration is increasing as the health professions, research and industry all work across borders. Differing health-care systems across the countries of Europe result from national and regional history and policy developments and priorities. Despite these differences, common interests and policies (e.g. in professional training, health information and health systems) that impact on national health-care practice are being explored and developed at the European Union (EU) and wider European level[19].

There are obviously serious challenges in the realization of interconnected healthcare. As we will demonstrate later, digital health is hard enough to realize on a national level, let alone EU wide harmonization. It is however very important that the framework of collaboration is developed on a European level and national stakeholders are involved in the issue of cross-border harmonization. Solutions like MyHealthAvatar can play a very important role going forward in this direction.

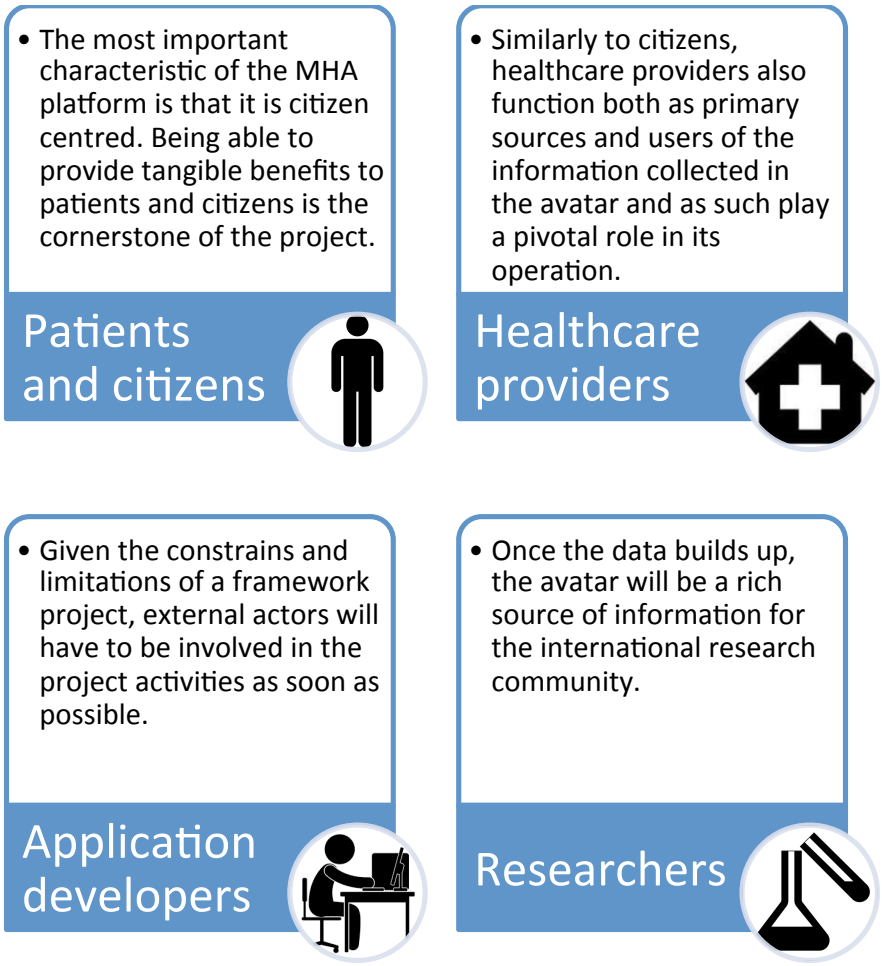
[17] http://www.idc.com/getdoc.jsp?containerId=prUS25696715

[18] http://ec.europa.eu/health/cross_border_care/policy/index_en.htm

[19] Health technology assessment and health policy-making in Europe – Observatory studies series no 14

3.2 Customers

The main stakeholder groups of MyHealthAvatar are the following:



Good exploitation means that we examine how we can ensure a wide participation from each stakeholder group and perform our actions accordingly. Careful planning is necessary as the involvement of different participants is interdependent, for example we cannot hope for serious involvement from citizens unless providers share their data with MyHealthAvatar and we cannot attract the attention of researchers until we build a meaningful database of health related data.

3.2.1 Patients and citizens

The core MHA platform provides several useful tools for citizens without specific health conditions. The modules, in conjunction with the main platform, are (and will be) designed to serve the specific needs of patients. In this segment we describe this separately, although in real life this distinction is blurred. The fact however that the core platform serves as a bridge between different modules and patients enables MHA to be effective for all target customers.

MHA for citizens without specific health conditions

MHA integrates users' fitness and health related data to provide a complete picture. The ease of information collection from a variety of sources and the innovative and smart visualization features guarantee an excellent user experience. The insights gathered during evaluation demonstrate that MHA has a strong appeal for the average citizen.

MHA for patients

We have realized early in the project that patients have different requirements from a health portal depending on their health problem, demographic and social characteristics etc. and therefore a segmentation methods should be applied. One of the main reasons for the failure of currently existing digital health solutions (especially PHRs) was that they tried to be very generic and reach out to everybody without providing clear benefits for users. In other words, they were trying to serve everybody's needs and ended up serving none of those needs particularly well. Obviously, we cannot create a different system for each and every segment; it is not only impossible but also prohibits the exploitation of synergies. A logical segmentation method is by health problems (diseases) and the first modules developed in the context of the MHA project have taken this direction. The platform handles diseases affecting a substantial part of the population differently from health issues affecting a smaller number of patients. This distinction is described below.

MHA and major diseases

We have developed diabetes specific tools[20] in MHA that are available in the web and the mobile platform as well. People with diabetes have the opportunity to gather and analyse all relevant information (glucose levels, insulin doses, food consumed, physical activity etc.) related to their condition. MHA helps users manage their diabetes smarter based on the objective data gathered from direct user input, wearable devices (fitness trackers, sleep tracker, etc) and mobile apps.

While many people have diabetes, the majority of users are not be interested in its features. Therefore the diabetes program is invisible in MHA until it is activated. This way we ensure that each user only perceives relevant information. Based on the diabetes specific features of MHA the platform could be further developed to include some other features that are useful for a large number of patients.

MHA and minor diseases

People with health problems affecting a smaller population (including rare diseases) are served with disease specific modules linked to the core MHA platform. This solution enables different user groups to harness the power of a uniform system without having to deal with a lot of unnecessary and complicated items. At present three separate modules[21] exist:

- Nephroblastoma

[20] MHA deliverable 9.4, p. 22 ff.
[21] MHA deliverable 9.4, p. 29 ff.

- CHF Risk Assessment
- Osteoarthritis

All these modules have seamless links with the MHA platform. In the process of developing the high end use cases we have fulfilled a huge number of requirements to make MHA comply with the most rigorous medical standards in relation to nephroblastoma, CHF and osteoarthritis; making MHA clearly distinct from competing solutions. The methodology created during these use cases can be transferred to future cases (and modules). What MHA offers for third party developers interested in linking a new module to the core is described below in chapter 3.2.3. Also, as the module based segmentation is closely linked to the modules themselves, they will be discussed in detail when the modules will be described in Chapter 5.

3.2.2 Healthcare providers

Engaging healthcare providers is one of the main cornerstones of a digitized health system. While the data collected by users are useful in their own right, it is really comprehensive system that has fundamental benefits to patients and citizens. Extensive interchange will however not happen in the near future for a host of reasons:

- Legal obstacles: healthcare providers have an obligation to make sure that the highly sensitive data at issue will be properly safeguarded and processed by another party where data is sent[22]. At present most organizations consider that the safest option is to not share any medical data with third party systems[23].
- Manifest barriers from the supplier side include lack of funding, fear of productivity loss, the risks of incomplete data and privacy concerns.
- Patients/citizens themselves have to be convinced that the benefits outweigh privacy and other related risks.

While our intention is to encourage healthcare providers to link their existing electronic records with MHA, we realize that we have to be prepared for a slow and cautious process. The main elements of our approach towards healthcare providers are the following.

1. MHA has built and demonstrated a functioning link with a HIS[24]. Due to the restrictions, the system does not contain real patient data but all its functionalities have been tested. Based on our experience obtained through this practice and the broad usability of the created ontologies / databases, the link with other proprietary systems could be established with minimal effort.
2. The modularity of MHA allows the gradual integration of healthcare professionals into the system. The already available modules (nephroblastoma, CHF risk assessment, osteoarthritis) have been extensively tested by relevant health professionals and can be

[22] MHA deliverables 11.1, p. 22 and 11.3, p. 15 ff.

[23] For legal aspects with regard to data sharing among digital avatars, third-party social networks and sharing for biomedical research, see MHA deliverable 11.3, p. 27 ff

[24] For more information concerning data collection by linkage with hospital information systems and other external data warehouses see MHA deliverable 11.3 p. 18 ff.

utilized in practice. MHA can create a network of professionals, each of them linked to MHA through a specific module.

3. MHA is able to provide tangible two-way benefits for healthcare partners. The provider gets the benefit of becoming a part of a comprehensive system while MHA becomes richer with each participating provider. Emphasize is placed on this when communicating with interested parties.

3.2.3 Application developers

External application developers should play a major role in the expansion of the MHA platform. The main idea is that we provide a base containing the data and some basic tools while third parties create applications that are linked to the platform and utilize its resources. There are two basic possibilities to link an external tool to MHA:

A. An application is wrapped into a separate application, so it needs to communicate with the platform via the API.

B. MHA administrators give third parties credentials to access the repository (under the guidance of the administrators) and they can upload the models and the pertinent information themselves.

We have already created an API for application developers that is currently being used in the four high end use cases[25]. This blueprint can be followed in a similar or modified format in the future for linking other applications.

Our aim is to create a win-win situation where developers gain users by leveraging the information content of the platform while the MHA platform will be more engaging to users with every new linked application. Ideally this starts a snowball effect of attracting users, developers and also healthcare providers. Our offering to third parties includes the following:

1. A place to host their application(s).
2. A chance for their application to be used with some very real world data from various data sources
3. Dissemination of their application.
4. User Interfaces (when needed).

3.2.4 Researchers

The information collected in the repositories of the avatar can be the base of a variety of health and/or wellbeing related research. The quantity, accessibility and structure of the data define its usability for research purposes. This approach has one great promise but also possesses some very real dangers.

[25] MHA deliverable 3.6, p. 7 ff.

The promise is revenue generation. Most existing electronic health systems found that users are not willing to pay for the provided services, e.g. practically all major PHRs are available free of charge. As there are limited options for revenue generation from other sources, some of these have clearly indicated that this is their chosen business model. This is not only true for smaller players, 23andMe has recently stirred some huge waves by opting to let pharmaceutical companies utilize their collected database of some 800,000 citizens[26].

The danger of this approach is of course the potential for misuse of very sensible data[27]. Very serious legal and ethical issues arise from leveraging even anonymous data for other purposes. The MHA project has a well prepared team (led by the University of Hannover) to ensure that only the safest and most reliable options will be examined.

Research collaboration can be based on the data stored in the main platform but it is more likely that a particular research project will find MHA through one of the modules. The flexible structure of the modules probably fit the unique requirements of research projects better than the more invariable core database. The work performed in the Nephroblastoma use case is a live example for cooperation between medical researchers and the MHA consortium.

[26] http://www.forbes.com/sites/matthewherper/2015/01/06/surprise-with-60-million-genentech-deal-23andme-has-a-business-plan/

[27] Deliverables 11.1, p. 30 f. and 11.4, p. 22 ff.

3.3 Competition

There is no shortage of initiatives, applications and comprehensive systems trying to make eHealth a successful reality. Some are aimed at particular user groups, some never want to go outside a provider setting, some strive to be a national solution and some even want to be openly global. Given the complexity of the issue and the huge amount of initiatives, it is impossible to give a thorough analysis but in this chapter we tried to summarize the main approaches taken.

A logical argument is that as healthcare systems are organized nationally, digital health should also be aligned. This approach is accepted and followed by many countries, although there are differences in the actual method of implementation. Healthcare however is not just a governmental branch but can also be considered as a huge economical venture. Consequently, many digital health initiatives have been started by private corporations. There are many differences between these two main approaches but the most important might be the expected length of period for a return on investment. While businesses need to secure financial viability within a fairly short timeframe, governments may afford to swallow initial costs in the hope of future returns. In addition, on a national level, better health outcomes may also offset actual higher costs, while corporations must ensure financial profit to succeed. Based on the differences we created five different groups that will be explained shortly and analyzed in detail in this chapter.

National approaches

1. Focus on the adoption of EHRs: The idea here is to first digitize healthcare data and when this process is fairly advanced, establish interoperability between the separate systems.
2. Linking separate EHRs together: In contrast to the first approach, some countries decided to first create an integrated system from the parts already available and then add new parts and features to a unified system.
3. National PHRs: Unlike the first two approaches that both build on EHR capabilities (based on data stored at healthcare organizations), some countries try to build a citizen focused PHR-like system from scratch and then create the necessary links to separate health data silos.

Business approaches

4. Payer populated PHRs
5. Untethered PHRs

3.3.1 Focus on the adoption of EHRs

The United States decided that the digitalization of healthcare should be the primary aim followed by establishing interoperability among the different systems and this aim has been heavily backed up by both propaganda and funds. As of December 2015, more than 482,000 health care providers received payment for participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs with over 21 billions of USD payed out since January 2011.

While the use of EHR has indeed spread rapidly (a recent survey found EHR adoption at 62.8 % in January 2015, a slight increase from 61 percent in January 2014[28]), there are clear warning signs. 10,000 (4,601 completed) unique audits were conducted last year with a finding that 22.7% of EPs failed to meet meaningful use standards[29].

The real issue however seems to be that the two-step approach has a real danger: the growing number of independent systems only increases problems associated with data sharing. The issue has been recognized on the highest level, a US Senate panel recently heard of woes in implementing electronic health records and lawmakers mull legislation to ease the administrative burden in health IT systems[30]. The real benefit of digital health for citizens comes from the comprehensive nature of these systems and this approach is not making serious inroads in this direction.

3.3.2 Linking separate EHRs together

There are many countries in the developed world where electronic health data storage and transfer are built on decades of experience. National e-health systems are typically based on EHR and these are now being complemented with PHR capabilities. The most advanced examples supplied by the following countries:

Finland: The Patient Data Repository offers citizens the opportunity of examining their own medical records on their computer, easily and regardless of time and place[31].

While these systems together provide a wealth of information about patients that are available for patients themselves, the emphasis has clearly been on medical data provided by healthcare professionals. According to experts, this is about to slowly change, patient empowerment is fast becoming a keyword. Involving and engaging the patient does not only mean giving access to relevant information but also giving the patient an active role as a co-player in the care and treatment process.

[28] http://www.fierceemr.com/story/survey-doc-ehr-adoption-leveling/2015-02-09

[29] http://www.e-mds.com/25-practices-are-failing-meaningful-use-audits

[30] http://www.cio.com/article/2899140/healthcare/ehr-adoption-up-challenges-in-interoperability-and-meaningful-use-remain.html

[31] http://www.kanta.fi/en/earkisto-esittely

Denmark: Sundhed.dk, the official portal for the public Danish healthcare, enables patients and healthcare professionals to access to personal health data anytime anywhere. The portal has 1,4 million unique visitors per month out of a population of about 5,6 million and is a powerful back-end integration platform including data from 120 existing sources[32].

Sweden: My Healthcare Contacts ("Mina vårdkontakter") is a national e-health portal for all citizens enabling secure login to any healthcare service in the country. Sweden is planning to make online access to full electronic medical records available to all citizens by 2017. Through the initiative My Care Pathways ("Mina vårdflöden") patients will be able to follow and manage their care processes online[33].

3.3.3 National PHRs

There are a growing number initiatives when rather than building on existing EHR systems, digital health is based on a totally new system. Some of these examples are built on a national scale while some start small in order to be able to adapt to changing needs and regulations. Let us see an example for each.

Australia

Personally Controlled Electronic Health Record – PCEHR went live in 2012 but has come under heavy scrutiny after about 18 months of operations over its failure to attract citizens and especially doctors to participate[34]. Nearly two-years after a review was performed on the government's struggling e-health platform, new changes based on recommendations the review made were introduced into legislation[35] in September 2015. The rebranded system[36] is trying to learn from the lessons, but other than replacing an opt-in method to an opt-out one, few other changes are really visible.

[32] http://www.smartandhealth.com/index.php/homepage-2/96-expert/366-ehealth-denmark-national-health-portal-sundhed

[33] http://medicinex.stanford.edu/conf/submission/view/332

[34] http://www.zdnet.com/article/australias-struggling-e-health-records-under-review/

[35] http://www.zdnet.com/article/pcehr-renamed-to-my-health-record-automatic-account-creation-trialled/

[36] https://myhealthrecord.gov.au/internet/ehealth/publishing.nsf/content/home

eRedbook – UK

The eRedbook is a national pilot project in the UK[37]. The actual software is developed by a private company but the project is supported by NHS and the Royal College of Paediatrics and Child Health. The eRedbook is building on an offline tool, the paper based Redbook, to ease the learning curve. The project has first been introduced in Liverpool and Sefton in 2013 and it is available in the greater London area since 2015. The project has not built a PHR from scratch, it is based on Microsoft's Health Vault, one of the most well known untethered PHRs (see more about these later).

Other countries

Almost all developed countries are examining the possibilities of embracing digital health, they are at different stages. The table found in Appendix 1 summarizes where different countries are at the moment.

3.3.4 Payer populated PHRs

This type of PHR is tethered to an insurance provider or employer that is populated with claims information. The best examples for this approach are in the US. PHRs in this model rarely include any clinical information directly from health care providers, but some allow members to enter basic information. Specific capabilities vary, but all large health plans such as Aetna, Cigna, Anthem and United Healthcare offer some type of payer-populated PHR[38]. So far, no payer populated PHR has demonstrated its ability to become a comprehensive tool used outside the boundaries of its inception.

As arrangements between payers and providers become more complex under value-based care programs in the US, the relationship between payers and providers also increase in complexity. The line between payers and providers continues to blur, new alignment of clinical and financial value is heralding a major shake-up of the traditional players[39].

[37] http://www.eredbook.org/

[38] http://assets1.csc.com/health_services/downloads/CSC_A_True_Personal_Health_Record.pdf

[39] http://www.forbes.com/sites/athenahealth/2015/06/04/health-care-providers-to-payers-we-still-dont-really-trust-you/#2485b118379b

3.3.5 Untethered PHRs

Untethered PHRs are controlled by the patient rather than by the provider, employer or health plan. The patient can manually populate the record or authorize certain payers, pharmacies, providers or other organizations to do so with information from their systems (provided those organizations have an agreement in place with the PHR vendor). Untethered PHRs also allow users to integrate third-party solutions into their record.

Until recently, the three most well-known entrants into the untethered PHR space were Microsoft HealthVault (launched in 2007), Google Health (launched in 2008) and Apple's HealthKit (launched in 2014). In 2011, Google announced it was discontinuing the Google Health service. Microsoft publicly acknowledged abandoning efforts to make profits in the US and its role would be simply to increase the brand relationship[40]. While it is still early to draw definite conclusions about Apple, the first reviews of Apple's own HealthKit app, Health, were (at best) lukewarm with several privacy concerns surfacing straight launch[41].

Apart from these giants there is a multitude of untethered PHRs available for consumers. While some of these systems have started up with great promises, in reality, none have really gained any traction with consumers. A study in the International Journal of Medical Informatics identified 27 limited PHR-type systems in 2000; only 7 of those systems were still available in 2003. Furthermore, the initial 27 identified were "beta releases" that were in early stages of development and had not achieved widespread use[42]. The main reason for their collective unsuccessfulness is that:

1. There are hardly any partnerships between untethered PHR vendors and provider organizations to date.
2. Direct-to-consumer does not work in an industry where people expect third parties—insurance companies or state healthcare—to pay the bills[43].
3. Most PHRs currently act as a repository of information. As it turned out, few consumers are interested in a digital filing cabinet for their records only.

As a further proof of their shaky position, design of PHRs has not evolved much since they first arrived in the 1990s, long before Google or Microsoft showed an interest in this area[44]. There is a strong consensus among industry players that PHRs will never see widespread adoption until full cooperation between patients, insurers and healthcare providers is achieved[45].

[40] http://www.ft.com/cms/s/2/6e10b422-f58d-11df-99d6-00144feab49a.html#axzz3GDzHFbut

[41] http://www.zdnet.com/article/move-over-healthkit-why-apples-researchkit-is-proving-the-real-hit-with-doctors/

[42] http://issues.org/26-4/etzioni/

[43] http://www.forbes.com/sites/neilversel/2014/06/03/apples-healthkit-connects-with-mayo-and-epic-but-dont-call-it-revolutionary/#14c14c4d58a3

[44] http://www.healthcareitnews.com/news/parsing-paradox-underused-phrs?page=1

[45] http://blog.zesty.co.uk/phr-market-past-present-future-personal-health-records/

3.3.6 Competitor summary

The below table summarizes not only the advantages and disadvantages of the described approaches but also the necessary conditions that must be met before they can be commenced. The table may assist stakeholders to be able to assess the feasibility of a particular approach.

Approach	Advantages	Disadvantages	Prerequisites
Focus on the adoption of EHRs	• Competition forces efficiency	• Separate systems hinder interoperability • Developer interest also works against interoperability	• None, existing EHR systems are an advantage
Linking separate EHRs together	• Clinically valid database • Strong buy-in from healthcare providers	• Hard to establish customer/patient orientation • Must remain in a national setting	• Unified national health system • Strong EHR base
National PHRs	• Flexibility to opportunities and constraints	• Development from scratch • Has to build up buy-in for all stakeholders	• None, system is based on what is already available
Payer populated PHRs	• Clear business model • Promise of quick benefits means engaged stakeholders and rapid / focused development	• Relatively small reach (only available for members) • Inability to expand	• Strong private insurance companies
Untethered PHRs	• Flexibility	• Unproved business models • Link to EHRs close to impossible	• None

4 Strategic direction

4.1 SWOT analysis

The following table of Strengths, Weaknesses, Opportunities and Threats (SWOT) has been prepared to systematically consider aspects of MHA in terms of these characteristics. The table not only lists the different SWOT factors, but also shows how well MHA performs regarding that particular factor on a 1 to 5 scale. The number is the average of scores given by the consortium partners.

Strengths

- Technical background (4.67)
- Legal and ethical framework (5.00)
- EU wide approach (3.83)
- Scientific base (4.67)
- Integration of heterogeneous data sources through ontologies (4.00)
- Good balance between health and fitness (3.67)
- Facilitating better health conciousness for users (3.83)

Weaknesses

- Lack of financial resources (1.50)
- Uncertainty looming with the end of the project (2.33)
- Low number of end users (2.00)
- Lack of managerial resources (3.00)
- Limited interaction with healthcare professionals (3.50)
- Limited functionality (3.17)
- Unproved business model (2.17)

Opportunities

- Utilize specific use cases for growth (4.33)
- Health status assessment and risk analysis (4.33)
- Synergies within the VPH community (3.67)
- Create incentives for third party API developers (3.67)
- Provide insights based on the analysis of the collected data (3.50)
- Additional tools for physicians for better treatment (4.00)
- Better health outcome for users (3.17)

Threats

- Competition from national systems - a solution provided by linked EHRs (3.33)
- Competition from untethered PHRs (3.33)
- Growth is very slow through specific use cases (2.83)
- No demand to go beyond the borders - national systems satisfy citizens' needs (3.00)
- Physicians disregarding fitness and/or patient entered data (2.83)
- Security breach of stored MHA data (4.50)
- Difficulties of a large scale implementation (3.33)

All partners recognize that the termination of the original MHA project presents unique weaknesses that must be addressed if we want to ensure the continuation of the results. This main function of this business plan is the facilitation of that continuity. We also need to consider strategies to counter the listed threats to be able to have success in the exploitation phase.

The factors listed above are not equally important. We have therefore not only determined how MHA performs in these respects but also quantified the importance of the particular strength/weakness/opportunity/threat in the setting of the MHA platform and its competitors. We asked consortium members to rate the factors from this perspective as well (also on a scale of 1 to 5) – the higher the rating, the more important the given factor. The consideration behind this exercise was simple: if a factor is not particularly important, a lower result in the actual score is not as significant as with a very important factor. In this respect three weaknesses have stood out from the pack as shown in the below table:

Factor	Importance score	MHA performance score
Lack of financial resources	5.00	1.50
Uncertainty looming with the end of the project	4.17	2.33
Low number of end users	4.67	2.00

These large differences confirm the need for all partners to focus on the realization of the exploitation activities.

4.2 Business model

Ensuring sustainability after the project's official end can happen in a variety of ways. The most important aim we have had in mind was to ensure that the MHA platform is used by a large number of people. In the exploitation plan we examined a number of possibilities but as the project was nearing its end, making it open source has appeared to be the most viable solution.

By choosing this option, sustainability of the platform can be reached with or without further efforts from the consortium members:

A. A successor of the MHA consortium remains in charge of operating the software. Revenue comes from charging a support fee to those customers who rely on the avatar for maintenance and support.
B. Some other entity takes on the above responsibility or the open source community itself provides the required accessories.

Below is the model in an easily understandable format.

<table>
<tr>
<td>Key partners

Healthcare providers
1. Household and community health care
2. Health centres/clinics
3. Hospitals

Application developers

Wearable device developers</td>
<td>Key Activities

Activities performed during the MHA project

Key Resources

MHA project partners</td>
<td>Value Proposition

MHA source code – proprietary

MHA source code – open source</td>
<td>Customer relations

Dedicated Personal Assistance

Communities

Channels

Personal selling

Online distribution</td>
<td>Customer Segments

PHR developer company

PHR developer community</td>
</tr>
<tr>
<td colspan="2">Cost Structure

Zero costs after project’s end

Customer service department</td>
<td colspan="3">Revenue Streams

License fee

Consultancy fees</td>
</tr>
</table>

MHA project partners have unanimously expressed their intention to keep exploring the different options with regards to exploitation. While the official end of the project means that further development of the core platform will not be continued, individual project partners will carry on refining MHA modules. Project partners have also discussed the possibility of creating a start-up company for the commercial utilization of MHA. While no concrete steps have been taken in this direction, it is certainly one of the possible options.

The results of MHA are incorporated in several other European projects (see chapter 6.1 for details). While these projects are still ongoing at the moment, MHA will be featured in their related exploitation activities, likely creating new business opportunities for MHA as well. These will be followed up by BED and also other partners participating in the aforementioned projects.

4.3 MHA turned into open source

It was decided by the consortium to upload the scripts/source codes of most MHA components into a public code repository. Project partner LUH has defined open source licenses for MHA components in 2015[46] and later provided instructions for the developing parties how to attach license notices into the codes. In particular, LUH prepared some guidelines agreed these with the project coordinator.

[46] Legal Report on Software Licensing in MHA

The guidelines[47] describe how to license components "open source", explaining the steps which partners will need to follow before uploading the codes into the public repository. The upload of the codes to the public repository will be coordinated by the project coordinator. The preliminary licensing steps include:

- what copyright and license notices you need to attach to the source files and where to place them
- how to complete copyright notices
- how to provide the license text along with the code
- what exceptions some developers need to add to the license terms of certain components (e.g. ICCS/Tool Execution Engine, BEDS/ MHA Web Application (Backend), MHA API and Data anagement)
- what requirements you need to follow for software dependencies

It will be the responsibility of the developing parties (BEDS, ICCS, FORTH) to upload their codes under selected licenses into the designated part of the repository by themselves.

[47] 'Open Source Instructions' prepared by LUH

5 Products and services

5.1 MHA as a functional prototype

MyHealthAvatar is a solution that offers access, collection and sharing of long term and consistent personal health status data through an integrated digital representation of an in silico environment, which helps to deliver clinical analysis, prediction, prevention and treatment tailored to the individual citizen. MHA can be described as a personal bag carried by individual citizens throughout their lifetime. It is a companion that will continually follow the citizen and will empower them to look after their own health records[48].

MHA has a large number of features that together make it suitable to become a comprehensive platform for all health and fitness related tools for individuals. We demonstrate the capabilities and business potential of MHA through examining these features. The MHA platform and its constituent features are listed in the sections below together with a brief analysis of their functionalities, innovation and potential business impact.

5.1.1 PHR

The solution

The definitions of a PHR are many but in reality these definitions do not differ significantly. One universally accepted one that we can use is: 'A PHR is a tool to access, collect, track, manage and share actual, up-to-date information about your own health or the health of someone in your care in a secure and confidential environment.' Based on the results we claim that MHA is a PHR and more. The competitor analysis (chapter 3.3) contains more detailed information of PHRs and their roles in healthcare.

Innovation

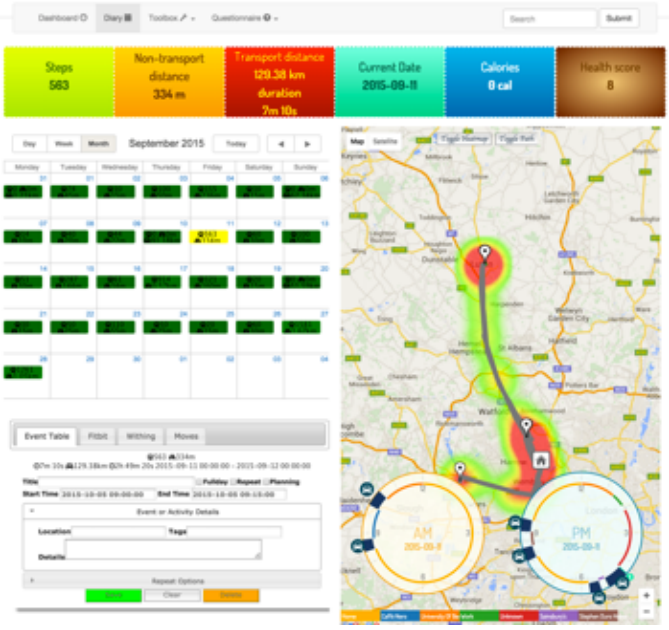
MHA contains many elements of the currently available PHRs. There are, however some additional novel features:

- Integrated behaviour changing programmes, such as health living tips, reminder (delivered to the users through the dialogue based user interface on the application).
- Semantic search engine, that brings up documents from trusted sources.
- Visualization of lifelong medical data in a user friendly interface including medical images
- Advanced visualization of the abovementioned activities, life patterns and PHR.

Visualization is observed on several levels:

1. The web based platform shows your daily activities, including your movement and activity, daily step counts, travel distance, etc.

[48] MyHealthAvatar project, Description of Work (DoW) document p. 7



2. A web-based three dimensional avatar rendering suite has already been integrated into MHA platform. The rendering of 3D avatar is available as a data browser as well as an educational tool. Currently the 3D avatar is still a standalone component but it has the potential to be connected with the citizen's health status. The general 3D avatar will be replaced by the specific avatar for the particular user. The user's individual health issues will be visualized through the avatar. Some examples for visualization options and their benefits include:

   - If the blood pressure is out of the normal range, indications are shown in the 3D avatar.
   - We can visualise some of the biomarkers with some widgets or glyphs on the 3D avatar, for example we can visualise the test results of liver function on the liver.
   - We can even show some of the disease development, if one of the organs is not functioning normally, how other parts of the body will be affected.

   Apart from providing easier comprehension for patients and healthcare professionals, visualization enables better tracking of a particular health problem through time and also a better understanding of correlations and interdependence of different body parts and diseases.

Business impact

If the collective experiences of the past 10-15 years are any indication, today's PHRs are not financially self sustaining. Consequently if MHA only offered the functionalities of a standard PHR (even with novel elements described above), business viability would be similarly questionable. The necessary services and features that MHA offers are a prerequisite of a well-functioning system but, this is clearly not enough. The rest of this chapter explains what puts MHA above the accepted roles and capabilities of currently available PHRs.

5.1.2 Automated data collection

The solution

What we have learned from our own experience during the three years of the project are in line with findings of different reports: people's motivation to manually enter fitness and/or health related data quickly wanes. This is a very serious issue: if the data is missing or incomplete, the usability of the system is seriously compromised. We anticipated this issue from the very beginning of the project and have decided to counter it with enabling automatic data capture whenever possible[49]. While several competing systems offer the possibility of incorporating external data from medical devices, fitness trackers and smartphone applications, MHA further puts the emphasis on the merging of information.

Innovation

1. Recognition and recording of activities of daily living. After annotation MHA automatically recognizes all the places that the user visits.
2. A user-friendly dialogue based user interface for interactive collection of daily living data (e.g. mood, food, photos, glucose). The ability to easily record consumed food is a great addition.

Business impact

Automated data collection is a tool to enhance the usability and the effectiveness of a system. It is designed to increase overall business potential.

5.1.3 Link with external sources for health related information collection

The solution

Health data currently resides in many places: at home, GPs' offices, healthcare institutions etc. A standalone system that has no connections to at least some of these external sources is a recipe for failure. External sources can be many, but obviously the most important are hospital information systems (HIS).

The platform of MHA aims to support the 4D digital representation of a given patient but of course parts of the patient's clinical and social history are already stored and managed by third party systems. For this reason proper mechanisms and infrastructure should be in place for retrieving relevant user information from these external data sources. Whenever it's possible such "linking" with the third party systems should be based on available standard interfaces since they allow the building of generic ports and interfaces and the reuse of existing code bases[50].

[49] MyHealthAvatar project, Description of Work (DoW) document p. 11

[50] MHA deliverable 3.4, p. 8 ff.

Innovation

MHA has developed a framework to ease the process of linking MHA to other health information sources (Medical/Biomedical databases, Drug databases, Hospital information Systems, Electronic Medical Records, Personal/Patient Health Records, etc.).

A new architectural layer is proposed and developed to host the adapters, gateways and other components which are responsible for the linking with the external data sources. The components belonging to this layer interact with the main backbone of the MHA platform and the semantic infrastructure, and other repositories. MHA emphasizes in the semantic integration layer and the semantic transformation of these data in order to be uniformly accessible, through MHA common information data model, via MHA published APIs. Relying on these ontologies MHA has built a working link with a real HIS. The link has been tested thoroughly with artificial data (the transfer of real data is not allowed according to current legislation).

Business impact

The biggest deficiency of current PHRs is their inability to connect with external systems. For users, real value would be only delivered if all their health related information was available in one place. For this to be achievable however, national and European legislations must also change. MHA's functioning link with a HIS means that it is ready to embrace that possibility.

5.1.4 Real actions based on the collected information

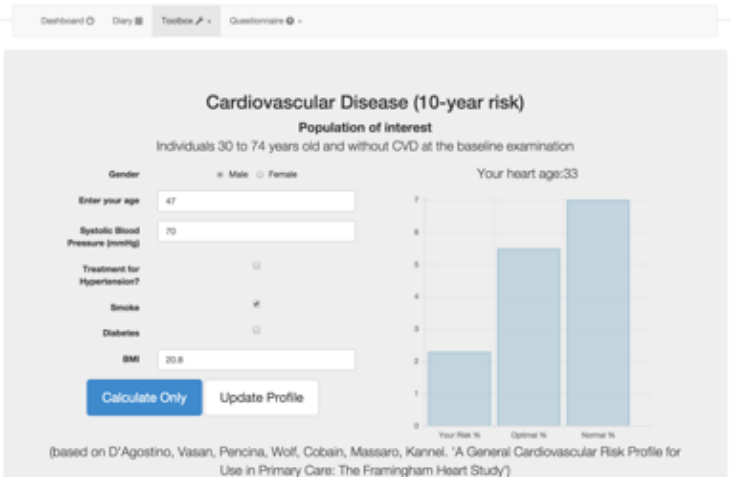
The solution

MHA stores a large variety of data and information. Simply storing and displaying this data intuitively is beneficial for users. Observing patterns and discovering salient values have the potential to provide new insights and thus create the possibility of behaviour change and consequently improve fitness levels and health status of an individual. Real value would be delivered however taking this one step further with MHA able to synthesize all the available information and provide actionable insights for users. This can possibly take many forms, the common ground is that the focus is on the future (what the user should do) instead of the past (what the user has achieved so far).

Innovation

<u>Individualised risk analysis of long term diseases</u>

The toolbox includes four established risk assessment models from well-known clinical studies (i.e. the Framingham study) to predict risk of having cardiovascular disease, hypertension, diabetes and stroke according to the user's profile.



Medical alerts

Any relation can be examined between existing data elements. Alerts can be issued for the user in case the conditions are relevant. Apart from looking at particular data within MHA, the system could include new solutions (e.g. fall detection) to offer a more complete package.

Business impact

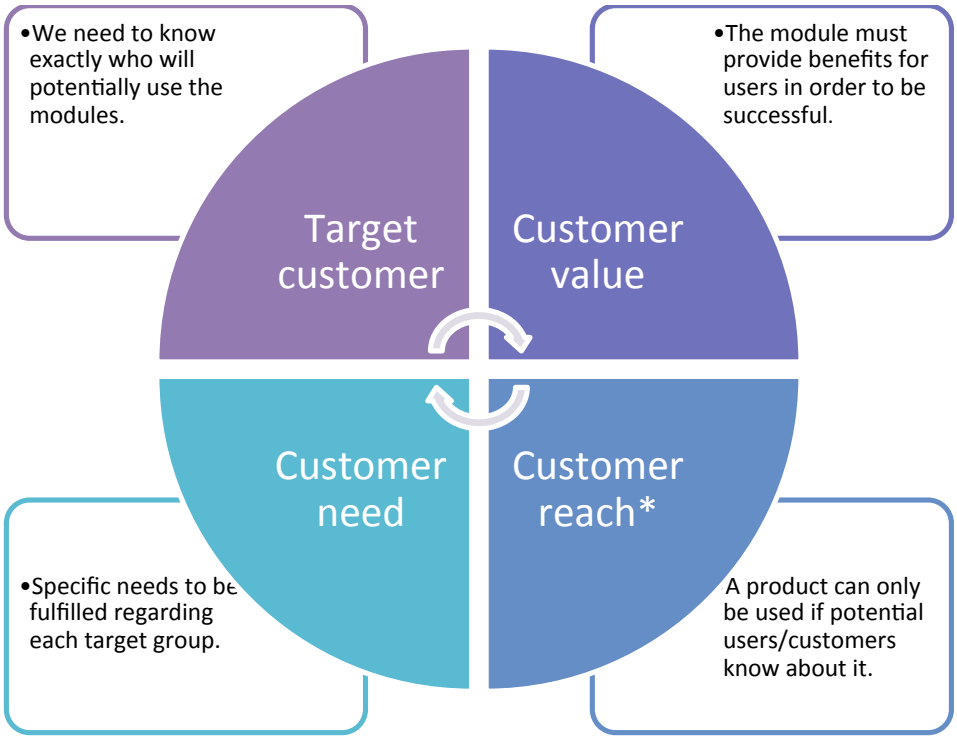
One of the main lessons learned from the low success rate of PHRs and also from the waning interest in fitness trackers[51] is that these products and solutions need to provide insights and advice, not just data. The innovative solutions offered by MHA point in this direction. These are the kind of services that users may be prepared to pay for.

[51] http://www.macworld.com/article/2880363/fitness-trackers-need-to-provide-insights-and-advice-not-just-data.html

5.2 MHA modules

The core of the project is the MHA platform where the data is stored and managed. The platform however follows a modular design, most of its capabilities can be utilized through applications that are linked to the platform but are not an integral part of it. This is already true for most tools developed by project partners but it will reach its real significance when it will provide an opportunity for third parties to link their applications to the platform.

The modularity of the MHA platform is one of its most important features. In this part we analyze the already existing modules from a marketing perspective. For the sake of clarity we used a uniform and comparable structure to describe all the modules. In the analysis we use the following dimensions:



** This business plan does not contain a detailed marketing communication plan but we wanted to at least provide hints about the best ways to reach the different target groups.*

5.2.1 Nephroblastoma module

The module, in conjunction with the MHA platform, assists doctors in formulating personalized strategies for nephroblastoma patients.

The following table summarizes what this module offers for different stakeholders.

Target customer	Nephroblastoma patients and their parents	Physicians	Cancer researchers
Customer need	Patients want the best possible individual therapy available for them.	Precise, timely and easily available information about the disease and patients. Evidence based support in therapy choice.	Developing and validating in silico models.
Customer value	1. Better understanding of treatment (through demonstration) 2. Result of prediction improves further treatment outcome	1. Supports decision making in the treatment process 2. Part of in-silico patient record as an extension of clinical record	In-silico profiling could be used as: 1. input for the use of other models 2. statistical tool to categorize patients 3. guide model adaptation for new patients
Customer reach	Patients will be reached by the treating physician	1. Relevant conferences 2. Publications	1. Interfacing actions among research projects 2. Publications 3. Online dissemination

5.2.2 CHF Risk Assessment module

The module empowers citizens, patients and doctors by providing a supportive environment for the self-management of patients/citizens with cardiovascular disease risks. We define the "CHF Real-time patient monitoring" and the "CHF Risk Assessment" service provided by MyHealthAvatar platform in order to:

- Assist individualized out self-monitoring of their own health-status
- Provide risk analysis for personal risk monitoring for developing a cardiovascular related episode in the future

The module is available through a mobile application which is able to acquire data from medical sensors used by the user to gather biomedical data that can be used to assess if a CHF episode is eminent and to provide appropriate notification to the user. The application sends appropriate notification events to MHA platform with all CHF episodes detected.

The following table summarizes what this module offers for different stakeholders.

Target customer	Healthy citizens	Patients	Physicians
Customer need	Measure CHF risks and indicate need for prevention	Early detection of exacerbations of the disease	Opportunity for early and effective intervention
Customer value	Measured risk provides motivation for healthy lifestyle	1. Real time mobile monitoring enable intelligent alerting 2. Automatic data collection through wireless medical devices	Better indicators for potential treatment modification
Customer reach	1. Marketing during related prevention campaigns 2. Joint marketing with fitness trackers	1. Through treating physician 2. Patient organizations	1. Relevant conferences 2. Publications

5.2.3 Osteoarthritis module

The module is a supportive and integrated environment for the long-term management of knee osteoarthritis condition and is intended to be used by both medical professionals and patients. The system will allow the medical professionals to carry out personalized treatment and better follow-up and the patients to play a key role in monitoring and managing their own health.

The following table summarizes what this module offers for different stakeholders.

Target customer	Healthy citizens with known risk factors	Patients	Primary care physicians / general practitioners
Customer need	Assistance and advice for prevention	Effective condition management	Easy-to-use, systematic condition management
Customer value	Decreased chance or slower emergence of the condition	1. Continuous monitoring of related medical data 2. Offering advice and assistance	Better insight of the condition and its progress
Customer reach	Marketing during related prevention campaigns	1. Through treating physician 2. Patient organizations	1. Relevant conferences 2. Publications

5.2.4 Pre-Diabetes module

The module is enriching the functionalities of the MHA platform in terms of enhancing user experiences in behaviour monitoring and facilitating their lifestyle management. The module incorporates verified risk assessment models for diabetes, personal behaviour intervention modules that allow for planning and remaindering services for daily physical exercises, diet control and medication where necessary.

The following table summarizes what this module offers for different stakeholders.

Target customer	Healthy citizens	Pre-diabetic patients
Customer need	Avoid diabetes	Manage and improve condition
Customer value	1. Risk assessment 2. Warning at early signs	1. Monitoring activities, diet and other health-related behaviours and events 2. Intervention of lifestyle
Customer reach	1. Marketing during related prevention campaigns 2. Joint marketing with fitness trackers	1. Through treating physician 2. Patient organizations

5.2.5 Future modules

The main value of MHA is the data collected over a long-term period for individual citizens/patients. It is expected that such a long term data collection may contribute towards many aspects of a wide range of applications. While MHA will provide a set of data analytic services, it is not possible for the platform core developers to develop all the possible applications that may utilise the value of the data. Therefore, we invite third parties to be involved in the development of MHA related applications by offering development APIs.

We provide an agnostic API able to support external application developer need. This API is also used by the already existing Pre-diabetes, CHF and OA applications. This agnostic API framework aims to ease the development and hosting of software applications that need to deal with MHA services and data access by third party applications. This API allows applications to embed on demand MHA business logic to process data from and to MHA platform. API is able to support needs for extra functional services such as database, web server, or publish/subscribe messaging systems and extent traditional PHR like systems to be able to support all MHA innovation features and services.

6 Other exploitation

6.1 Connections with other related projects

MHA fits into a network of more or less similar projects, which are concerned with developing ICT health care solutions where health data is used in an efficient intelligent way to improve the treatment and care of patients and citizens. Many of these projects are connected to the well-known VPH network. Our results can only be enhanced by identifying and utilizing synergies with these projects. For this purpose we reached out to some of these initiatives and started negotiations about possible cooperation. The outcomes of MHA are expected to be used differently within these projects. Details can be found in the following subchapters.

6.1.1 iManageCancer

IManageCancer is a H2020 project offering services to support self-management in cancer care. MyHealthAvatar will be integrated into the architecture of the iManageCancer platform to support the lifestyle and physical activities of the cancer patients. An overview of iManageCancer is provided in Section 6.1.1.

MyHealthAvatar and its app will be adapted to support long-term care for cancer patients. The following lifestyle factors are relevant for the self-management of cancer care.

- *Weight control*
- *Diet*
- *Physical exercises*
- *Social activities*
- *Mood & stress*
- *Alcohol and smoking*
- *Side effect/pain/fatigue reporting and handling*
- *Sleep*
- *Appointment management*
- *Information and education*

Weight control & physical activities share a lot in common with the general health. Within this project we need to tailor them for cancer. MyHealthAvatar contributes to the more effective interaction between the patient, his/her family and the clinician, caregiver, by offering PHR in combination with the e-diary and physical activities of the patients. The iManageCancer personal health record will facilitate information sharing, enhance education and accelerate acceptance of the proposed technology. MyHealthAvatar will provide a place for patients to record their own lifestyle which is highly related to their self-management of the disease, and hence to further enhance their involvement and active participation in the care process. It will also give special focus on patient education and technology acceptance. These techniques will recommend to the patient educational resources related to their condition and they will assist them in depth for their health status or disease in order to make informed decisions regarding their healthcare, which will act as a mediator between the patients and their care givers.

6.1.2 MyLifeHub

MyLifeHub is an UK EPSRC-funded project (i.e. a UK National Research Council). In MyLifeHub, MyHealthAvatar is used as the ICT platform to support patient information collection, self-management and the assessment of quality of life of ophthalmic patients.

MyLIfeHub involves three UK partners from the MyHealthAvatar consortium, including BED, LIN and ANS.

Visual impairment is one of the most feared forms of medical disability, which imposes a great social and economic burden on our society. It has a significant impact of quality of life (QoL). The fast growth of the Internet of Things (IoT) technology offers researchers a variety of opportunities to establish QoL profiles of individual person with increased reliability and validity by monitoring their lifelogging data. MyLifeHub features new techniques, which provide wearable sensors to connect with the environment, allowing for a constant monitoring of the behaviours of people's vision. It is utilized as a platform to assess the impact of visual impairment on the QoL of ophthalmic patients both in general health terms and in vision specific terms.

Acquiring patient-based data for QoL assessment and Patient Reported Outcome Measures (PROMs) has been increasingly adopted as an important measure to estimate the impact of eye disease and to assess the effectiveness of ophthalmic treatment, for either individuals or groups of patients,. This allows for comparison with other available alternatives, prioritisation and allocation of resource in ophthalmic care. Visual impairment has a significant impact on quality of life (QoL); reduced visual acuity seriously affects patients' daily and social activities, with substantial increased risk of mortality, fracture, falls, depression and other emotional distress.

The study will examine 50 participants in either a single visit or number of visits over the course of up to 3 months. Participants who take devices away from the hospital setting for self-use will be invited back to return the devices so that the health data collated over the 3 month period can be extracted and then sent to the University of Bedfordshire and University of Lincoln for analysis.

The objectives of the clinical study are:

- To assess feasibility of application of novel visual function and ophthalmic disease monitoring technologies in patients and ophthalmic care professionals
- To assess the impact of visual impairment on the Quality of Life of ophthalmic patients both in general health and vision specific terms.
- To build an interoperability hub that will allow the collection of data from a range of IoT assets into a common, internet-enabled environment, providing profiles of lifestyles of individuals, which will enable interoperability, accessibility and innovation from novel applications and services in healthcare.
- To track the level of physical and social activities before and after eye surgery

Self-reported activity and compliance data by patient including:

- Behavioural measurements.
- Patient-reported outcome and experience measures.
- Clinical measures such as intraocular pressure.

The recruitment criteria include:

- Any ophthalmic patient attending for clinical or theatre treatment between the ages of 18 and 100. This will include patients with pathology, especially age related macular degeneration, diabetic retinopathy, glaucoma, cataract and cancer along with healthy subjects.
- Clinical staff involved in ophthalmic care and members from professional bodies will also be invited to enrol in the study.

The following sites will be recruiting: Bedford Hospital NHS Trust, Hinchingbrooke Healthcare NHS Trust, Ealing Hospital and Moorfields Eye Hospital NHS Foundation Trust.

Here is a description of the clinical scenario:

- Oculoplastics: A visit at two weeks before the surgery (first appointment before surgery), the nurse will teach the patients how to use the technology and the self-monitoring will start. On the day of surgery (2 weeks after first visit) patient will meet the nurse (discuss any further queries). Post op two weeks after the surgery (finale visit) study terminated. Group of patients to be involved; unilateral ptosis surgery, Bilateral blepharoplasty, Unilateral Floppy Eyelid syndrome patients.

  Measurements; steps, HR, sleep activity, O2

- Glaucoma: Following the diagnosis of the condition (first visit), the patients will start the medication together with the self-monitoring for 2-4 weeks when follow up visit occurs, next follow up visit at 3-4 months.
- Important to integrate in the platform the medications (antihypertensive) taken and what time for these patients to detect effect on IOP.

  Measurements: steps, HR, sleep activity, IOP.

- Cataract: Following the diagnosis of the condition (first visit), the nurse will teach the patients how to use the technology and the self-monitoring will start. On the day of surgery (up to 3 months after first visit) patient will meet the nurse. Next visit is 5 weeks postop when study terminated.
- For patients with both glaucoma and cataract conditions, there is some evidence to show that the cataract surgery will help bring down the IOPs. Also, the absorption of the medicine may become greater because of the wound.

  Measurements: steps, HR, sleep activity, IOP.

- AMD: Following diagnosis of Exudative AMD, when patient listed for Injection (first visit) nurse will meet the patient and self monitoring will start. On the day of injection patient will meet the nurse and 1 month later on postop visit when study will be terminated.

  Measurements; steps, HR, sleep activity, IOP.

A sample size of 50 patients would allow for sampling of a wide range of participants including those in clinic and theatre, to healthy volunteers (consisting of staff and members from professional bodies). Given the project duration we believe it to be a realistic and practically feasible number to recruit from all the named sites. It covers a satisfactory number of the populous which makes sense for the ICT evaluation to be able to cover the minimum level of variety in gender, age, background, conditions, etc.

In MyLifeHub, the MHA platform will be used as the main platform to collect patient information from the participants from MEH. LUH has already offered a legal framework to allow this to take place[52]. This will be a very good example of applying the MHA in a clinical setting.

6.1.3 CHIC

Developing robust, reproducible, interoperable and collaborative hyper-models of diseases and normal physiology is a sine qua non necessity if rational, coherent and comprehensive exploitation of the invaluable information hidden within human multiscale biological data is envisaged. Responding to this imperative in the context of both the broad Virtual Physiological Human (VPH) initiative and the paradigmatic cancer domain, the large scale integrating transatlantic CHIC project (http://www.chic-vph.eu/) develops a suite of tools, services and secure infrastructure that supports accessibility and reusability of VPH mathematical and computational hypermodels. These include a hypermodelling infrastructure consisting primarily of a hypermodelling editor and a hypermodelling execution environment, an infrastructure for semantic metadata management, a hypermodel repository, a hypermodel-driven clinical data repository, a distributed metadata repository and an in silico trial repository for the storage of executed simulation scenarios. Multiscale models and data are semantically annotated using ontological and annotating tools. An image processing and visualization toolkit, and cloud and virtualization services are also being developed. In order to ensure clinical relevance and foster clinical acceptance of hypermodelling, the whole endeavour is driven by the clinical partners of the consortium. Innovative cancer hypermodels are collaboratively developed by the consortium cancer modellers and provide the framework and the testbed for the development of the CHIC technologies. Clinical adaptation and partial clinical validation of hypermodels and hypermodel Oncosimulators are under way. Indicative strategies, algorithms, systems, results as well as the outcome of clinical adaptation and partial clinical validation of hypermodels are presented.

The CHIC project has developed a data repository that provides for a secure storage of clinical data, imaging data, histological data, therapy, etc. CHIC grants access to its data repository to host the medical data of a synthetic patient, generated by MHA. The medical data of the synthetic patient allows MyHealthAvatar to demonstrate the utility of its platform by allowing execution of oncosimulations using the medical data.

This collaboration is beneficial for both projects. MyHeathAvatar is able to demonstrate that amongst other external sources, many of which could be clinically oriented in a commercial way (e.g.

[52] See deliverable 11.1, Appendix 4 – Appendix Consent form for the external projects MyLifeHub and CARRE, p. 64 f.

HIS), tools and resources can be provided, so that collected data from research resources (clinical, modeling, trials etc.) can be used for educational, research (model adaptation and validation) and clinical purposes (executions of validated models with real data) either from within the platform (depending on the number and kind of stored models), or by bringing together the third part resources and applications that are connected to the platform, the latter thereby acting as a "transit" center for data and authorization.

On the other hand, the CHIC project proves true one of its initial assertions, pertaining to the storage and use of collected and created data not only for its own purposes, but instead to make them accessible after the end of the project to other projects as well.

6.2 Individual exploitation

This section collects all the individual exploitation plans for the MHA partners. They have different interests on MHA outcomes and due to their respective nature (industry, academic, research or community) their business goal is completely different and the benefits they expect from MHA as well. We have classified the exploitation plans according to this nature and the requested information is slightly different.

6.2.1 University of Bedfordshire (BED)

A number of new research proposals or ideas have been put forward, which will make use of the MyHealthAvatar platform. A brief summary of these proposals and ideas is given as follows:

- MyHealthAvatar for peer-support: The success of diabetes management depends on the ability of patients with diabetes to successfully sustain effective self-management behaviors, taking prescribed medications, following diet and exercise regimens, self-monitoring, and coping emotionally with the rigors of living with diabetes. Productive health care visits and nurse case management programs are important means of supporting patients' diabetes self-management but alone often cannot adequately meet many patients' needs. Higher levels of social support—especially illness-specific or regimen-specific support—are associated with better diabetes and other illness self-management. Peer support among patients with the same chronic health problem may be a particularly effective intervention, combining the benefits of both receiving and providing social support. "Peer support" is defined as "support from a person who has experiential knowledge of a specific behavior or stressor and similar characteristics as the target population." MyHealthAvatar has been designed with inherent features to support self-management. A research proposal has been put forward to extend and evaluate the platform with respect to its capacity to support peer education among the communities for diabetes care.

  Clinical collaborator: Mrs Emma Wilkinson (University of Bedfordshire) - Healthcare Specialist in Diabetes.

- MyHealthAvatar for healthcare research in frailty: There has been research interest in utilising MyHealthAvatar in frailty research. The idea is to use the MyHealthAvatar app as a way to collect patient information in order to detect early signs of frailty. We expect two MSc students (MSc by Research) to work on this topic.

Clinical collaborator: Prof. David Hewson (University of Bedfordshire) – Professor of Health and Aging

- MyHealthAvatar for sport science: Research in sports science is interested in exploring the correlations between the activities and health (i.e. measured according to bio measures such as glucose, blood pressure). Normally such a test is done in a lab environment intensively within a short period of days. However, researchers are particularly interested in exploring the relationships during daily life. MyHealthAvatar may play such a role to support their research. It has been decided that one MSc student (Rachael Champion) will start to use MyHealthAvatar to work on this and we are seeking further support for MSc by Research to explore this area.

  Domain Collaborator: Dr Daniel Bailey (University of Bedfordshire) – Senior lecturer in Health, Nutrition and Exercise

- MyHealthAvatar for patients with memory problems: To help patients which start to have early sign of memory problems, doctors from memory clinics often help them with hints about their past experience with a purpose of stimulating their own memory. Since MyHealthAvatar records the daily activities of individuals without requiring much of their efforts, it is seen potentially as an ideal tool used by the doctors and patients for the treatment of memory problems. Currently through the collaborator we are seeking a trial of the system by the patients in memory clinics.

  Domain Collaborator: Professor Lia Kvavilashvili (University of Hertfordshire) – Psychology, Learning, memory and Thinking

- MyHealthAvatar for Care home: Advinia is a network of care homes providing the full spectrum of care services. The senior management team has been involved in care since 1999 and works in partnership with staff, residents, family and social workers. It provides homely facilities without an institutional feel. Following an initial meeting on 10th Feb 2016 with the Care Home owner, Mr. Sanjeev Kanoria, who has expressed a great interest in using MyHealthAvatar as a place for clinical records and lifestyle activity, the next meeting will set up on 1st March 2016 to continue the discussion with Mr. Len Merton (CEO) to arrange details in the collaboration.

  Collaborator: from Advinia: Mr. Sanjeev Kanoria (owner), Mr. Len Merton (CEO). Prof. Gurch Randhawa (University of Bedfordshire) – Professor of Public Health

- MyHealthAvatar for Africa: Through our contact in Nigeria, we have sent letters for the expression of interest for research to the ministry of Health and Executive Governor. Through discussions with colleagues from Africa, we realised that many rural areas in Africa still lack the most basic system of healthcare records. Records are vital to medical decision-making because they allow the doctors to see all the relevant information about the patients' health, such as previous visits, medication given and vaccine history. Without records, there is nowhere to store lab results, and consequently basic errors can occur on important matters such as blood transfusions. At a national level, medical records are needed to collectively provide up-to-date information about the health of the population: the Ebola outbreak in West Africa has especially highlighted the need for an effective record system which could deliver advanced warnings of the outbreaks, monitor the long-term health of survivors, and assess the effectiveness of treatments. We believe that MyHealthAvatar has the potential to fulfil this need. It is cost effective to deploy and maintain, since it requires only a web-based app to communicate with a server in Europe, so it is ideally suited to use in developing areas

Collaborator: Mr. Bilyaminu Auwal Romo

6.2.2 Foundation for Research and Technology – Hellas (FORTH)

FORTH's exploitation actions focus primarily on transferring basic research results to more applied research endeavours with the prospect of providing prototypical (open-source) implementations of algorithms, methods and systems to consortium partners, other labs and institutes within FORTH and to the relevant research and industrial community.

During the lifetime of the project FORTH shared technologies on semantic integration, model evolution and summarization with the successfully finished EURECA and p-Medicine EU funded projects

In addition, the semantic backbone within the iManageCancer project is based on the relevant technologies developed within MyHealthAvatar.

Semantic Integration, Model Evolution & Summarization are enabling technologies for new H2020 proposals and as such many new proposals include those developed technologies as well.

Forth is also planning to provide open-source implementations for exelixis and RDFDigest.

The courses "CS460 - Database Management Systems" and "CS562 - Advanced Database Topics" in Computer Science Department of University of Crete included lectures about schema matching, model evolution and data integration. The courses continue up to now one of them in the Spring and one in the Fall of each year. The course "Semantic Web" in the Department of Informatics Engineering at the Technological Educational Institute of Crete started in the fall of 2014 included lectures about ontology evolution and summarization. The course is continued as well up to now taught each fall.

In the future FORTH aims to participate in future projects to develop the following: Smart PHR systems, Personalized Health Systems, Semantic Interoperability mechanisms, Semantic Summarization algorithms and tools, PHR systems and effective health computing applications.

6.2.3 Universitaet des Saarlandes (USAAR)

USAAR was instrumental in the development of the MHA use cases. They will utilize the nephroblastoma use cases in Pediatric Oncology. This use case will be validated together with developments within the CHIC project in order to demonstrate the benefit for the care of patients with nephroblastoma.

Other use cases of MHA will be further elaborated and validated by integration in iManageCancer. This will help to disseminate these use cases and will increase the understanding of IT as a need for healthcare of today. The exploitation of MHA within iMangeCancer will sustain these use cases and will foster patient empowerment. As a consortium member of iMangeCancer USAAR will put a lot of energy to successfully path the way to maintain the use cases developed within MHA. Within the

consortia of MHA, CHIC and iManageCancer STaRC (Study Trial and Research Centre) will be discussed as a legal entity to maintain these projects like p-medicine.

6.2.4 Institute of Communication and Computer Systems (ICCS)

Based on the institution's main focus, the exploitation plan involves three main points.

Models

Currently the ICCS models, including the Nephroblastoma Oncosimulator used in the Nephroblastoma Use Case are partially validated through the work in MHA but also in other VPH related projects (CHIC, P-medicine, etc.), which means that they currently retain a non-commerical form. The validation procedure is ongoing, and after its completion (which is most likely to be after the end of MHA), a commercial medical-based platform (including a later version of MHA) could offer to hospitals/doctors etc. enhanced personalized medicine capabilities, in the form of clinical decision support systems, powered and enriched by the work done in the context of VPH.

Model Supporting Infrastructure

The work done for the creation of the model repository in WP5, including the API's and the interfaces it offers, can be highly usable either as a standalone platform, or as a part of a greater integrated medical platform, to provide support for any model creator who wishes to offer their models to establish or enhance the platform's disease prediction capabilities. This support can be given regardless of the model's simulated disease (cancer, CHF, stroke, etc.), design approach or internal mechanisms. That includes mathematical/statistical models, mechanistic/multiscale models and hybrid approaches. The Nephroblastoma Use Case is an indicative example of the infrastructure's use. However, the generality of the infrastructure's internal mechanisms that handle the models, as they are described in WP5 deliverables, guarantees the aforementioned universal compatibility with any disease.

A potential profit source could emerge from a specialized service offering to publish, test, and promote models from third parties, by:

a) Giving them rights to upload and handle the model information in the internal model repository
b) Providing sufficient data from various sources to further train and evolve the model under certain legal and ethical data and privacy protection guidelines.
c) Being a major contributing factor to the dissemination of the model and its features through the platform's reputation and
d) Designing the proper interfaces in the front-end (many modelers usually produce the models as simple command line executables).

Education

Knowledge acquired through the project is incorporated into the postgraduate course entitled "Multi-scale Cancer Modelling and In Silico Medicine", started in autumn-winter semester 2014

(http://www.vph-institute.org/news/new-postgraduate-subject-on-multiscale-cancer-modelling-and-in-silico-medicine-mscm-ism.html). This course has been proposed and is taught in the School of Electrical and Computer Engineering, National Technical University of Athens (NTUA) by Georgios Stamatakos, ICCS-NTUA. This course extensively exploits the outcome aspects of research projects funded by the European Commission. In the course's curriculum there are specific parts pertaining to the mathematical and biological principles on which the ICCS models are based (basic education), the necessary technological requirements to put models into clinical practice (technology) and the significance of the validated models in aiding a clinician's work, though the interpretation of the execution results, thereby giving the clinician a new easy-to-use tool, to support his/her decisions (medical education).

Furthermore, and as an initial education stage, partially validated models, simulating a hypothetical patient's disease progress (based on data acquired from literature), running through a model supporting infrastructure are suitable for general public education. The Nephroblastoma educational scenario (as part of the MHA toolbox), through its triple form of results (table of numerical values explaining the tumor's evolution, graph of tumor volume evolution over time, 3D reconstruction of initial and final tumor volumes), can be used to notify the patient and/or their parents of the new methods that are used to specify the treatment scheme. Extending this notion, the general public can be informed that such tool do exist for a variety of diseases (with cancer being an indicative example, given through the MHA platform), and show the basic biological mechanisms, disease progression, and response to treatments, (health literacy).

As a further extension of the work done in WP5, PhD or post-doctoral research positions have been designed in ICCS-NTUA in the field of in silico oncology/medicine.

6.2.5 Leibniz Universitaet Hannover (LUH)

LUH has deep expertise in data protection in medical context, as well as in legal informatics and intellectual property. MHA and similar projects combine these diverse areas and permit LUH to provide highly specialized legal counsel.

The best practices developed can also be carried on to future projects.

The legal and ethical principles that are explained and used for MyHealthAvatar are applicable to all types of medical projects through the nexus of sensitive (health) data. Examples include the concept of informed consent, the principles of purpose limitation and data minimisation and the need for ethical approval of a competent ethics committee when medical research is done without consent because it is impossible or impracticable to obtain it for the research. Similarly, the specificities of health services provided over the internet can be transferred to other similar projects.

However, MyHealthAvatar also presents distinctive legal challenges: this is especially true for the question how an electronic voluntarily given consent can be ensured in platforms such as MyHealthAvatar and how a disproportionate level of surveillance by the provider and other third parties can be avoided. Moreover, hospitals information systems (HIS) have been investigated to

avoid incorrect and corrupted data stored in the digital avatar. Other fields are the classification of tools in medical devices, and liability issues.

Elements of the legal framework developed for MyHealthAvatar can be carried on to future projects that will continue exploring these legal issues.

6.2.6 Technological Educational Institute of Crete (TEI-C)

As a research and academic organization TEI-C's exploitation actions focus primarily on transferring research results to prototypical (open-source) implementation, methods and systems to consortium partners, other labs and academic communities.

TEI-Crete is doing academic utilization and exploitation of MHA results. The syllabus of the undergraduate courses "Multimedia eHealth services" and "Modelling of physiological systems" in the Computer Engineering Department of the Technical Educational Institute of Crete include the lessons learned in WP3 related to modern architectural approaches for developing large scale infrastructures and topics related to semantic interoperability and integration standards.

Also, the tools developed in the context of MHA project are used for the practical training of students and the conduct of experimental evaluation.

In addition, the course in "Research Methods", taught by Prof. Tsiknakis, of the graduate "Informatics and Multimedia" includes aspects of the MHA experiences regarding quantitative research methods, architectural design, iterative system modelling and evaluation methods."

6.2.7 University of Lincoln (LIN)

LIN has developed a visual data analysis suite in WP8 to support data aggregation and interpretation from heterogeneous sources (e.g. wearable sensors, mobile apps, etc). Examples include estimating/predicting individual's overall daily active scores and assessing his/her night driving capability using lifelogging data, such as walking steps, travel duration, distance, and monitoring individual's behaviour patterns. Knowledge acquired through the project is being incorporated into our postgraduate courses.

MHA platform has been promoted in a number of events, including medical image understanding and analysis (MIUA) conference (2015) organized by LIN, and industry showcases organized by LIN and demonstrations in MSc lectures (i.e. advanced software engineering) and several hospitals, such as Lincoln hospital, St George Hospital London. The key techniques have been recently presented in (IASTED) Biomedical Engineering Conference, in February 2016, Austria. We will further present the MHA in relevant conferences/communities.

The results of MHA will be utilized in the MyLifeHub (UK EPSRC) project where LIN is also a consortium member. For details see the previous chapter

LIN is a consortium member for MyLifeHub project. MyLifeHub uses the MHA platform as the main platform to collect individual information from the participants with focus on ophthalmic care. The

outcome of MyLifeHub will be directly exposed to potential beneficiaries through our collaborator at Moorfields Eye Hospital (MEH). For details see the previous chapter.

LIN will also exploit the outcome of MHA to other areas of healthcare, such as personalized pregnancy care in term of nutrition, exercises, lifestyles, where MHA will be tailored for self-management of maternal health.

6.2.8 AnSmart Ltd (ANS)

As a UK based SME, ANS is involved in MyLifeHub by providing in-kind support to the project. ANS will also continue to host the project platform beyond the duration of MyHealthAvatar and will contribute to further dissemination of the project outcomes in order to attract new users from the general public. The increased engagement from the public may bring further exploitation opportunities.

7 Appendix

7.1 E-Health in European contries

Country	Status
Austria	In December 2012 Austria introduced an Electronic Health Records Act (EHR-Act). These provisions are the legal foundation for a national EHR system based upon a substantial public interest according to Art 8(4) of the Data Protection Directive 95/46/EC.
Belgium	Since 2008 the eHealth-platform provides a series of so-called “basic services” which can be used by all actors in the healthcare sector and which can be integrated into the various – EHR and other - applications (“added-value services”) offered by ICT-providers.
Bulgaria	The Personalised Information System (PIS) is an electronic record system set in place by the National Health Insurance Fund (NHIF). The PIS was launched in 2009 and some of its modalities were extended in 2013 ensuring wider access and more services to its users.
Croatia	Croatia has a very advanced legal system regulating the Electronic Health Records (EHR) in place. Although not yet operational due to technical challenges, the Croatian authorities believe that the EHR system will be functioning in 2015.
Cyprus	In Cyprus, eHealth is still at a very early stage. EHR systems have not been implemented on a full scale, but are in place at the two major General Hospitals of Cyprus, as well as at some local health centres.
Checz Republic	The Czech Republic has not developed an eHealth system yet. A strategy proposal was prepared by the Department of Informatics in Medicine of the Ministry of Health at the end of 2013 and discussed internally, but it was not yet approved.
Estonia	Estonia is the first country in the world that has implemented a nationwide EHR system, registering virtually all residents' medical history from birth to death. It was launched on 17 December 2008.
France	A Patient Electronic Record (DMP - Dossier Medical patient) exists but has not been adopted and used on a massive scale. It remains a complex tool to use.
Germany	Germany’s federal cabinet has approved a new law designed to ensure that the so called electronic health card system is operating by 1 July 2018. There is a long history of setbacks since 2004 when the government officially began working towards this goal. Progress was usually halted by strong opposition by healthcare professionals.
Greece	From 2000 Greece started developing Integrated Information Health Systems for the majority of Regional Health Directorates. However the results are different systems without interoperability among the regions.
Hungary	The Elektronikus Egészségügyi Szolgáltatási Tér (Electronic Health Service Space) is an ongoing project set to converge the scattered aspects of eHealth. MENTA is a related application planned to be the link between EESZT and citizens.
Ireland	The development of EHRs is at an early stage in Ireland and there is no specific legislative framework regulating EHRs.
Italy	The Ministry of Health in 2008 set up an inter-institutional working group to define specific national guidelines for the creation of an Electronic Health Record system.
Latvia	Electronic Health Records (EHR) are at a development stage in Latvia and initial pilot

	phase was launched on the first of April 2014. The aim of eHealth and Health Information System (HIS) is to create a single data centre.
Lithuania	Electronic Health Records (EHR) are in the initial stage of development in Lithuania. They will be implemented as a part of the State Electronic Health Services and Cooperation Infrastructure Information System (ESPBI IS).
Malta	Malta has an e-Government platform with an increasing number of services being made available. There is currently no comprehensive eGovernment or eHealth legislation in place.
Netherlands	The vast majority of GP's and all pharmacies and hospitals use EHR's. In hospitals, computerized order management and medical imaging systems (PACS) are widely accepted. The national infrastructure is still far from being generally accepted.
Norway	Norway has been an early user of information and communications technology (ICT) in the health and care sector. However, patient medical records tend to be spread in the different health care institutions, clinics and other.
Poland	At this point in time there exists no obligation to store and process HRs in an electronic form. Transition from a voluntary system of EHRs to an obligatory one is postponed to 2017.
Portugal	In May 2012, the National Platform for Health Data was finally launched in Portugal.
Romania	Health Electronic Record (Dosarul Electronic de Sanatate) (EHR) is the Romanian national electronic health record which is currently being developed.
Slovakia	From 1 January 2017 all health care providers (i.e. individuals in private practice and institutions) will be obliged to record the patient's health data into his file in the Electronic Health Book on the provided health care.
Slovenia	EHRs are set by each health providers that decide how their EHRs systems are designed and implemented. Slovenia is currently implementing the project eHealth (eZdravje) and one of the components of the project is the establishment of national EHRs.
Spain	The healthcare system in Spain is a Social Security Health system, decentralised to the 17 Autonomous Communities which have the competence to establish their own healthcare systems.
Switzerland	In 2007, the Swiss Federal Government has approved a national strategy for adoption of e-health. A central element of this strategy is a nationwide EHR. It is planned that the nationwide EHR infrastructure is implemented with a decentralized approach.
United Kingdom	In England, the National Health Service (NHS) Summary Care Record (SCR) was first introduced nationally in 2008. The SCR is stored (as read-only pdf files) on a central NHS computer (the NHS Spine) and accessed nationally by authorised healthcare staff.

7.2 Comparing the most popular PHRs

	Microsoft My Health Vault	WebMD Personal Health Record	No More Clipboard	Caresync	Health companion
Creating an account	Strict requirements for password. You need to have a Microsoft account.	E-mail adress and password.	Username and e-mail adress. Strict requirements for password which only appear after typing in a pwd.	E-mail adress and password.	Username, e-mail adress and password.
User friendlyness	Provides help during set up.	Provides help during set up.	Provides help during set up, furthermore, there is written help for every option and every page	Provides help during set up.	Sometimes confusing, no help during set up.
Design (1 to 5 scale)	5	3	3	4	3
Customizability	Yes, content and format of pages.	No	Yes, but only the content of the opening page	No	No
Supported apps and devices	27 apps and 185 devices	No	No	Fitbit, iHealth, VitaDock, Withings, Telcare, ManageBGL, Bodymedia, BodyTrace, Fitbug, FitLinxx, Fleetly,Fatsecret, Jawbone up, Runkeeper, Omron, Qardio	No
Multi account	In the same account you can make different profiles for family members, pets, doctors.	You can create sub accounts for family members. Same username and password, but you can switch to another subaccount.	You can have 9 profiles in one account.	You can add family members or pets to your account.	You can make profiles for your family members.

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Connection with providers and family			Information sheet for doctors: e-mail address to send EHRs, and fax number with personal barcode. If you subscribe to premium service Nomoreclipboard will contact your doctors and manage your data, make appointments. There are some doctors in the system, for them you can send info directly. You can print an emergency wallet card which contains a code for emergency responders to be able to view your account.	You can send e-mail invitation to caregivers or family members to have access to your profile. You can adjust what information they can see. If you purchase premium service they will collect, and upload your health records from all your providers.	You can give an information sheet with a HealthCompanion e-mail address to your doctor to send your records, or make an own secure e-mail address to exchange info with your doctor. You can also give him a temporary account access. For family members you can transfer account control, or share account access if they have a different account. You can mark each information as private or public. There is a social portal where you can talk and share information with your companions
Functions			Contact details, general medical information, emergency walletcard, data tracker, information sheet for doctors how to send your records, upload documents, premium service (NoMoreClipboard will contact you doctor and manage your health records)	Add contact details and general medical information, data tracker, upload documents, premium service (Caresync will contact you doctors and manage your health records, make new appointments), connect apps and devices, appointments, medicine reminder, set tasks and goals, share your profile	Add contact details and general medical information, connect to your provider, upload documents, share information, social portal, screening tracker, health risk questionnaire and score, health info, reward system, insurance and expenses manager

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Health tracker functions	The most important trackers, you can add a lot of details. • Weight, Height, body composition, body dimensions, exercise, menstrual calendar • Food and drink: you can add a food/ingredient and it counts a lot of data (calories, carbohydrates, protein, fibre, cholesterol, total, satured, monosaturated, polyunsaturated fat, vitamin) • Blood glucose, blood pressure, cholesterol, peak flow	Many health trackers, but not very detailed, mostly you can only add dates • colorectal scan, eye exam, foot exam, pap smear, mammogram, urine protein level measurement etc. • Exercise, sleep, step, weight, height, body fat, calories used, waist measurement • cholesterol, triglycerides, fasting, non-fasting blood sugar level, forced expiratory volume, hemoglobin A1c, peak expiratory flow, resting hearth rate • Medication, mood, pain, stress, tobacco	You can only add dates and values, it doesn't provide any further help, it makes charts. BMI, steps, blood pressure and heart rate, calories, carbohydrates, glucose, cholesterol, triglycerides trackers.	The very basic trackers, and you can only add dates and values, but you can connect it with apps, which provide more info, and options. It makes graphs from your data. mood, pain, blood pressure, hearth rate, blood sugar, height, weight, BMI future options: wellness, fitness, labs	You can only track your screenings
New functions	Share your profile or part of it, food tracker (it calculates the calories and the components, vitamins), add family history, add insurance info, you can print your emergency profile	Health alerts, Vision, Health tracker: many new options (don't know if necessary), add insurance, employer info	Add pregnancy details, family, and social history (smoking, caffeine etc.), insurance and employer info. Emergency wallet card with a code which provides access to your profile for emergency responders, information sheet for doctors how to send your records with a personal barcode, invite people to have acces to your profile	Tasks and goals manager, medicine reminder, share the profile or part of it	Messaging with your doctors, share information, health questionnaire, screening tracker, social portal, reward system, medical expense manager

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Medical information and recommendations	No	It provides basic info for the health trackers and advises articles	No	No	Yes, it provides various medical information and recommendation
Strengths	multiple profiles, share profile information, food and calorie tracker, you can add notes to everywhere, absolutely detailed, many supported apps and devices, very detailed, many options	Multiple profiles,Vision tracker, you can add notes everywhere in almost every case you can chose from options	There is a help option for every function and page, doctors can send your health record electrically (although you need to pay for it), you can share your profile	You can add notes almost everywhere, the medications, allergies, conditons, appointments parts are very detailed, task manager, medication reminder, you can share the profile, you can connect apps	You can connect your providers, and get your records electronically, share profile. Health score, screening calendar, lot of medical information, social portal, expense manager
Weaknesses	It doesn't provide any medical information suggestion or advice	You always have to add the dates, sometimes it asks for too many deatils which are not necessary, you can only use UK measurements	You can only add an illness if it is on the list, there are only US measurements, no medical information or recommendation, need to purchase a subsription to be able to upload documents	US measurements, there should be more, and more detailed trackers, It doesn't provide any medical information suggestion or advice	Difficult to use the website, in the health risk questionnaire there are a lot of unnecessary and confusing question, no tracker functions, no emergency profile, designed only for US citizens
Technical issues	There is a problem when I try to add the dates	There is no "back" option from health trackers, you have to log in again, there is a problem when you try to add the date in the appointments part	No	When you try to add a profile picture, you can only add a completely square picture	When you add your weight and health it should calculate your BMI, but it doesn't, you cannot add additional immunization