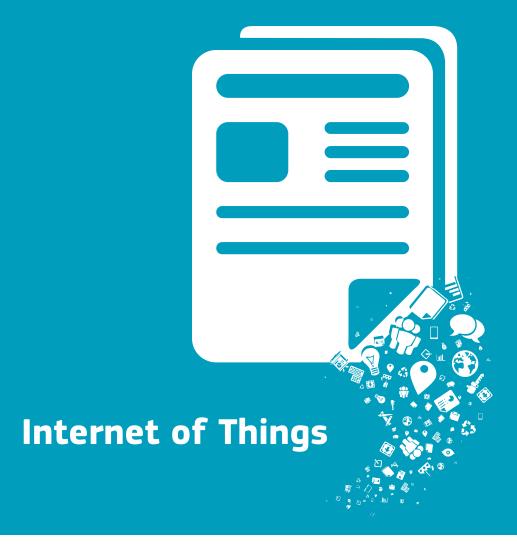




Business Innovation Observatory



Smart health

Case study 46

Internal Market, Industry, Entrepreneurship and SMEs

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Internet of Things

Smart health

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1. Executive summary

Smart Health, covering intelligent, networked technologies for improved health provision, is recognised as one of the most promising remedies to the rising per capita healthcare expenditure associated with ageing. Smart Health innovations allow healthcare providers to cure afflictions more effectively, to care for patients more efficiently, and to prevent illnesses more frequently.

Smart Health solutions combine technological developments in mobile and portable devices, mobile data connectivity, application development, sensor technology, and big data analytics and cloud computing, with novel ideas on patient co-management, health monitoring of remote communities, and prevention of unhealthy lifestyles, to name a few. As such, Smart Health has the potential to deeply transform the healthcare sector.

Consequently, Smart Health solutions are considered to have a tremendous market potential, especially given the fact that EU-wide expenditure on medical care and cure is estimated to amount to approximately 10% of gross domestic product¹. However, quantitative data that falls within the Smart Health domain is rarely tracked or tagged as such in formal statistics. A comparison of several market analysis, as well as the recent EUR 40 billion HITECH act of the Unites States federal government, does show that the market size and growth estimations of Smart Health offer ample opportunities for success to Smart Health entrepreneurs.

Smart Health solution providers offer hospitals and other healthcare organisations the opportunity to not only be more effective and efficient, yet to significantly modernise their healthcare delivery systems. These solution providers are entrepreneurs that combine a strong understanding of the technologies underlying Smart Health solutions with specialised knowledge of specific healthcare challenges, illnesses and afflictions, and with in-depth analysis of specific segments of the healthcare market. This allows them to spot radically new possibilities for care, cure, and prevention.

Smart Health innovation typically generates highly skilled jobs, as Smart Health solutions require technology specialists to develop the technologies that enable their development, as well as tech-savvy hospital staff to manage and operate these solutions.

The drivers that spur Smart Health innovation include continuous developments in ICT, e-location technology, and broadband data connectivity. Also, the economic and societal challenge that ageing poses to Europe encourages both the public and the private sector to explore the possibilities of Smart Health.

The obstacles that hamper the development and uptake of Smart Health include inconsistent and immature technological infrastructure among healthcare providers, unhelpful hospital culture and insurer behaviour towards yet unproven innovations, diverging approaches to electronic health records throughout Europe, and limited financial reach of public sector healthcare organisations.

Policy approaches to address these obstacles could focus on sustaining the technological and financial pillars on which the Smart Health concept is built by continuing to support developments in mobile ICT, broadband connectivity, and Smart Health innovation. Also, increased public sector investments and field demonstration opportunities can remove some of the barriers Smart Health entrepreneurs experience when engaging the European health market.

Moreover, streamlined public-sector procurement processes, fast payment initiatives, and deliberate public-sector procurement of innovation can help Smart Health SMEs survive financially. As a final consideration, Smart Health uptake could benefit from carefully harmonised electronic health records initiatives that address the privacy considerations that exist throughout Europe.



2. Smart Health

2.1. Presentation of the trend

Smart Health is the name given to innovative, smart, networked, technology driven solutions that generate healthcare advantages in cure, care, and prevention by introducing novel ways to treat, manage, and monitor patients. Smart Health is seen as one of the most encouraging opportunities for engaging the increases in healthcare spending associated with ageing in Europe.

Technology-wise, Smart Health leverages on the release of new and advanced smartphones, tablets, and other portable devices, and on improvements in mobile data connectivity including mobile broadband and 4G networks, new sensor technology and big data analytics, cloud computing, and many other hardware and software technologies. As such, Smart Health is part of the concept of the Internet of Things, wherein everyday physical objects will be connected to the Internet and be able to communicate and interoperate with other devices.

Smart Health solution providers consider themselves to have several fields to work in: the healthcare provider's premises, the patient's home, and the street. In each of these fields, Smart Health solutions offer a broad range of healthcare applications, from management of chronic diseases to prevention of afflictions.

In clinical healthcare, Smart Health solutions allow caregivers of hospitalised patients that require close attention to deploy non-invasive sensors that collect comprehensive physiological information. This information can be automatically uploaded to the cloud, where it is stored and analysed. The results of this analysis can be transmitted wirelessly to healthcare professionals for further analysis and review of this continuous and automated flow of information.²

In remote monitoring, small, wireless solutions make it possible for patients in distant and rural areas to engage in effective health monitoring from a specialist, as the monitoring tools now travel to the patient instead of the other way around. This way, patient health data can be captured securely through a variety of sensors on location, and then can be transmitted wirelessly to a healthcare centre where it will be analysed using complex algorithms and presented to medical specialists for patient recommendations.³ The result of these recommendations may be that patients with chronic diseases are less likely to develop complications, and that any acute complications would be diagnosed far sooner that would be the case if patients had to undertake long travels for each monitoring

effort. Moreover, the collected data can feed preventative healthcare activities by using it to develop advice on healthier lifestyle options.⁴

Figure 1: Remote monitoring through Smart Health



Source: David Niewolny⁵

Smart Health solutions also generate possibilities in the field of prevention of illnesses and early intervention in unhealthy or at-risk lifestyles. Elderly individuals that live alone may have their homes be equipped with devices that can detect disruptions in everyday activity around the house, such as a fall, and alert relatives or emergency responders. Others may consult smart devices that can measure and compute calories burned and calories taken in, and that provide dietary or exercise advice.

As will be detailed in this report, Smart Health innovation is considered to have excellent market potential, and has the possibility to increase the efficiency of cure and care, to advance preventative treatments, and to allow complex patient data collection and analysis in real time. These are considerable advantages for a sector challenged by an ageing population, vast health cost increases, and budgetary pressures.

To do so, Smart Health innovation relies on a highly skilled workforce of technology specialists, tech-savvy healthcare providers, and Smart Health entrepreneurs that can combine the latest developments in technological innovation to very complex healthcare challenges. Figure 2 shows the complex architecture of a Smart Health platform and its associated devices and software.

The companies featured in this case study are a mix of young, small companies and companies that are more mature. Most of them are strongly embedded in networks of healthcare providers. Table 1 on page 4 provides an overview of the company cases referred to in this case study.



Health and activity monitor Application Server Code Repository Server Sensor Gateway Application Repository **Applications** Middleware Middleware Middleware SMS API Core os P SMS Embedded Sensors RFID/NFC BT, BT LE ZigBee Mobile IP Wi-Fi, BT, BT LE, RFID, ZigBee, NFC Local Sensor Network Mobile Stationary multisensor multisensor

Figure 2: Architecture of a Smart health platform with its associated devices and software

Source: Ovidiu Vermesan & Peter Friess, 2014, Internet of Things – From Research and Innovation to Market Deployment

Table 1: Overview of the company cases referred to in this case study

Company	Location	Business innovation	Signals of success
MYSPHERA	ES	A system that allows to access the real time location of patients, staff or assets via tags, bracelets and labels	Funded by business angels and venture capitalists;
			 Participated in several FP-funded projects;
			 Awarded Best Company for Investors in The Entrepreneur's Day of the Comunidad Valenciana 2013.
Y000М	i	NL Tablets and portable devices that allow for natural interaction over distance between healthcare professionals, patients, families, and caregivers.	Participated in several FP7 projects
			 Secured innovation funding from health insurers;
			 Teamed-up with major healthcare providers to further develop its solutions.
Trilogis	IT	A location based service which can track patient routing through smart cameras.	 Deployed its solutions within several hospitals in Italy;
			 Participated in several FP7 projects.
Nissatech	RS	MyCardioAdvisor, a new generation of intelligent, interconnected and secure mobile solutions that allow for real-time monitoring of complex health	 Deployed MyCardioAdvisor at several health organisations;
		situations.	 Participated in several FP7 projects.



2.2. Presentation of the companies examined in the case study

This section describes four European SMEs that have developed Smart Health solutions in response to a clear healthcare need. For each company, the innovation is described as well as the problem it is meant to solve.

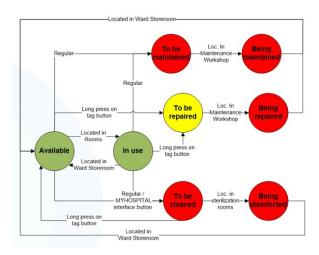
Problem 1 – Hospitals need to improve the efficiency of their services, reduce waiting times, and enhance clinical safety. Also, they need to increase the visibility of their processes, patient flow and saturated areas in surgical areas and emergency departments, in order to upgrade patient security and increase care time by healthcare professionals, and to reduce time spent searching for assets and equipment.

Innovative solution $1-{\sf MYSPHERA}$ has developed a solution that allows access to the real time location of patients, staff and/or assets via tags, bracelets and labels. People and assets carry an identification tag that sends an identification frame by radio frequency. The frames are received through a beacon network and passed on to a server, which passes it on to computers, laptops, smartphones and tablets used by hospital staff to see where persons and equipment are located.

The solution is based on radio-frequency identification (RFID) technology combined with Bluetooth, data mining and business intelligence tools. Users are offered visual and audible location information and alerts which they can access on their PC's as well as on their mobile and portable devices.



Source: MYSPHERA



Source: MYSPHERA

Problem 2 – Humans thrive on the quality of interaction with other humans. Fundamental contact consists of 60% body language, 20% tone and intonation, and 20% content. Nowadays, fewer young people live close to their grandparents. Also, caregivers need to be more and more efficient with the time they spend with the elderly.

Innovative solution 2 – YOOOM has developed a solution that deploys tablets and portable devices to allow for natural interaction over distance between healthcare professionals, patients, families, and caregivers, aimed at the elderly, and providing superior natural interaction over distance through a unique panorama technology.

The aim is to provide for an environment that supports patients in their recovery and wellbeing by reducing social barriers and providing solutions to loneliness and lack of a support group, which are considered the biggest problems patients experience in their recovery process.



Source: MIIND



Problem 3 – In a hospital environment or in a nursing home, patients may need continuous care. One aspect of elderly care pertains to monitoring their movements to avoid dangers and injuries. Elderly patients that suffer from different afflictions require care and attention to specific risks and dangers. All the while, caregivers need to be ever more efficient with their time and energy

Innovative solution 3 — Trilogis developed a location based service which can track patients through smart cameras. It is possible to create tailor-made alerts according to each patient's specific situation and needs.

Especially those that care for patients that suffer from Alzheimer or that have what is referred to as a mild cognitive awareness can greatly benefit from the possibility to track patient movements and be warned when they venture near potentially hazardous areas or objects.

Trilogis has made the deliberate choice to develop a solution that can work with a great variety of real-time location systems, allowing them to deploy their solution in nearly any enterprise system environment already present in a hospital. This differentiates them from their competitors that generally sell packages that include real-time location systems.

Problem 4 – More and more, questions on health and wellbeing are translated into complex care and treatment programmes that require extensive information analysis and follow-up. This can be time and resource consuming.

Innovative solution 4 – Nissatech has developed MyCardioAdvisor, a new generation of intelligent, interconnected and secure mobile solutions that can be personalised to a large degree, allowing for dynamic, realtime monitoring of complex health situations. The solution combines wearable sensing technology with existing and emerging possibilities for mobile data transmission. Through accessible and easy-to-grasp interfaces on websites and mobile apps, MyCardioAdvisor attempts to help the user understand what data is collected, what the use of the collected data is, and what can be learned from it. By putting cardio data in a broader lifestyle context, and by leveraging social media possibilities, the solution tries to motivate users to live a healthy lifestyle and exercise regularly.



Source: Nissatech



3. Socio-Economic relevance

3.1. The market potential of the trend

Currently, the market for healthcare software and devices is characterised by solutions that are application-specific, that hardly communicate with each other, and that consist of a wide variety of highly divergent architectures. While individually these solutions are designed to decrease costs of healthcare delivery, a far more sophisticated approach is needed to achieve the long-term goal of per capita cost reduction in healthcare.⁷

The emergence of Smart Health has the potential to deeply transform the healthcare sector. New solutions, made possible by new technologies and combinations, are developed by medical technology companies, mobile phone manufacturers, software companies, research organisations, and pharmaceuticals around the world. These new solutions have the potential to change dynamics within the health sector, and to disrupt established relationships among patients, doctors, hospitals, and insurers. Those failing to keep up with the latest developments run the risk of being steamrollered by what is considered a wave of technological innovation rarely witnessed in recent history.⁸

The market potential for Smart Health products and solutions is widely considered to be very high, and is expected to grow very rapidly. Specific numbers that detail market size or that directly support growth expectations are hard to come by, as quantitative data that falls within the Smart Health domain is rarely tracked or tagged as such in formal statistics. However, a comparison of several figures does shed light on the market size and growth estimations of Smart Health.

As the benefits of Smart Health solutions are relevant to virtually the entire formal health sector (e.g. hospitals) and informal health sector (e.g. in the homes of the elderly), it is important to realise that, across the European Union, expenditure on medical care and cure are estimated to amount to approximately 10% of gross domestic product. With an ageing population and the associated impact on demand for health care and cure, Smart Health solutions are expected to help mitigate overall cost increases on health, and to be a commercial success story at the same time. Despite the difficulties associated with data availability, a recent study on the market deployment of Internet of Things solutions shows that the global market for Smart Health is expected to grow by more than 19% annually. 10

Another indicator for the market potential of Smart Health stems from the market uptake of its underlying technological drivers. For instance, Real-Time Location Systems (RTLS) comprise one of the key technological drivers for Smart Health. The European market for RTLS is not very much developed compared to the United States. Worldwide, the market for RTLS is estimated at EUR 16.8 billion. Some stakeholders notice a rapid expansion of demand for RTLS in both the formal and informal healthcare domain.

The global Smart Health market for other technological drivers, such as wearable devices, algorithms for smart analytics, and easily accessible health databases, is estimated at EUR 1.7 billion. This figure is expected to grow to EUR 34 billion by 2020.¹³

Also, the market performance of concepts that overlap the Smart Health trend can help to demonstrate its market potential. The global market for mobile health solutions is estimated to reach EUR 49.3 billion by the end of 2020, at a compound annual growth rate of 32.3% between 2013 and 2020. This growth is expected to be driven primarily by demand for mobile blood glucose meters and mobile cardiac monitoring devices. In Europe specifically, this growth is expected to be also driven by demand for mobile solutions

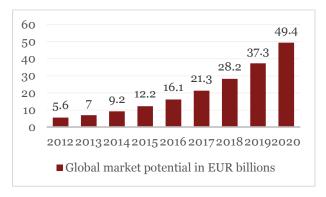
towards preventive medication services. ¹⁴ Figure 3 below shows the global mobile health industry market size projection from 2012 to 2020.

Growth scenarios for the Smart Health market are foreseen to progress in three waves.¹⁵ The first wave is driven by patient"For the future, it's an important moment. We are expanding fast. What we do is we focus on specific domains, but actually, generally speaking we are in a fast expanding market, so I would be positive." – **Trilogis**

centred care and is already under way, analysed to occur between 2010 and 2016. This wave focusses on solutions for patients that are currently ill or unhealthy.



Figure 3: Global mobile health industry market size projection from 2012 to 2020 (in EUR billions)



Source: Statista - The Statistics Portal, available at http://www.statista.com/statistics/295771/mhealth-global-market-size/

The second wave is driven by consumer engagement with Smart Health solutions and is expected to occur between 2015 and 2020. This wave focusses on solutions that help consumers achieve and maintain a healthy lifestyle. The third wave is expected to be driven by scientific advances in preventive medicine and should take place between 2018 and 2025. Solutions developed in this wave will focus both on consumer lifestyle and on societal and environmental conditions in the macro environment

3.2. The social potential of the trend

Smart Health solutions allow healthcare providers to work with toolsets that have the potential to reshape their sector, offering remedial and prevention advantages to health workers in Europe and worldwide, generating more efficient healthcare delivery systems, and offering to reduce per capita healthcare expenditure.

At the same time, Smart Health solutions positively influence the demand for high-skilled workers, both directly and

"We are looking to grow to double our headcount in the summer of 2015, mainly technical consultants and analysts." – MYSPHERA indirectly, and also have implications for healthcare education. This underlines the need for enhanced collaboration between educators, healthcare providers, and technology companies. Smart

Health solutions require highly skilled workers to develop them, and similarly highly skilled workers to implement the solutions in healthcare environments and operate them in real-time interaction with patients and other care providers.

Also, Smart Health innovation will generate IT support functions that relate to the hardware and software enabling a Smart Health solution to operate. Thus, deployment of Smart Health solutions in healthcare environments will generate more knowledge-intensive jobs and will require more knowledge workers to perform them. To illustrate, one of the SMEs in this report employs thirty technology

developers and two sales representatives, and looks forward to 25% growth annually.

Concerning the implications for **healthcare education**, educational institutions will have to prepare future

healthcare workers for working with Smart Health solutions that feature curative managements effectively comanaged by the patient, preventative programmes that

"Healthcare needs all the engineering talent possible that is often wasted on lowimpact areas of the tech industry" – **Forbes**¹⁶

entail real-time monitoring of patients within their homes, and analytical reports that can be generated and customised with great ease.

3.3. The Smart Health value chain

The position of Smart Health solution providers in the Smart Health value chain is located in between technology developers and healthcare providers. Typically, Smart Health solution providers are not involved with direct patient care or cure, and are not directly involved with developing the information and communication technology or devices that enable their innovative solutions to deliver Smart Health benefits. Instead, they typically combine advances in software development and the increased opportunities offered by mobile and portable devices with a novel view on patient management, treatments and therapeutics, and preventive medicine. The resulting Smart Health solutions constitute the value that Smart Health entrepreneurs add to existing technology for healthcare providers.

The activity that adds this value takes place within the companies that think-up, develop, market, and implement Smart Health solutions. This takes a strong understanding of the technologies underlying a Smart Health solution, which may include mobile app development, artificial intelligence, big data analytics, and smart sensor technology.

It also requires specialised knowledge of specific healthcare challenges, specific illnesses and afflictions, and in-depth analysis of specific segments of the healthcare market. On top of that, designing a Smart Health concept involves the spotting of new possibilities for patient involvement in aspects related to care, cure, and prevention.

The companies that manage to combine these building blocks into Smart Health solutions can be found throughout Europe and in the United States (e.g. in Silicon Valley), as well as in East Asia. Typically, Smart Health entrepreneurs are located in regions that combine the presence of technology companies with the presence of state-of-the-art hospitals.

These are also the geographical locations where the Smart Health value chain has the potential to create jobs. As described above, the types of jobs that may be generated include highly skilled technology specialists to develop the



technologies enabling Smart Health innovation and to mass produce the associated hardware as well as highly skilled and technology savvy hospital staff to implement, manage, and operate these novel solutions.

Smart Health solutions, as well as highly skilled healthcare technology specialists, can unlock the innovative potential of Smart Health to address the wide variety of challenges posed to the complex and highly differentiated healthcare sector.

Looking at the Smart Health value chain, the companies described in this report are all situated in-between technology companies that supply them with building blocks of hardware & software, and healthcare providers that require their innovative concepts and solutions to more efficiently provide better healthcare. Alongside them on the value chain are the high-end manufacturers that can take-on the mass production of any hardware required specifically for their solution. The Smart Health value chain may also feature technological universities that can take on the role of technology provider to the Smart Health solution provider.

The Smart Health value chain is financed by investors, by healthcare providers both from the public sector and the

private sector – big and small –, by insurance companies, by patients, and by governments. Typically, investors provide risk-bearing capital to Smart Health entrepreneurs with the aim to collect dividends on the profit they expect Smart Health entrepreneurs to make when selling or licensing their solutions to healthcare providers. Healthcare providers pay Smart Health entrepreneurs from their budgets for products, services, and licenses that help them engage specific challenges related to cure, care, or prevention. These budgets are typically made-up of government subsidies from public taxes, patient fees, insurance reimbursements, gifts and sponsorships, and interest on capital and real estate.

Insurance companies finance the Smart Health value chain from their participants' contributions, both directly by providing funds for development projects and field demonstration activities, and indirectly by reimbursing healthcare providers for any Smart Health-related treatments covered by their policies. Similarly, governments fund the Smart Health value chain from the public offers both directly when providing funding to research and development projects that relate to Smart Health, and indirectly when subsidising healthcare providers, the elderly, or the poor.

4. Drivers and obstacles

Smart Health solutions benefit from continuous developments in ICT, e-location technology, and broadband "Nothing is mature." - **Trilogis** data connectivity. Also, the economic and societal challenge

that ageing poses to Europe encourages both the public and the private sector to explore the possibilities of Smart Health. However, inconsistent and immature technological infrastructure among healthcare providers, unhelpful management culture in hospitals and the behaviour of health insurers, diverging approaches to electronic health records, and limited financial reach of public sector healthcare organisations, each serve as obstacles to the development and uptake of Smart Health innovations.

4.1. Technological developments in ICT, e-location technology, and connectivity

The development, deployment, and uptake of Smart Health solutions are driven in part by developments in ICT, connectivity and mobile devices. As this technology field keeps advancing, overall developments in information and communication technology allow ever-more sophisticated data processing with increased computation speed.

Moreover, developments in location-based consumer technology enhance the e-location possibilities of smartphones and tablets.

Smart Health solutions are enabled by specific technologies that generate the usability, connectivity, and capabilities on which their functionalities rely. These technologies include smart sensors for measuring, monitoring and analysing health status indicators (e.g. blood pressure), and low-power operational devices (e.g. highly energy-efficient tablets, or smartphones that harvest kinetic energy).¹⁷

Part of the appeal of Smart Health solutions is the possibility to monitor health-related data from a distance, and to analyse and act upon this information in real-time. As such, Smart Health solutions are driven also by higher levels of sophistication and uptake of advanced mobile devices, and increased connectivity of these devices to mobile data networks. As mobile devices acquire more capabilities, the possibilities for tele-health solutions will increase. As state-of-the-art mobile devices become more wide-spread, deployment and proliferation of Smart Health solutions in cure and care environments will become less disruptive to everyday life and less complicated.



4.2. Maturity of on-site ICT infrastructure

Smart Health solutions often operate in tandem with existing ICT infrastructure of healthcare providers. The level of sophistication of this infrastructure and related logistic and patient systems determines the potential success and costs related to the deployment of Smart Health solutions. A more sophisticated infrastructure allows for easier and earlier benefits. A less sophisticated infrastructure requires more adaptation and customisation of systems and software and entails more complex deployment trajectories.

Providers of Smart Health solutions at times experience a maturity gap between their applications and the ICT infrastructure of healthcare providers. As Wi-Fi has become the dominant form of local area wireless technology, solution providers in the domain of Smart Health are heavily leveraging on it. However, not all healthcare organisations can facilitate Wi-Fi access within their infrastructure, while at the same time Wi-Fi is not always seen as the most accurate technology for location functionality.

Typically, both the physical and the ICT infrastructure of hospitals have not been designed with extensive and divergent use of mobile data networks in mind. Also, many medical devices were not designed for interoperability or data communication with other medical devices, computational systems, or consumer devices. As a result, Smart Health solution providers often encounter the need to develop custom communication layers, which adds to the implementation costs. ¹⁸

Wi-Fi is typically accurate up to five or ten meters. Ultrawideband location technology is typically considered to be far more accurate. However, Wi-Fi is the current standard, and more promising technologies would require a significant transition effort.

Providers of Smart Health solutions therefore sometimes choose to expand their offerings when engaging the market to include services and support related to the broader IT infrastructure of healthcare providers. Moreover, providers of Smart Health solutions often consider it crucial that a healthcare provider is able to work with electronic health records. When working with electronic health records is not an option, be it for technological reasons, because of privacy legislation, or otherwise, the uptake of Smart Health solutions becomes more problematic.

As an environment in which a large number of devices need to communicate amongst each other, the Smart Health environment faces challenges related to the technology standards of these devices and of the digital infrastructure on which they operate. The trend can especially benefit from standardisation of communication protocols to increase interoperability. ¹⁹

4.3. Ageing

Ageing is considered to be one of the greatest social and economic challenges of the coming decades for Europe. It is estimated that by 2025, 20% of Europeans will be at or over the age of 65.²⁰ This development and the challenges that ageing poses to healthcare systems in particular serve as a significant driver for the development and uptake of Smart Health solutions. Smart Health solutions are widely recognised to be of major importance to the improvements in patient management and care, the development and implementation of novel therapeutics, and the enhancement of preventative care possibilities that are needed to provide an ageing population with optimal health care.

4.4. Hospital culture

Another challenge related to the large-scale uptake of Smart Health solutions in cure and care environments is that it requires a new way of thinking about patient management, hospital culture, and the role of the patient vis-á-vis the healthcare or treatment provider. Hospital culture can serve as a barrier to the successful uptake of Smart Health solutions, as these innovations typically require changes in the way hospital staff operates, changes in the role of the patients within cure or care processes, and changes to rules and regulations with which hospitals and other healthcare providers work. Moreover, these changes should have a budget neutral effect, as the vast majority of hospitals can ill afford cost increases.

The companies interviewed for this case study indicate that, for the most part, the healthcare industry seems not yet ready to accept the transition that deployment and uptake of Smart Health solutions entail.

As an example, Smart Health solution providers point to the practice of a lot of hospitals to forbid the use of smart phones within the hospital walls. Hospitals typically disallow smart phones for reasons to do with patient safety, patient privacy, and uninterrupted operation of medical equipment.²¹ Solution providers at times have difficulties to start the conversation about these potential risks, and are confronted with hospital managers who can be reluctant to change. More success stories are needed, and these would need to be well described and well disseminated in order to prove the value and benefits of the Smart Health concept.

4.5. Electronic health records

According to Smart Health solution providers, electronic health records are indispensable to the uptake of Smart

Health. However, not all healthcare providers work with electronic health records, and Smart Health entrepreneurs

"EHRs are a necessary step before installing our product."

- MYSPHERA

have a hard time delivering the benefits they have to offer



to markets where the use of electronic health records is the exception rather than the rule.

The reasons why healthcare organisations are not working with electronic health records relate to formal legislation, the associated need for organisational change, and the steep investment costs. In some EU countries (e.g. Germany), using electronic health records and communicating their content across organisational boundaries are not legally possible. Legislators in these countries consider electronic health records currently unsafe in terms of privacy, cyber-security, and governance.

In Germany, electronic health records are used in roughly 20% of the hospitals, the rest are working with hard copies.

"In Germany, they are not an early-adopter market with regards to electronic health records. That makes it more difficult and more time consuming to go to that market." – MYSPHERA

Although Smart Health entrepreneurs consider the German healthcare market as a very interesting one because of its size and because it is technologically advanced on many other counts, they experience serious difficulties in adapting their solutions to an

environment without electronic health records.

4.6. Public procurement processes

Smart Health solution providers often lament the procurement processes in which they need to enrol when

"If we had just one procurement system in hospitals throughout Europe, this would help SMEs versus big corporates." – **Trilogis** offering their products and services to organisations in the public sector and the semi-public sector. Public procurement processes are considered to be slow, complicated, and inflexible. Also, procurement

processes seem to be different with every procuring organisation, and seem to emphasise the importance of a strong financial and administrative track record amongst potential contractors. As a result, small and new companies have a hard time winning public bids over large companies, having to allocate valuable company resources to the bureaucratic administrative requirements of public procurement processes. This still occurs despite the efforts of the European Commission through its Procurement of Innovation Platform that aims to address these issues.²²

4.7. Market finance and public budgets

One of the main concerns for Smart Health solution providers relates to the financial state of their market. They experience limited financial reach on the side of the healthcare organisations that should be their buyers, and when they do manage to sell their solutions to healthcare providers, payments tend to be slow and bureaucratic.

The main issue for European Smart Health entrepreneurs is to attract venture capital. These entrepreneurs need venture

capital for initial development of their solutions and for growing their companies. Initial development of Smart Health solutions is capital intensive and requires a large upfront investment at an early stage. However, investors typically want to see an attractive proof of concept before they decide to provide capital. Growth capital for companies that have surpassed the stage of initial development is also difficult to attract, as the venture capital market in Europe remains limited in size and risk averse in its pickings of European start-ups.

Smart Health solution providers report limited financial reach on the side of their potential clients. Especially in countries struck hard by the financial crisis, such as Spain and Portugal, austerity measures have reduced the investment budgets of hospitals and other healthcare providers to zero. Consequently, Smart Health entrepreneurs in these countries flock to academic hospitals that participate in European grant programmes to fund their development activities. Table 2 on page 12 shows the source of funding for each of the company cases, and notably all four companies report to have benefitted from FP7 grants, which evidently are an important driver to the development and uptake of Smart Health solutions.

This challenge is accompanied by the behaviour of health insurance companies, as noted above. Healthcare providers that provide treatments or therapeutics that are not reimbursed by insurance companies find themselves exposed to financial risk, as the associated costs can often not by passed on to the patient. In most cases, the patient would not be able to pay the substantial sums featured on the invoiced for these treatments, leaving the healthcare provider with no choice but to pay for the treatment costs themselves. As a result, healthcare providers steer clear of any treatments or therapeutics for which the insurer will not pay, including those that are driven by Smart Health solutions, and will not invest in the development or uptake of such solutions. Insurers however, will not pay for treatments or therapeutics whose effectiveness is not convincing for them

The financial burden of proving the benefits of a Smart Health solution in a way that convinces insurers is placed on the shoulders of the Smart Health solution provider, which, as noted above, finds it hard to acquire the substantial sums necessary to deliver a proof-of-concept in this stage. This is compounded by the fact that a proof-of-concept in practice implies testing the solution in a care or cure environment, where most organisations fear the associated financial risk.

Smart Health solution providers that manage to sell their innovations to healthcare providers and to implement their solutions within a cure and care environment face additional financial risks that relate to the solvency of the healthcare provider and the time it takes for invoices to be paid. Especially large healthcare providers tend to have slow and bureaucratic payment processes, which they have developed



around their relationships with large pharmaceutical companies and equipment providers. Typically, Smart Health solution providers are SMEs that do not have financial buffers that can sustain them while waiting for hospitals to pay their invoices. Similarly, when working with small, independent healthcare providers, Smart Health entrepreneurs are exposed to the risk of the healthcare provider becoming insolvent due to changes in insurance policies, which for instance may result in more restrictive coverage of their treatments.

As a result, many Smart Health entrepreneurs move their focus to the healthcare markets in the United States. Smart

"Our next step is to establish a subsidiary in the US. It's a big market with good opportunities. We were contacted by some guru's in the US in this space that already helped our competitors" – MYSPHERA Health solution providers consider these markets to provide good opportunities, and move to obtain first-mover advantage. Moreover, American Smart Health 'gurus' actively scout for promising solutions in Europe and contact European entrepreneurs to help them enter the American health

market. European Smart Health entrepreneurs say they also have started to focus on Latin America, as governments there are seen to invest substantial amounts in new hospitals and in improvements to their networks of healthcare organisations. Especially entrepreneurs that

speak Spanish proficiently consider Latin American markets to be less challenging than those of Germany, the UK, or Scandinavia, simply because more money appears to be available for innovative solutions.

Table 2: Source of funding for company cases

Company	Source of funding
MYSPHERA	MYSPHERA is funded through investments by business angels, venture capitalists from the United States, and through FP7 grants. Also, their current sales help to keep their operations afloat.
Y000M	Y000M funds their development activities through several European grants, including FP7, and through innovation funds made available by health insurance companies.
Trilogis	Trologis funds their development through sales revenue and through FP7 and Horizon 2020 grants.
Nissatech	Nissatech funds their development and their operations through sales revenue and through participation in collaborative research projects within FP7.

5. Policy recommendations

The analysis of drivers and obstacles above provokes several policy recommendations that have the potential to contribute to a business environment more conducive to the development and uptake of Smart Health innovations. The technological and financial pillars on which the Smart Health concept is built benefit from sustained support for developments in mobile ICT, broadband connectivity, and Smart Health innovation. Increased public sector investments and field demonstration opportunities can remove some of the barriers.

Smart Health entrepreneurs experience financial difficulties when engaging the European health market. Streamlined public sector procurement processes, fast payment initiatives, and deliberate procurement of innovation can help Smart Health SMEs survive financially.

Finally, carefully harmonised electronic health records initiatives that address the privacy considerations existing throughout Europe can encourage the deployment and uptake of Smart Health solutions, which have electronic health records as a prerequisite to their success.

5.1. Sustained support for developments in mobile ICT, broadband connectivity, and Smart Health innovation

As improvements in ICT, connectivity, and mobile devices drive the possibilities for the development and uptake of Smart Health solutions, it is important for policymakers to sustain their support efforts for technological advances in these areas. Moreover, all four companies featured in this article have benefitted from FP7 grants, showing the extent to which such grants are an important driver to the development and uptake of Smart Health solutions. Consequently, it seems important for policymakers to continue to provide these grant schemes and to improve them constantly.

Smart Health solution providers mentioned specific areas in which grant schemes such as Horizon 2020 could be further improved to encourage and support the development and uptake of Smart Health solutions. For one, Smart Health solution providers think it would be beneficial if policymakers would encourage or even would require more focus within



consortia and within projects. Typically, they would favour small-scale consortia that focus on development and exploitation of a single good idea over diverse, large-scale consortia in which several stakeholders pull a good idea in different directions to develop something that nobody can exploit.

Similarly, they consider it of primary importance that such grant schemes support innovative companies to actually deliver their products to the market to generate societal value. Good ideas that do not reach the market usually do not generate societal impact.

Also, Smart Health entrepreneurs suggest that grant schemes such as Horizon 2020 could focus more on the final stages of innovative development, where business plans and investor relations become more important. This increases the chances of the output of the project being exploited as opposed to landing in a desk drawer.

5.2. Increased public sector investments and field demonstration opportunities

Many actors in the market for Smart Health solutions in care and cure environments need extensive convincing of the added value and benefits of each potential Smart Health solution within a healthcare delivery system. Especially healthcare providers and health insurance companies will only invest time and resources on proven concepts. As proof-of-concept in Smart Health is rather expensive, solution providers could benefit from more **field demonstration opportunities** that display and disseminate the added value of their innovations, and that allow them to convince healthcare providers and health insurers of the benefits their innovation has to offer. In initiatives that facilitate on-site demonstration of Smart Health innovations should include the possibility of funding demonstration activities.

Moreover, improved development and uptake of Smart Health solutions in Europe will require increased availability of public budgets to Smart Health innovators. In Europe, close to 75% of health financing comes from public sources.23 At the same time, Smart Health entrepreneurs interviewed for this case study report that hospitals in some EU countries have zero budget available for healthcare innovations, while others prefer to wait for Smart Health entrepreneurs to develop and test innovative healthcare innovations on their own dime or backed by venture capitalists. Given the potential of Smart Health innovations both in terms of slowing the increase in healthcare spending and in terms of labour-market productivity, let alone in of health as an intrinsic value, public investment in Smart Health by public healthcare providers can offer great societal and economic returns.24

5.3. Streamlined public sector procurement processes, fast payment initiatives, and procurement of innovation

The large role that public sector organisations play in the healthcare sector and the more-than-considerable sums of money flowing through them have a significant impact on the financing of Smart Health development and uptake. As the majority of Smart Health solution providers are composed of SMEs and young companies, the relatively slow and cumbersome administrative processes that appear to accompany most money flows in the public sector negatively influence Smart Health innovation. The European Commission's guidance for public authorities on public procurement of innovation is an important effort in this respect. Care should be taken to ensure its most effective dissemination. Furthermore, a review or its uptake can be considered, as well as a benchmarking initiative that ranks European governments on improvements in procuring innovation.

Slow processing of invoices in public procurement processes may put Smart Health solution providers in a financial squeeze. Long waiting times before payment is costly for businesses. Even worse, it is dangerous for companies that do not have large financial reserves, such as most Smart Health entrepreneurs, or that are in an unstable financial situation, such as many start-ups. Under the wrong circumstances, what starts out as a minor liquidity squeeze might cascade into the bankruptcy and closing of a company.

To combat late payment, policymakers may encourage public sector healthcare providers to streamline their purchase-to-pay processes. Also, they may encourage public sector healthcare organisations to look into the possibilities of supply chain finance, a financial arrangement wherein a financial intermediary, such as a bank, leverages the credit position of the (public sector) buyer to make early disbursements possible on invoices of the (SME) seller.²⁵

Given the size of the public sector within the healthcare domain, public sector healthcare organisations can throw considerable financial weight around. As a demand-side impulse to Smart Health innovation, both public sector healthcare providers and health insurance companies could take up the role of procurers of innovation, actively applying the 'Think Small First' principle²⁶ to their processes and not shying away from risk when presented with the opportunity to adopt something innovative — naturally without jeopardising public or patient safety.



5.4. Carefully harmonised electronic health records initiatives that address privacy considerations

Smart Health solution providers consider electronic health records as a crucial prerequisite for the uptake and implementation of Smart Health innovations. The fragmented and diversified approach of the European healthcare sector to electronic health records makes it difficult for Smart Health entrepreneurs to deliver the benefits that their innovations have in store. Smart Health innovation may benefit from a harmonised approach to electronic health records in terms of technological standards, implications to organisational structures and processes, and legislation related to privacy.

More specifically, a harmonisation effort may be needed that focusses on the setting and the context in which electronic health records are deployed, the content of electronic health records, and the actors that are authorised to author and access electronic health records²⁷.

With regards to the setting and the context of electronic health records, issues to be settled include whether electronic health records should be used in primary care, in acute hospital care, in tertiary care, or in all of the above. Also, a matter of debate relates to the scope of use of

electronic health records within these settings, such as prevention, diagnoses, therapeutic, monitoring, palliation, research, or some or all of the above.

With regards to the content of electronic health records, the question is whether to include easily readable summaries, whether to limit the records to these summaries, and whether to include emergency and discharge records.

Furthermore, it should be settled who will have access to this content and who can author the records. Discussion exists as to whether or not nursing staff or administrative staff may add or remove information from electronic health records, and whether civil servants or employers may have access to them.

Conversely, additional concepts have been developed such as the electronic nursing record and the electronic administrative health record to exist alongside electronic medical records and electronic patient personal health records.

Moreover, the concept of electronic health records sparks a controversy across Europe about privacy. Considering the horizontal nature of any debate on data protection and data privacy, Europe has a clear role to play in establishing a comprehensive and dedicated framework of rules and regulations.



6. Appendix

6.1. Interviews

Company	Interviewee	Position
MYSPHERA	Salvador Vera	CEO
Trilogis	Giuseppe Conti	СТО
Y000M	Robbert Smit	Founder
Nissatech	Dragan Vučković	Managing Director

6.2. Websites

MYSPHERA	www.MYSPHERA.com
Trilogis	www.trilogis.it
Y000M	www.Y000M.com www.miind.org
Nissatech	www.nissatech.com

6.3. References

- ¹ Ovidiu Vermesan & Peter Friess, 2014, Internet of Things From Research and Innovation to Market Deployment
- ² David Niewolny, 2013, How the Internet of Things Is Revolutionizing Healthcare, Freescale White Paper
- ³ Ibid.
- ⁴ Ibid.
- ⁵ Ibid.
- 6 Ibid.
- ⁷ Ovidiu Vermesan & Peter Friess, 2014, Internet of Things From Research and Innovation to Market Deployment
- ⁸ Soreon Research, 2014, Smart Wearable Healthcare Report 2014
- ⁹ Ovidiu Vermesan & Peter Friess, 2014, Internet of Things From Research and Innovation to Market Deployment
- 11 Interview with Salvador Vera, CEO of MYSPHERA
- 12 Interview with Giuseppe Conti, CTO of Trilogis
- ¹³ Soreon Research, 2014, Smart Wearable Healthcare Report 2014
- ¹⁴ Research and Markets, 2104, Global mHealth Market Report Forecast 2012-2020
- ¹⁵ Oliver Wyman, 2013, The volume-to-value Revolution Rebuilding the DNA of Health from the Patient In (White Paper)
- ¹⁶ Forbes, 2013, Healthcare's Trillion-Dollar Disruption
- 17 David Niewolny, 2013, How the Internet of Things Is Revolutionizing Healthcare, Freescale White Paper
- ¹⁸ Ovidiu Vermesan & Peter Friess, 2014, Internet of Things From Research and Innovation to Market Deployment
- ¹⁹ David Niewolny, 2013, How the Internet of Things Is Revolutionizing Healthcare, Freescale White Paper
- $^{\rm 20}$ DG Health and Consumers website on Ageing, accessed January 2015, available at http://ec.europa.eu/health/ageing/policy/index_en.htm
- ²¹ Website NHS Choices your health, your choices, accessed January 2015, available at http://www.nhs.uk/chq/pages/2146.aspx?CategoryID=68&SubCategoryID=162



- ²² Procurement of Innovation Platform, 2014, Guidance for public authorities on Public Procurement of Innovation, Available at www.innovation-procurement.org
- ²³ European Commision, DG Health and Consumers, 2013, infographic on 'Investing in Health', available at http://ec.europa.eu/health/strategy/policy/figures/index_en.htm
- ²⁴ Commission Staff Working Document, February 2013, 'Investing in Health'. Social Investment Package
- ²⁵ See the Business Innovation Observatory case study 24 on Supply Chain Finance of early 2014 available at http://ec.europa.eu/growth/industry/innovation/business-innovation-observatory/files/case-studies/24-ibm-supply-chain-finance_en.pdf
- ²⁶ http://ec.europa.eu/growth/smes/business-friendly-environment/small-business-act/index_en.htm
- ²⁷ EuroRec, Official Website, 2015, accessed January 2015, available at http://www.eurorec.org/whoarewe/introduction.cfm