

ENSAFE– Combined Draft Business Plan

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1 Introduction

This document provides an overview of the business model for ENSAFE as a service in the four participating countries – England, Italy, Netherlands and Sweden. It provides an evidence base that includes analysis for the potential demand for the services made possible by the ENSAFE product portfolio, and understanding of the potential market and routes to market for the service and also the ‘offer’, including the value proposition and benefits to potential customers.

1.1 Background

1.1.1 UK

Assistive technology, often defined as telecare, telehealth and telemedicine, refers to devices usually connected to a telephone, from emergency response alarms to monitors and sensors that help independent living. Assistive technology already enjoys a prominent profile among some health practitioners and policymakers in the UK. The Telecare Services Association estimates that 1.7m people already use telecare in the UK, including older people, people with disabilities, people with mental health problems or people with cognitive impairments such as dementia.

The Foundation for Assistive Technology (FAST), defines assistive technology as:

“Any product or service designed to enable independence for disabled and older people.”

Another commonly used explanation is *“any device or system that allows individuals to perform tasks that they would otherwise be unable to do, or increases the ease and safety with which tasks can be performed”*. (Royal Commission on Long Term Care, 1999).

This includes a wide range of devices from simple ‘low tech’ items such as calendar clocks to more ‘high tech’ items such as automatic lighting and telecare sensors. Until recently, ‘aids and appliances’ resided in the organisational shadows of the NHS and social services. That is now changing. A more modern expression, ‘assistive technology’ (AT), is now becoming commonplace as a result of technological advances and a growing appreciation of how it can support independence (Audit Commission, 2004).

1.1.2 Netherlands

In the Dutch health care system a transition is ongoing towards more self-reliance and self-care of patients. The Dutch government supports and tries to accelerate this transition and believe that eHealth could play a major role in this. In July 2014 the Ministry of Health, Welfare and Sport (VWS) has formulated three goals in the field of eHealth which they want to accomplish with caregivers and caretakers in the next 5 years:

- 80% of chronically ill people (and 40% of the general population) has direct access to medical data and health records and can use these in mobile apps or internet applications;

- 75% of the chronically ill and vulnerable elderly is able to perform measurements independently, mostly in combination with remote telemonitoring of a care professional;
- Everyone who receives home care is able to communicate 24/7 remotely with a care professional using a display (and domotics).

eHealth is the use of new information and communication technologies, internet technology in particular, to support or improve health and healthcare.

Over 90% of doctors list examples of eHealth that they find promising. Doctors listed a broad range of eHealth applications as pilots and good examples. Use of eHealth among nurses is on the rise. Among nurses, use of the internet for looking up information, for example, or showing patients information, increased. The use of apps for care and health increased in this group as well. The use of telecare (communication via a video connection) and medicine dispensers among nurses increased in care in particular- this almost doubled, to around one fifth of the nurses (Source: 2015 eHealth monitor by Nictiz and Nivel).

1.1.3 Sweden

In March 2016, the Swedish Government decided on a new vision for e-health, in relation to both health care and social services. The vision declares that by 2025 Sweden will be the world leader in the use of digital health solutions that allow people to:

- achieve good health and welfare
- develop and strengthen their own resources for increased independence and social participation.

Care needs are increasing as the population grows - people are living longer and subsequently more people need more care. Healthcare costs in Sweden are therefore rising dramatically while the efficiency of the health care system continues to decline.

Swedish citizens are now increasingly well informed about their health. As a result, there is a need for a new relationship of shared decision making between patients and health care providers. Providers also need to be more attentive to patient values, preferences, and cultural backgrounds.

Although laws and other regulations require healthcare providers to coordinate an individual's care needs, in practice much of the responsibility lies with the patient herself, or with her relatives, to coordinate her own care. Currently, a lack of coordination between the different parts of the healthcare system entails not only unnecessary suffering for the patient, but also puts unnecessary strain on an already taxed health care system.

Patients who lack the correct information often seek care unnecessarily, usually due to ignorance or undue concern. Others may wait too long before contacting their GP, which often results in more costly and/or complicated treatment, and unhealthier patients.

Technological advances in information technology and an expanded evidence base gained from research on clinical practice have the potential to transform health care, but such advances have not been adequately harnessed.

It must become easier to get health care, easier to get in contact with health care providers, and easier to navigate the health care system. Health care needs a new overall concept. A concept that builds on digital services, and one which ensures effective delivery processes, and capitalises on the patient as a resource.

To improve the health care system it is also important that health service employees have a digital work environment that enables high quality and supports the processes in which staff operate.

New technologies, digitisation and the Internet are some of the keys to finding new efficient ways of working smarter. In Sweden, the government firmly believes that the digitisation of the healthcare system needs to be given greater priority, and has developed a strategy and action plan to achieve this.

Telia, Sweden's largest provider of telecoms infrastructure & services, expects more than half of Sweden's 4.6 million households to be connected to health services in the home within three to five years. The company estimates that the market will by then be valued at "several billion SEK per year".

1.1.4 Italy

Demography:

Every analysis concerning Welfare in Italy, as in the majority of the EU countries, must take into account the impact of demography. The Italian population in particular is one of the oldest in the world, because of two main reasons: low birth-rate and longer life-expectancy. In 2015 there have been 488.000 births, 15.000 fewer than 2014 and marking a new lower since the unification of Italy. Besides, 2015 has been the fifth year in a row in which fertility has decreased, reaching a new-low of 1,35 child per woman. The average age of a mother giving birth has raised to 31,6 years old. Over-65 years old are 13,4 million, accounting for the 22% of the total population. The population in active-age (15 to 64 years old) has decreased to 39 million (64,3% of the total) and so did the Under-14 population (8,3 million, 13,7% of the total). The index of dependency ratio has raised to 55%, the one related to old age-dependency ratio has raised to 34,2%ⁱ.

Public Spending:

The healthcare model in Italy is universal and (almost) completely freeⁱⁱ, characterized by the predominance of public spendingⁱⁱⁱ. Even though private and indirect (e.g. through medical insurance) healthcare are rising, it is not likely that the government will lower the expenses on public healthcare; nevertheless, the demographic data stated above suggest that this model will soon be facing a sustainability crisis.

eHealth:

a recent report by Ibsa Foundation for Scientific Research stated that 88% of the Italians use the internet to access information related to their health status; elderlies are doing this almost as frequently as younger people, but with less awareness about the risks of misinterpret the information available online (also related to therapies, accessing the health-services, etc.). Nevertheless, the eHealth offer in Italy is largely insufficient both for quality and quantity. The

Politecnico di Milano^{iv} has recently stated that “eHealth in Italy is no longer a dream, but it is not reality yet”. Therefore, the usage of devices capable of increasing the connectivity of the elderlies related to health and well-being appears a) in accord with an increasing demand; b) without an adequate offer (both public and private); c) competitive on the market, because it would be not linked to the commercialization of a single device or product, but to the offer of a very qualified service, conveyed in terms of supply chain and networking.

2 Demand Analysis

2.1 Market Drivers

Desk research and insight gathered from potential partners across the UK provides us with a strong foundation to build the ENSAFE as a service offer. These are summarised below.

UK

<p><u>Political</u></p> <p>Policy changes</p> <p>Political forces</p> <p>Accreditations</p> <p>Personalisation</p> <p>Normalisation</p> <p>Integration</p> <p>Early intervention</p> <p>Increased regulation</p> <p>Scandals (Winterbourne)</p> <p>The move from residential models to community models</p>	<p><u>Economic</u></p> <p>Budgetary pressures</p> <p>Supporting people funding cuts</p> <p>The macro and micro economy</p> <p>Wage cost inflation</p> <p>European funding</p> <p>Cuts in mental health services</p>
<p><u>Social</u></p> <p>Population demographics</p> <p>Staff</p> <p>Customer knowledge</p> <p>Increasing co-morbidities</p> <p>Entrepreneurs</p>	<p><u>Technological</u></p> <p>Advances in technology</p> <p>Big data</p> <p>The 'internet of things'</p> <p>Inter-operability</p>

Collaborative design	
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2.2 Political & Legal Factors

Legal factors

The legal context for products such as ENSAFE are relatively unclear given that the market is still relatively small, however as the health and care sector is subject to a wide range of legal and ethical guidance from a personal and data perspective, it is expected that the business model will need to overcome the following factors in each new country of adoption:

- Concern that technological solutions may be installed without fully involving or obtaining the consent of the individual involved. This can be particularly relevant when the equipment is used to support individuals with mental health difficulties
- Concerns about particular types of technology, such as those used for monitoring individuals movements, and how they may affect the privacy of the individual
www.alzheimers.org.uk/site/scripts/documents_info.php?documentID=579
- Concerns about the use of computer technologies that rely on sharing and storing information and the need to ensure such information remains confidential, is not misused or negligently passed into the wrong hands. This concern has been heightened by recent news stories concerning the loss of personal data.

2.2.1 UK

Funded by UK taxpayers, the UK Government allocates the majority of funding for health and care services through the National Health Service (NHS) via the Department of Health and national body 'NHS England'. As such, all care is provided as 'Free at the point of delivery' to any citizen that needs it.

Current policy trends encourage the use of devices that support independence, choice and control in the home or in residential care. Approaches such as self-directed support, person-centred planning personalisation and reablement, as well as the focus on the ageing population, encourage the use of assistive technology.

Within this context, the vast majority of the health sector and a significant part of the wellbeing sector are driven by national directives from NHS England and its published strategy - The Five Year Forward View (2014). <https://www.england.nhs.uk/ourwork/futurenhs/nhs-five-year-forward-view->

web-version/5yfv-exec-sum/ and The Care Act, 2004, <http://dpac.uk.net/2015/03/car-act-summary-of-main-points/>

These strategic themes are translated into national business plan priorities* and when applied to the ENSAFE product portfolio, provide for a strong business case that digital innovation can support both the ‘system’ and patients to benefit from our offer and improve health outcomes for patients.

Political and priorities and policies	Implications for ENSAFE
Improving health – closing the health and wellbeing gap	
Mental health & dementia - early intervention, shorten waits for treatment and expand crisis services.	ENSAFE sensors and digital data sources will help to support patients at home. Earlier detection facilitates earlier intervention and integrated support (digital and face-to-face). https://www.alzheimers.org.uk/technologycharter
Learning disabilities - increasing the number of people living in homes in the community rather than an NHS setting.	ENSAFE sensors and digital data sources will help to support patients at home. Earlier detection facilitates earlier intervention and integrated support (digital and face to face). “The Business Case for Enhancing the Lives of People with Learning Difficulties through the use of Personal Care and Support Technologies” 2015 (Doughty K, Barnard S, and Longley-Cook R)
Diabetes and obesity - targeting people at high risk with help to modify their diet, control their weight and become more physically active.	The ENSAFE GoLivePhone, when integrated with self care and self management platforms, provides an additional opportunity for patients to make lifestyle improvements that will help them to live better and reduce their dependence upon clinical expertise and improve comorbidities that can make existing conditions escalate more quickly.
Transforming care - closing the care and quality gap	
Support doctors to harness digital technology and increase use of pharmacists.	The ENSAFE service offer provides additional assistance and data to help inform clinical decisions around individual cases.
Controlling costs and enabling change – closing the finance and efficiency gap	
Making better use of technology, further developing leadership and supporting scientific research and	The ENSAFE service offer provides health and care services the opportunity to reduce reliance upon more expensive resources, thereby supporting improved efficiencies and

innovation.	return on investment to the government and the tax payer.
We will empower patients and engage communities, increase patient choice and develop more personalised services	The ENSAFE service offer provides the opportunity for individual patients and their families to take ownership of their health by using technology to help them and their carers stay healthier for longer.

* <https://www.england.nhs.uk/wp-content/uploads/2016/03/bus-plan-16.pdf>

Article 8 of the Data Protection Directive (95/46/EC) qualifies health data as a special category of data to which a higher level of data protection applies. Within the context of the likely functionality contained within the ENSAFE product suite, and its application to support additional care by professionals, it is expected that data collected via ENSAFE as a service would be considered as ‘health data’ and ‘processing health data’, and therefore would be subject to the higher level of data protection.

It is therefore expected that Article 8 would apply and our business model will ensure that explicit and unambiguous permissions have been granted by the end user (or their nominee, such as a carer). This consent will therefore be applied when registering a user onto the ENSAFE system.

“The data controller must clearly inform users whether the data is protected by any medical secrecy rules, or not. Further information must be made available whether the data will be combined with other data stored on the device or collected from other sources, and clear examples of the consequences of such combination of data, what the purposes are of further processing and to what third parties the data may be transferred. Such information must be made available in a clear and easily accessible manner before users decide on installing apps or buying devices (also before downloading the app).” <https://chino.io/compliance-resources>

2.2.2 Netherlands

In Dutch healthcare, we can distinguish several key partners in order to gain a better understanding of who’s who and who does what, we distinguish between private individuals, healthcare providers and healthcare purchasers. The Netherlands has a population of 16.8 million. As “policyholders” – i.e. having a contract with a health insurer – these private individuals are one of the three key players in Dutch healthcare. Healthcare providers play another key role in healthcare. Healthcare providers are defined as all organisations, institutions and individual healthcare providers who offer healthcare, assistance and support. In other words, the term “healthcare provider” refers to more than merely an institution that provides healthcare services. Healthcare purchasers are (depending on the type of care) healthcare insurers, healthcare administration offices and local authorities which are responsible for purchasing care as well as implementing the core healthcare acts and act as a mediator between care providers and care takers (Source: This is how Dutch healthcare works. Maaik de Vries & Jenny Kossen, 2016).

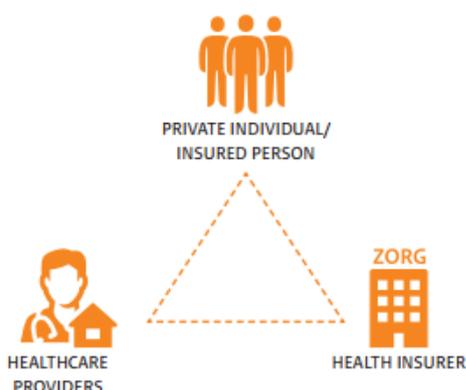


Figure 1: Healthcare in the Netherlands by Ministry of Public Health, Welfare and Sport (January 2016)

This past year a number of organisations in the healthcare sector have expressly made contact to jointly deal with obstacles to eHealth. Examples are the eHealth Implementation Agenda that was published in 2014. As been mentioned in the introduction the ‘eHealth and improvement of healthcare’ letter (Minister and State Secretary of VWS, 2014) can give a significant boost to this national control. In this letter the Minister and the State Secretary set concrete targets in the area of e-Health for the next five years. In the table below these priorities are outlined, together with the implications for ENSAFE.

According to the letter the government wants to make every effort, together with parties in the healthcare sector, to realise these objectives and formulate an ‘eHealth step-by-step plan’/ ‘roadmap’. The government will contribute to these efforts with measures for removing specific obstacles and with a programme to promote the exchange of information. This programme when applied to the ENSAFE product portfolio provide for a strong business case that digital innovation can support both the ‘system’ and patients to benefit from our offer and improve health outcomes for patients.

Political and Priorities and Policies	Implications for ENSAFE
40% of Dutch citizens and 80% of the chronically ill have direct access to certain medical information and can use this information in mobile apps or Internet applications.	
Ease and service for healthcare users	The ENSAFE GOLIVE phone when integrated with self care and self management platforms provides an additional opportunity for patients to make lifestyle improvements that will help them to live better and reduce their dependence upon clinical expertise and improve comorbidities that can make existing conditions escalate more quickly.
Awareness of the possibilities to the right of having access to medical information	ENSAFE sensors and digital data sources will help to support patients at home. Earlier detection facilitates earlier intervention and integrated support (digital and face to face). Links with formal care will be established.
Electronic communication between	The ENSAFE GOLIVE phone when integrated with self

healthcare providers and end users.	care and self management platforms provides an additional opportunity for patients to make lifestyle improvements that will help them to live better and reduce their dependence upon clinical expertise and improve comorbidities that can make existing conditions escalate more quickly.
We will empower patients and engage communities, increase patient choice and develop more personalised services	THE ENSAFE service offer provides the opportunity for individual patients and their families to take ownership of their health but using technology to help them and their carers healthier for longer.
75% of the chronically ill and the vulnerable elderly who can and want to do so can take independent measurements, in most cases in combination with telemonitoring.	
Making better use of technology, further developing leadership and supporting scientific research and innovation.	THE ENSAFE service offer provides health and care services the opportunity to reduce reliance upon more expensive resources, thereby supporting improved efficiencies and return on investment to the Government and the tax payer.
We will empower patients and engage communities, increase patient choice and develop more personalised services	THE ENSAFE service offer provides the opportunity for individual patients and their families to take ownership of their health but using technology to help them and their carers healthier for longer.
Anyone who receives care and support at home can use home automation and consult a healthcare provider via a computer screen 24 hours a day if desired.	
Support healthcare providers to harness digital technology.	THE ENSAFE service offer provides additional assistance and data to help inform clinical decisions around individual cases. Links with formal care will be established.

There is no specific legislation for eHealth as it is a variant of existing care. There is legislation that imposes conditions on the digital nature of eHealth. However, these laws are not specific to health care, but apply to all digital handling of confidential information. So since eHealth is considered to be a variant of existing care it must comply with existing laws.

The philosophy underpinning the Dutch healthcare system is based on several more or less universal principles: access to care for all, solidarity through medical insurance (which is compulsory for all and available to all) and high-quality healthcare services. Inevitably, the Dutch system has also been shaped by a number of historical trends and developments and social conditions. Foundation of the healthcare system The Dutch healthcare system is governed by four basic healthcare-related acts: the Health Insurance Act (Zorgverzekeringswet), the Long-Term Care Act (Wet langdurige zorg), the Social Support Act (Wet maatschappelijke ondersteuning) and the Youth Act (Jeugdwet). In addition, there are several general laws in place (including the Competition Act/Mededingingswet) and a

number of specific healthcare acts (e.g. the Care Institutions (Quality) Act). From the general laws three have implications for ENSAFE as well, like:

- Fundamental Law that includes the right that everyone should give permission for interventions at their body and that the government should organize measures to promote public health;
- Civil Law which is relevant for who has authority over under-aged and incapacitated patients;
- Privacy Law includes the protection of privacy of citizens and patients and data collection and providing.

The four healthcare-related acts form the foundation of the Dutch healthcare system. The Health Insurance Act (which provides for hospital care) and the Long-Term Care Act (which focuses on other types of care) account for the bulk of the healthcare budget available in the Netherlands. The Long-Term Care Act is a national act governing healthcare throughout the Netherlands. In implementing the Health Insurance Act, private health insurance companies play a key role in a system based on “regulated competition” and a number of specific public requirements. The Social Support Act and the Youth Act provide for other forms of care and support. The roughly 400 municipalities in the Netherlands are primarily responsible for enforcing these two acts.

2.2.3 Sweden

National governance and policy documents on the digitisation of Swedish social and health services have been around for a number of years. Sweden’s first e-health strategy was approved in 2006, and updated in 2010.

It is now almost a decade since the publication of the first e-health strategy, since then both the world and the Swedish health service system have developed and changed considerably. Sweden aims to centralise the national coordination of e-health initiatives in order to properly leverage the work being carried out by various public and private parties.

The basis of the continued development of eHealth solutions, is the Swedish Government’s and the Association of Local Authorities and Regions’ recent decision to endorse a common vision for e-health work by 2025. This Vision replaces the latest e-health strategy from 2010, while building upon its ideas.

The concept of e-health in Sweden is defined as the use of information and communication technologies (ICT) in accordance with the World Health Organization’s definition of health ("a state of complete physical, mental and social well-being "). The concept of e-health and digitisation in this context includes all social services run by the state, municipalities or private actors, encompassing the entire Swedish health care system as well as some areas of dentistry.

The term includes both *information digitisation*, ie the process whereby analog information is transferred to digital format, and *societal digitisation*, ie the broader societal process through which various ICT activities become more and more closely integrated with day-to-day society, thus affecting it profoundly.

In Sweden, the concept of *welfare technology* is closely related to e-health and digitisation, and is sometimes overlaps these areas. Welfare technology is defined as the knowledge and use of technology to promote increased safety, activity, participation and independence for people with disabilities of all ages, and their families.

In 2025, Sweden will be the global leader in the use of digital technology and e-health solutions that allow people to achieve a good and equitable level of health and welfare, as well as allowing them to develop and improve their own resources for increased independence and social participation.

Increased digitisation provides the required operational support to ensure that social welfare, health care and dental services all attain a high level of quality.

Equality is the basis for social and healthcare services in Sweden. This includes the premise that people living in different socio-economic conditions should have equal access to healthcare, based on their individual needs and situation. By providing digital tools that support initiatives tailored to the users, clients and patients, digitisation can make it easier for health care providers to work for increased equality.

The digitisation of health care services will be carried out with a clear gender-neutral perspective to ensure equal service, resources and influence between girls and boys, women and men. The work will also take into account the individual's right to protection against invasions of privacy, the need for privileged access management to personal data, and consent issues.

Improved efficiency is another goal of the digitisation of social services and the healthcare system. An increase in efficiency will be necessary if we are to achieve the required long-term, sustainable improvements in health and social services in order to manage the challenges posed by an ageing population and its growing expectations.

Apart from the perspectives already mentioned, the digitisation process will be driven with regard to a number of basic principles such as accessibility, usability and digital participation, and with a respect for the protection of privacy and information security.

The e-health strategy in 2010 singled out three main target groups:
The individual citizen, health and social care staff, and decision-makers.

The Vision aims to enable the digitisation of healthcare to allow citizens to achieve a good level of health and welfare, and to develop and strengthen resources for increased independence and social participation.

This means providing digital tools and services that leverage the users' own resources to achieve important goals such as improved health, increased participation, and self-determination.

By providing access to information concerning their own person, personalized digital support and clear communication pathways, the Swedish government believes people can be given the opportunity to increase control over their own health and well-being. For the elderly and people with impaired decision-making capacity, digital health services can be a tool for empowerment and autonomy. Furthermore, access to social and health care services may be improved by providing digital solutions that enable people to interact with care providers, and receive support in their own home. Digital solutions can also increase opportunities for the participation of relatives in care

provision, either through improved and simplified communication channels, or by improved access to medical information concerning their relative.

For this vision to be achieved, Swedish government also believes it is important that employees have access to support systems so that they can provide a social service and health care of the highest quality. On a general level, this means creating a digital work environment that supports the processes in which health care employees operate.

Digitisation also contributes to the development of new career paths when new types of needs or services arises, this can be attractive for long-term supply of competence. Digitisation can also mean a better working environment for women and men working in health care operations.

Sweden has a strong IT sector that contributes to economic growth and Employment. IT companies can also contribute in various ways to develop and streamline operations and at the same time find new business opportunities can contribute to growth and job creation.

The main responsibility for social services and health care lies with Sweden's municipalities and county councils. This includes organizing, managing, planning, developing, quality assurance and funding operations. The Government's responsibilities primarily concern legislative, regulatory, and grant allocation. There is also a general responsibility to both set goals and requirements when it comes for example quality and accessibility of public activities social services and health care and to follow them up.

Political and Priorities and Policies	Implications for ENSAFE
<p>Promote the use of digital e-health solutions through the provision of accessible, user-friendly, self-service systems.</p>	
<p>Ease and service for healthcare users</p>	<p><input type="checkbox"/> The ENSAFE GOLIVE phone when integrated with self care and self management platforms provides an additional opportunity for patients to make lifestyle improvements that will help them to live better and reduce their dependence upon clinical expertise and improve comorbidities that can make existing conditions escalate more quickly.</p>
<p>Electronic communication between healthcare providers and end users.</p>	<p><input type="checkbox"/> The GAIA tablet when integrated with self care and self management platforms provides an additional opportunity for patients to communicate with relatives and care givers.</p>
<p>Enable and empower people to attain a high level of health and well-being by developing digital services that encourage and facilitate self-service within healthcare, and which promote independent living.</p>	
<p>We will empower patients and engage communities, increase patient choice and develop more personalised services</p>	<p><input type="checkbox"/> THE ENSAFE service offer provides the opportunity for individual patients and their families to take ownership of their health but using technology to help them and their carers healthier for longer.</p>
<p>Making better use of technology, further developing leadership and supporting scientific research and innovation.</p>	<p><input type="checkbox"/> THE ENSAFE service offer provides health and care services the opportunity to reduce reliance upon more expensive resources, thereby supporting improved efficiencies and return on investment to the Government and the tax payer.</p>
<p>Increase the level and amount of healthcare provided in the home. Give people more control over their health and well-being through greater involvement and self-sufficiency. Increase relatives' involvement in the care of the elderly.</p>	

<p>Awareness of the possibilities to the right of having access to medical information</p>	<ul style="list-style-type: none"> <input type="checkbox"/> ENSAFE sensors and digital data sources will help to support patients at home. <input type="checkbox"/> Earlier detection facilitates earlier intervention and integrated support (digital and face to face). Links with formal care will be established.
<p>We will empower patients and engage communities, increase patient choice and develop more personalised services</p>	<ul style="list-style-type: none"> <input type="checkbox"/> THE ENSAFE service offer provides the opportunity for individual patients and their families to take ownership of their health but using technology to help them and their carers healthier for longer.

Legal factors

The focus in Sweden when it comes to legal and regulatory factors within digitisation and e-health, is the respect of the rights of the individual, i.e. the protection of personal integrity, data quality, safety and efficiency. The various laws and regulations that currently govern healthcare services in Sweden therefore focus strongly on the individual’s rights and interests. If laws and regulations need to be changed to meet the quality and efficiency requirements of digitised healthcare services, it is important that privacy and security needs also be met.

There are a number of laws currently governing Swedish healthcare policy, the following are the main ones:

Health Care Act (HSL) 1982: 763

HLS is a framework that contains the basic rules for all health care. It states what the county, municipality or other health care providers are required to offer the patient. Among other things, treatment, rehabilitation and habilitation for those in need of these care.

Public Access and Secrecy 2009: 400

The Act contains provisions on, for example, authorities handling the registration, disclosure and handling of public documents. The Act also contains provisions on confidentiality and the prohibition to disclose documents.

Patient Safety Act 2010: 659

This law aims to increase patient safety in health care. The Act contains provisions on notification of activities, authority, confidentiality and revocation of the right to practice medicine.

Personal Data Act (PUL) 1998: 204

The purpose of this Act is to protect people from having their privacy violated by the processing of personal data. This law gives patients the right to access their data stored in the healthcare systems various databases.

Social Services Act (SoL) 2001: 453

The Social Services Act concerns municipalities’ responsibilities for social services and addresses the issue of the right to financial assistance, home care, housing and special housing. SoL gives all persons residing in Sweden the right to social and economic security.

Patient Data Act 2008: 355

This law is used by healthcare providers processing personal data in the health sector. The Act also provides for the obligation to maintain patient records.

Patients' Act 2014: 831

This law is aimed at strengthening and clarifying the position of the patient within the healthcare system, as well as to promote patient privacy, self-determination and participation.

2.2.4 Italy

The Italian public-healthcare system presents some peculiar characteristics that need to be exploited when developing an innovative service. In particular, even when provided by private companies, the offer of any kind of product and/or service will have to take into account the network of services granted by the public spending or granted by different public institutions (Government, Regions, Municipalities, Local Healthcare Districts. Moreover, the expected partners in any Welfare-related initiative are constituted by ONLUS, especially the Social Cooperative and the *Fondazioni*, to which it is demanded the management and/or the financing of entire segments of the network of services.

Among the factors related to the institutions that need to be considered, two must be highlighted: a) the strong differences between regional laws (there are at least 21 different subjects legislating on regional of rules and local institutions to interact with when planning the services. The gap between North and South causes almost half of the country to be virtually inaccessible to innovative proposals that require a certain level of pre-existing services, a conscious involvement and suitable technological infrastructures. Even if in constant growth, the role played by private health-insurances is still marginal.

Eventually, it must be remembered that the healthcare organization in Italy suffers from the separation of the allocation of the budget between the “standard” health-services (hospitals, drugs, diagnostics, rehab, prevention, mental care) and the “social” health-services (assistance to elderlies, children, handicapped, homeless, minorities, etc.). The firsts are subject to regional laws and dispensed by Local Healthcare Districts, while the latter, even if legislated on regional level as well, are dispensed by the Municipalities (about 8000 throughout the country). The guidelines given in the “eHealth Action 2012-2020” plan, and acknowledged by the Ministry of Healthcare, are the following:

Political and Priorities and Policies	Implications for ENSAFE
Improve how chronic diseases and comorbidities and faced	The ENSAFE SERVICE, when integrated with self care and self management platforms, provides an additional opportunity for patients to make lifestyle improvements that will help them to live independently and/or reduce their dependence upon direct care assistance, even in case of comorbidities or chronic diseases.
Improve sustainability and efficiency of the health services	The ENSAFE service allows to optimize and reduce the time dedicated to the direct assistance of the elderly,

	and to reduce the need of inappropriate hospitalization
Promote health-security	The ENSAFE service connects the elderly to the social-service and healthcare network, increasing its security and inclusion, without undermining the quality of the service nor the privacy of the user.
Improve the legal and commercial framework for the development of eHealth products	Being located at the intersection between public, indirect and private spending, the ENSAFE service aims at covering different markets, creating a commercially competitive product
Increase the interoperability of eHealth services	The ENSAFE service is full interoperable
Support the research, development and innovation in eHealth context	The ENSAFE service connects devices of different kinds using an innovative interface, specifically developed for targets normally excluded from IT, and capable of adapting the usage of everyday objects to new applications.
Facilitate the comprehension and grant a higher spread of eHealth	The ENSAFE service allows elderly adults to exploit the most recent technological innovations to improve their health, their wellbeing, their autonomy and independency at their home.
Promote the international cooperation in eHealth context	The ENSAFE project gathers partners from four different countries, each of them presenting not only different Welfare systems, but also very diversified cultural, social and economic frameworks.

Legal factors

In the absence of a consistent national regulatory framework, the management of Digital Health Data in Italy is subject on one hand to the rules disciplining Privacy, on the other to the laws that regulates the adoption of so called Fascicolo Sanitario Elettronico (FSE)/ Personal Health Record (PHR).

The Health Data managing and processing must align in any case to the european and national framework on Privacy and Data Protection, in particular Legislative Decree of June 2003, no. 196, also known as **Personal Data Protection Code**.

In 2009, the national Data Protection Authority (DPA) formally approved "Guidelines on Fascicolo Sanitario Elettronico (FSE)/ Personal Health Record (PHR)", supplying the lack of legislation about

digital data processing.

The 2009 Guidelines, approved after a broad public debate with the sector stakeholders, fixed a first regulatory frame to protect health data while respecting personal privacy. The DPA established that the citizen has the right to choose in complete freedom the opening of a PHR, deciding which information will be included in it; it also established that the patient has the right of giving (or not) an informed consent about the creation of the record, and the right of obscuring any data or clinical fact. On the basis of these rules, the patient can take informed decision about his health without any lack of privacy. In a simple and detailed language, the informed consent letter specifies which stakeholder (GP, hospital doctor, pharmacist) can access to data, and indicates the allowed operations on the record.

On September 15, 2015 finally has been approved the **DPCM n.179, il Regolamento definitivo in materia di Fascicolo Sanitario Elettronico (FSE)/ Prime Ministerial Decree no. 179, Final Regulation on Personal Health Record (PHR)**. The Decree came at the end of a long and difficult legislative process, that created a general climate of uncertainty and distrust of the Government ability to guide the sector regulation.

This act regulates when is necessary an informed consent for health data processing, it stipulates the right of data obscuration, it fixes data security standards, how to act in case of *data breach*, and the obligation to nominate the *Data Protection Officer*.

The Regulation concerns:

- PHR contents;
- limits of liability and tasks of each stakeholder;
- data encode systems;
- guarantees and security measures for data processing;
- access authorizations, rules and levels to PHR;
- definition of a unique id code to permit anonymous access;
- interoperability standards for PHR at regional, national and european level.

2.3 Economic Factors

Despite the clear potential of assistive technology, it has not been comprehensively embraced by the health and care sector. The dual benefits of reduced costs and more personalised support are crucial given on-going budgetary constraints and our ageing population, yet its use in our sector has been relatively slow to develop and become embedded in everyday practice.

2.3.1 UK

Today's UK health and social care reforms aim to enable the health and care sector to achieve a more effective use of resources, including cost efficiencies, something which should encourage a

higher take up of assistive technology by providers and commissioners. For example, The Department of Health announced last year that it would provide up to £100 million in additional funding to Clinical Commissioning Groups (CCGs) to improve local services and prevent unnecessary admissions to hospital, including the commissioning of “any service which supports patients in the community and in their homes to help avoid unnecessary visits to hospital”. This supports the use of assistive technology.

However, there are additional economic factors that act as potential barriers to introducing a service or a product such as ENSAFE into the UK market.

“The opportunities for assistive technology service providers to develop new services that meet the needs of the individual are substantial, but there are challenges, including previously low levels of investment in many assistive technology services, the lack of care pathway commissioning for these services and the lack of awareness of assistive technology on the part of the public. At the same time, technological advances, coupled with some forward thinking research funding programmes, make the delivery of innovative assistive technology services at scale a real possibility.” (Department of Health, Research and Development Work Relating to Assistive Technology 2010 – 2011)

The complexity of the commissioning landscape is also a challenge in that since the introduction of the Health and Care Act in 2012, the structure of the sector has become increasingly challenging. There are few opportunities to enter the market at scale or via a formal structure. Previous national, regional and local structures (and therefore budgets) have now been dispersed into clusters of groups of organisations who have partnered together according to shared and variable priorities. This has been further compounded by a significant reduction in purchasing power and purchasing capability in terms of more widespread investment during a time of ‘austerity’ in the UK.

2.3.2 Netherlands

The total care expenditure in the Netherlands is 94 billion euros, including both health care as wellbeing services (Source: Centraal Bureau voor de Statistiek, 2013).

An eHealth funding checklist is designed for anyone who wants to have more insight into the way in which funding of eHealth is arranged within the Health Insurance Act and the Long-term Care Act. Innovators with an eHealth solution can check which type of healthcare providers they should focus on for the sales of the solution and healthcare providers could check whether or not eHealth solutions can be funded by for example health insurers. Healthcare purchasers agree that the use of eHealth can be a means to achieve their goals of quality improvements. During the purchasing of care they may therefore create development plans which are dedicated to eHealth. In addition, agreements are made with care providers about providing telecare under the Health Insurance Act.

Health Insurers fund eHealth solutions when the arrangement and the effectiveness of care does not change substantially with respect to the original care, because insurers fund the effectiveness and not the form it will be delivered in. Additionally points when eHealth can be funded are the presence of a positive business case, support with end users (patients and caregivers) and a substitution effect. They can finance eHealth from the regular purchasing procedures like telemonitoring, providing funding for (pilot) research and (financial) participation in startups for a limited amount of

time.

However, not all type of eHealth solutions fit under one of the different Health Care Acts or the policy of the health insurers mentioned before, so different funding routes need to be explored as well, like a direct consumer model.

2.3.3 Sweden

The total care expenditure in the Sweden is approximately 7 billion euros, including both health care and welfare services (Source: Government budget 2015).

With an ageing population, it is estimated that 80-85% of healthcare expenditure is on chronic diseases, with co-morbidities generating 50% of these costs. It is esimated that healthcare costs in Sweden will increase by 30% between now and 2050.

Social services and health care, are areas in which digitisation provides great opportunities for improvements in efficiency. These sectors account for a large part of Swedish public spending and are also sectors that the large majority of people come in contact with during their lifetime.

For social services and health care consumers, digitisation involves completely new opportunities for independence, participation and influence. Most people want to be independent, to participate and have both influence and control over issues and decisions that affect their health and social life situation. To meet these needs requires new tools for communication within and between health care service providers, and between these providers and their users, clients and patients.

2.3.4 Italy

Research conducted in 2015 by the Monitoring Centre of Digital Innovation in Health of The School of Management of Politecnico di Milano, revealed that in 2014 the overall expense for Digital Health in Italy increased by 17% compared to 2013, reaching the total amount of 1,37 billions of euros. Despite this trend, the final volume is still marginal (about 1,3% of Public Health Budget, that means only 23 euros per-citizen).

Nonetheless, according to that research, the benefits of digital innovation in Health are clear and measurable. For instance, the widespread adoption of Electronic Personal Health Records all over the Country would strongly decrease labour costs and rationalize information flows and data management, while improving the service outcomes. Expected annual savings amount to 1,6 billions euro. Furthermore, the implementation of digital services (such as personal records download by the web, online reservations for examinations or visits, diffusion of Apps and self-service boxes) would permit savings up to 350 millions euros/year to the Public Budget, and about 4,9 billions euros/year to the citizens, without considering time savings (transfers, waitings) and quality of life improving.

The most relevant fact concerns the use of digital technologies for Health and Wellness. About 11% of citizens in the last year used Smartphone Apps to obtain nutritional information on food, and another 11% is interested in using them. Less used (6%) life-parameters monitoring Apps (pressure, cardiac frequency, ecc.), usually connected to wearable devices (i.e. watches, bands, etc.): nevertheless they seem to be a very promising application for the future. Many GP (44%)

recommen the use of such technologies, even if the main path to technology in Helathcare is still person to person word-of-mouth (47%). This research clarify that, in the near future, digital services will be potentially highly appreciated by the citizens, and that they already represent a big opportunity to ensure quality and economic sustainability to the Healthcare System. However, to reach all these goals you need to combine technological developement and *soft factors* like information and education of the citizens, without whom any effort will be doomed to fail.

2.4 Social Factors

Social factors that may influence the adoption of ENSAFE are related to socializing the notion of using personal technology to support better health. Access to the market will need to resolve two key issues:

- The ability to adapt to their methods of support to include a more digital approach
- The digital capability of patients

The ability of professionals to adapt their methods of support to include a more digital approach.

There is a level of fear that technology may be used to cut back care services and reduce human contact with service users. This may prove challenging for professionals who are used to delivering care in a certain way.

Despite these potential barriers, technology is being increasingly used either within the sector or by the public who are starting to use trusted technology within a health context, for example Apple Health <http://www.apple.com/uk/ios/health/>

2.4.1 UK

The digital capability of patients. There are 12.6 million people in the UK who do not have basic digital skills and these people are those who are most likely to be suffering from poor health. They are also those most likely to be further disadvantaged by age, education, income, disability or unemployment. There is also a general lack of awareness of products and services like ENSAFE amongst the general public.

The following evidence supports this direction of travel:

Digital requirements for new primary care models (Nuffield Trust, 7 April 2016): This briefing examines how technology can underpin a series of changes enabling primary care to meet the challenges of tight funding, a medical workforce shortage, more complex patients and the demand for seven day access. The report draws on six case study sites using innovations such as shared health records, patient portals for booking, remote consultation and telehealth.

<http://www.nuffieldtrust.org.uk/publications/digital-requirements-new-primary-care-models>

Outpatient services and primary care: A review of the published evidence concludes that, with appropriate safeguards and support, substantial areas of care traditionally given in hospitals can be transferred to primary care. <http://www.journalslibrary.nihr.ac.uk/hsdr/volume-4/issue-15>

(Health Services Delivery Research 2016;4(15))

Patient Activation programme: NHS England has agreed a five-year license to use the Patient Activation Measure (PAM) tool with up to 1.8 million people through key NHS change programmes

which could include better capacity and capability to adopt new technology.

<https://www.england.nhs.uk/ourwork/patients/patient-participation/self-care/patient-activation/>

In addition, ENSAFE partners carried out a potential user survey with 336 citizens across participating countries in late 2015. 60% reported that they needed some kind of support with medication, decision-making, their health or falls, 50% wanted emotional support and 44% expressed a desire to be supported with their health from technology. 38% expressed an interest in using technology to support their health at home.

2.4.2 Netherlands

The digital capability of patients. In the Netherlands there is a big group of citizens who don't have basic digital skills and these people are those who are most likely to be suffering from poor health. They are also those most likely to be further disadvantaged by age, education, income, disability, or unemployment. There is also a general lack of awareness of products and services like ENSAFE amongst the general public.

However, compared to other EU countries the internet skills in the Netherlands and Nordic EU countries are high. In 2013 13 percent of the 16 to 75 years had high internet skills, 44 percent average skills and 36 percent of low skills. On an average EU level this is respectively 12 percent, 35 percent and 30 percent. The Netherlands belongs together with Denmark, Sweden and Finland to the countries where less than 10 percent of the population has no Internet skills. In Romania, Italy and Portugal this share is above 30 percent. One possible explanation is that people in these countries at home are less likely to have access to the internet (Source: Centraal Bureau voor de Statistiek, 2014).

The following evidence supports this direction of travel:

- ECP is an platform which has as goal to strengthen the use of ICT in the Netherlands and conducts activities around different topics in order to create the necessary basic conditions and prerequisites for the development of an information society, like tackling digital literacy.
- Zorgbelang (organization which serves the interests of patients) has published an “eHealth Ruler”, an independent research to digital service providers. What hospital, mental health institution, doctor and the care and nursing homes are the most progressive in offering eHealth basic services? At whom can you make an appointment or request a repetitive prescription online? At whom can you see lab results and/or access your file digitally? This helps to create awareness among professionals as well as the citizens.
- In the Netherlands we have seen an increase in healthcare users who keep track of their own information on doctor's visits or treatments. More people also keep track of their physical activity. The role of the healthcare user as a source and recipient of medical information is likely to become more important. But possibilities in electronic information sharing between healthcare users and healthcare providers are still limited. Enabling the patient to share their medical information electronically could potentially also be a way to better facilitate information exchange between healthcare providers, in the cases where this is currently difficult to realise. An additional benefit could be that as the electronic sharing of

information between healthcare users and providers becomes more self-evident, both parties' eHealth priorities could converge a bit more.

- In terms of eHealth in care, the 2015 intermediate reports of the eHealth monitor (Krijgsman et al., 2015) showed that few people with care and support at home have access to applications such as telecare and medicine dispensers. Various tools can play a role in tackling obstacles:
 - public information campaigns;
 - clear and accessible guidelines and assistance. This can include legislation, funding, but also content-related guidelines, such as preconditions for unlocking patient information;
 - promoting promising pilots;
 - tools for ensuring commitment and reaching binding agreements.

2.4.3 Sweden

Just like the rest of the world, Sweden is facing challenges posed by an increasingly ageing population, combined with the increasing influence of a new generation of healthcare consumers who will demand the same level of digitisation in healthcare as they find everywhere else.

Sweden is well positioned to reap the benefits of digitisation's opportunities. Swedes are among the most digitally skilled citizens in the world, and both the business and public sectors have to a large extent already digitised their operations. Sweden is also home to a relatively large number of the world's leading information and communications technology companies, many of whom have contributed greatly to pushing digital development forward internationally.

Access to the market will need to resolve two key issues:

1. The digital capability of patients.

Despite generally high digital maturity there is still a large group of people in Sweden who don't have basic digital skills. Approximately 630 000 people in Sweden do not use the Internet, equivalent to 7 percent of the population. 50% of people over 75 are non-users. 14% of people between 66-75 years are non-users. These are also the people most likely to be suffering from poor health, or to be further disadvantaged by age, education, income, disability, or unemployment. There is also a general lack of awareness of products and services like ENSAFE amongst the general public.

However, compared to other EU countries, digital skills in Sweden are very high.

Internet access in Sweden in recent years has been stable at just over 90 percent, and 82 percent of Swedes use the Internet daily. It is increasingly common to have both computer, tablet and smartphone.

There are now on average 2.07 computers and 1.13 tablets per household. 92 percent have a computer, 81 percent a smartphone and 65 percent a tablet. From eight years of age, over half (55%) have access to their own smart phone.

On average, Swedes use the Internet 24 hours a week. More than 9 of these are via a mobile device. People between 16 and 25 spend an average of nearly 40 hours a week on the Internet. Swedes continue to use mobile phones more and more. 78 percent of population connects via the mobile phone, 65 percent each day.

Sweden belongs together with The Netherlands, Denmark, and Finland to the countries where less than 10 percent of the population lacks digital skills. In Romania, Italy and Portugal this share is above 30 percent. One possible explanation is that people in these countries at home are less likely to have access to the internet.

2. The ability of professionals to adapt their methods of support to include a more digital approach.

There is a level of fear that technology may be used to cut back care services and reduce human contact with service users. This may prove challenging for professionals who are used to delivering care in a certain way.

Despite these potential barriers, technology is being increasingly used either within the sector, or by the public who are starting to use trusted technology within a health context for example booking health centre visits via webservices and/or apps, using video services to interact with doctors and other medical practitioners.

2.4.4 Italy

The social factors that may influence demand for the ENSAFE services within the Italian market are two: a) the lack of technological skills among the elderly (the so called *digital divide*), and b) the possible perceived conflict between technological and human factor. The path to private market should necessarily consider both that factors, and solve all the involved issues.

Level of technological skills. Even in the Italian market, the elderly regularly use information technologies and devices. Nonetheless, they are still a minority. In Italy about 23% of 65+ citizens browses on the internet, a little more than 2 of 10. They are mainly men, about 66%, of high cultural and economical level. Anyway, the cellular phone is used by 75% of 65+ citizens. Use of technological devices is limited due to a cultural gap, but even to physical constraints (vision, mobility) that should be accurately considered.

The perceived conflict between technological and human factor. The peculiarities of the Italian social tissue (high sociality, good resilience of family-based welfare, high population density) determine the centrality and unique role of the human presence in social and healthcare, causing on the reverse a strong reluctance to accept technological innovation, perceived as a bad and not satisfactory 'replacement' of human care. Both the elderly in need of care assistance, and his close relatives, will tend to interpret any technological proposal as a renounce to the human presence as a pillar of the caregiving process.

In case that an ENSAFE product or service is required for partially self-sufficient and/or non-cooperating elderly, it becomes necessary to rely on the cooperation or on the supervision of a professional caregiver, such as an assistant or a caregiving manager.

The ability of professionals to adapt their methods of support to include a more digital approach.

The use of technological devices within a caregiving organisation, must face the same kind of problems have been considered for the final user's involvement: **a) digital divide** (especially regarding assistance workers, usually lacking of specific skills and having low profile educational

qualification); **b) perceived conflict between technological and human factor** as cultural driver of the caregiving organisation, usually humanistic-oriented.

Nonetheless, even among professional caregiving organisation the use of informational devices is constantly increasing. In particular, many work processes regularly involve:

- a) Dematerialisation of information flows and creation of electronic Personal Health Records to ensure completeness, day by day updating and personal or clinical data sharing;
- b) Dematerialisation of documents (i.e. individual projects or medical records) within the social and health services;
- c) Use of specific applications for the groupware work, and the updating of projects and documents, and for co-creation processes;
- d) Testing of domestic and AAL technologies to secure housing and caregiving environments;
- e) Use of Data Analysis for service customization, target segmentation, trends detection and real-time warnings.

This picture seems to safeguard the basic conditions for a wide spread (even on the commercial point of view) of purposed technology among those private professional caregiving organisation (profit or non-profit), that manage (at their own entrepreneurial risk) a large number of facilities and services on behalf of the Public Administrations, ensuring better promptness and spending capacity. The private service provider also ensures – at least on a theoretical point of view – high standards of skill and capacity in establishing a confidence relationship with the end user, and in supporting the decision of acquiring ENSAFE products or services.

2.5 Technological Factors

The AAL Joint Program has the main purpose of create synergies and collaborations in order to promote, among stakeholders of European countries, the development of technical solutions to cope with the relevant demographic changes concerning the Europe: ageing of population, low birth rates, changes in family structures and migration are issues that will have a great impact on elderly health care and long-term care.

In this perspective, health care paradigms are definitely aiming to enhance home care services at the expense of a more traditional services models, mainly based on hospitalization in dedicated facilities. Such approach offers a number of significant advantages: elderly can live in their homes preserving their own activities, life context, autonomy and independence, with the usual network of contact and relationship; public (or private) care services are involved to time limited and well defined sets of tasks, allowing a more efficient use of economic resources; the integration of the informal caregiver network (like family, neighbours, friends and volunteers) is simpler if elderly are not hospitalized.

ICTs (Information and Communication Technologies) can foster and facilitate the improvement of home care services model, enabling effective prevention and early diagnosis strategies, increasing social relation, monitoring the occurrence of anomalies.

From a practical point of view, technologies can have numerous applications, for instance, a number of user's physiological parameters can be easily obtained by the means of the most diffused home clinical devices, that user can use alone to monitor his state of healthiness. Besides, networks of environmental sensors and home automation equipment can be used to detect the presence of warning conditions occurring in the home. Another important feature is the monitoring of particular users' behaviours like the sleep habits, the frequency of access to the bathroom, the local position occupied in the home during the day and the quantification of user's motion.

The use of technology can generate positive results for a wide audience of users: final users (elderly people), informal and formal caregivers (relatives, assistants, physicians), local home care service providers, and even the national health system.

Elderly users, for example, can benefit of a 24h/7 care without employ any care-operators; users' psychological well-being can be directly reinforced with the perception of being continually monitored. Besides personal monitoring, an environmental monitoring can be used, so that the safety is guaranteed and every possible situation of abnormality can be identified early. Furthermore, the use of technologies that are easy and familiar for the users, such as smartphones, can enable to better convey advice and tips leading to the adoption of healthier lifestyles (regular intake of medication, personalized diet, exercises for physical or cognitive activities).

Using ICT tools for elderly care, caregivers can have "objective" information and data related with users' behaviour, in order to establish relationships between changes in behaviours and the context (for example, among medical therapies and habits). Analysis of data produced by human monitoring allows to access to information on behaviours non-mediated from user subjectivity. Moreover, the automatic study of trends also allows to detect parameters that vary slowly over time (e.g. decrease in motion activity).

Information related to the users' behaviour can be useful for care service providers to better optimize the performances, making more efficient the services: for example, by changing dynamically the priorities of service delivery according to the actual needs of users.

Even the national health systems can benefit of possibilities opened by ICT technology. A detailed knowledge of users' state of being can be exploited to rationalize and make more efficient analysis, doctor visits, hospitalisations. Costs related to hospitalizations (even for short periods) have the most impact on the costs dedicated to the care of elderly. Also home care can be made more efficient by analysing so accurate the information about the user's state of health.

ICTs can help to improve the efficiency of services, without being a substitute of human assistance. Innovations do not eliminate the human work but they integrate and improve it, by introducing tools that increase the amount of information available to the care operator (and those who manage the services), allowing to deliver services more informed, timely and customized on users' need.

In the context of the ENSAFE AAL-Project, the technological platform has been designed to be of help to a broad category of possible users. The users were divided into four possible scenarios (from Level 1, to Level 4) in which increasing the level, corresponds a worsening in the users' health condition and autonomy.

In the Level 1 and 2, the smartphone and home clinical devices play the key role.

In Level 3 and 4, a network of wireless environmental sensors will provide data related to the user's behaviour at home. In particular, the sensors to be used are as follows:

- **Bed and Chair Occupancy Sensor** - used to monitor the presence of a person on the bed or on the chair/armchair, consist of a sensitive pad connected to a wireless ZigBee Transmitter Module, which provides the network connection to the sensor. The pad used for the chair monitoring can be placed under a pillow; the pad used for the bed monitoring has to be placed on top of the mattress (under the bed sheet). Each time the user occupies or frees up the bed (or the chair), a message is sent over the network using the ZigBee wireless connection. The bed sensor is useful for monitoring and analyse users' nightly behaviour and habits, such as: the time spent sleeping, the number of times that users get up at night, and the sleep/wake up time. Furthermore, it can possibly be used for the generation of immediate warnings (for example, in case of numerous anomalous get up are detected).
- **Door Open/Close Sensor** - used to detect if a door (or a window, a drawer, a furniture door, etc.) is open. If installed on the perimeters doors (or windows) of the users' home, it can be mainly useful for security issues. If installed on a particular drawer (for example, the medicine cabinet), it can be used to monitor specific behaviours.
- **PIR (Presence Infra-Red) Motion Sensor** - a wall-mounted device that detects the motion of a person in the room. Typically used in security systems (or to turn on the lights automatically), it can be used to monitor the amount of movement of users inside their home. When the average amount of movement of an elderly person tends to decrease this may indicate a state of malaise.
- **Power Outlet Monitoring Sensor** - a ZigBee smart plug that enables to measure the instant electrical consumption. Can be used to detect if a particular appliance (for example the Television) is On or Off. It can be particularly effective to define specific behaviours of a user. For example, mixing data provided by the chair occupancy sensor and by the smart plug connected to the TV, the amount of time spent watching the TV can be estimated.
- **Toilet Occupancy Sensor** - allows knowing if someone is using the WC. The monitoring of the frequency with which the toilet is used, especially at night, is a very important parameter in order to assess the state of being of a person.

Data provided by the sensor system, will be sent via internet to an Ensafe cloud service, in which data will be collected and processed and made available to the end user and his caregivers. The technical platform of the Ensafe system is well suited to all European countries and, thanks to the use of cloud-based services, it is extremely scalable and flexible.

Despite some of the barriers to market access and creating new social norms related to the adoption of technology in health and care, there is overarching evidence that the benefits of assistive technology outweigh any potential reservations.

For example: new developments in assistive technology are likely to make an important contribution to the care of people in institutions and at home. Video monitoring, remote health monitoring, electronic sensors and equipment such as fall detectors, door monitors, bed alerts, pressure mats and smoke and heat alarms can improve older people's safety, security and ability to cope at home.

<http://ageing.oxfordjournals.org/content/30/6/455.short>

2.5.1 UK

The NHS England Widening Participation project aims to provide people with digital skills to allow them to take charge of their own health. A project report outlines the key findings which demonstrated fewer GP appointments, fewer NHS 111 calls, fewer A&E visits and increased use of GP online systems. (Tinder Foundation, July 2016)

“Improving digital health skills has the power to reduce the pressure on frontline NHS services. By helping people to move non-urgent medical queries from face-to-face and emergency channels to online ones, we found we could potentially save the NHS an estimated £6 million a year, representing a £6 return on investment for every £1 spent on the programme in year three.”

http://nhs.tinderfoundation.org/wpcontent/uploads/2016/07/Improving_Digital_Health_Skills_Report_2016.pdf (Tinder Foundation, July 2016)

2.5.2 Netherlands

In the region of Eindhoven several healthcare providers work together in a specific geographical area to deliver types of care which otherwise are difficult to provide in a cost-effective way, like night care in the extramural setting. The best practice is designed to combine both resources and efforts of healthcare organizations to be able to organize and deliver care in a more efficient and cost-effective manner whilst not compromising the quality of care provided. This collaboration also allowed for the use of technology and remote types of monitoring to create further gains in quality and efficiency and resulted in a high quality remote monitoring centre. This shared facility serves as an interoperable hub where eHealth products and services can be connected and integrated with several healthcare providers at once instead of organising this subsequently.

Another development which highly supports the implementation of eHealth services is the revised direction of the RZCC (Regional Care Communication Centre). Together with its stakeholders (care providers in the region of Southeast of Brabant) the RZCC organised several work sessions to stress the importance of care communication and working together in this matter. The sessions led to a reassessment of the mission and principles of the organisation.

The aim of the RZCC is to increase the quality of patient care by initiating, facilitating and encouraging electronic information exchange between care providers and between providers and patients in the Southeast Brabant region.

Together the stakeholders agreed on the following principles:

1. We do not compete on patient data; the patient's interest is always leading! Where possible we will enforce this.
2. The partners catalyse care communication in the Southeast Brabant region via the RZCC.
3. We create substantive and administrative commitment for a specific project calendar.
4. We strive for full participation within the projects.
5. Projects linking sectors have absolute priority over sector-specific projects.
6. Everyone can participate; here we use the WHAT (Working Apart Together) concept.
7. Disclosing patient data we do together as a region (e.g. personal health record).
8. Commitment in projects automatically means participation in the costs, collaboration and resource availability.
9. We must meet quality standards and only work with standards.
10. In the assessment of the projects, the added value for the patient is of utmost importance.

2.6 Conclusions

Having considered the evidence base, it is clear that ENSAFE as a service provides a clear opportunity to take advantage of national policy and other economic conditions across the participating countries, as well as playing an important role in furthering the cultural and technological innovation that can not only generate more efficient and effective services, but also improve the experience and health of patients.

2.6.1 Italy

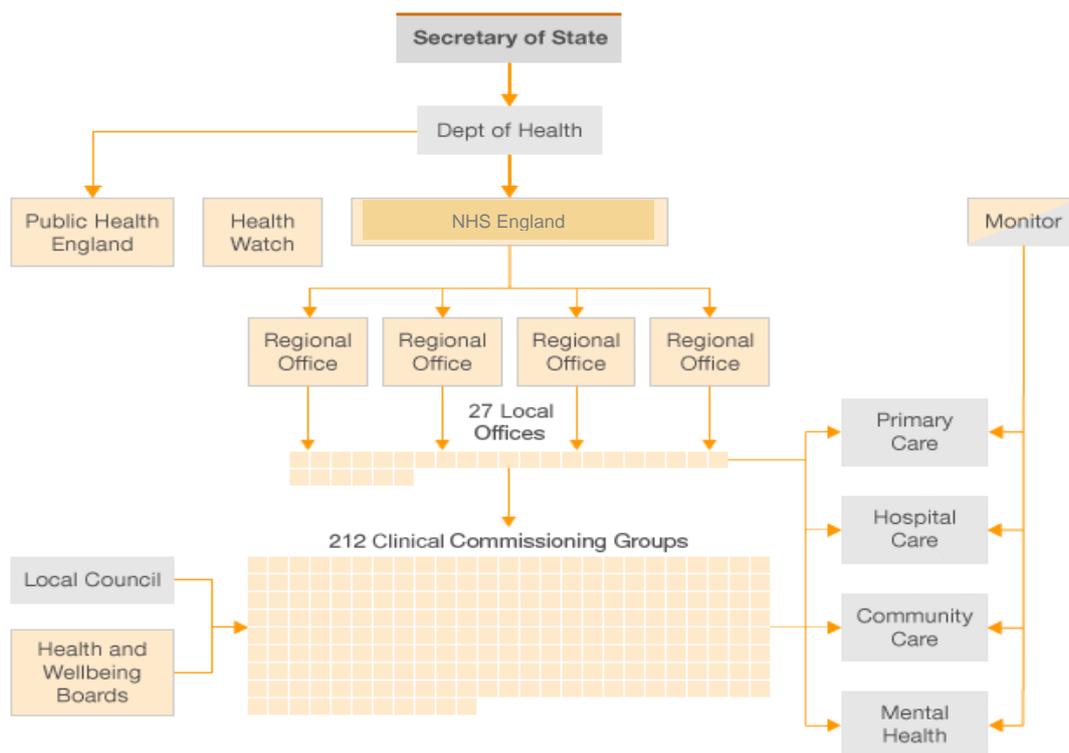
Taking account of this picture, ENSAFE as a service represents a clear opportunity for improving the quality of life of the elderly, in full accordance to the guidelines adopted by the Ministry of Health, to the general market trends and to the existing Welfare System rules. The commercial deployment of products and services should manage all the system's issues, in particular: public spending-review constraints, local and regional differences, the increasing (but still weak) out-of-pocket demand. In this frame is going to be crucial the involvement – as buyers or as intermediaries – of the **private** (profit and non-profit) **companies**, who are strongly linked to the Public Administrations as service providers. In conclusion, the regional market that seems to be better equipped for a commercial offer are those with the highest GDP and services-standards (for example: Emilia-Romagna, Lombardia, Piemonte, Toscana, and the Autonomous Provinces of Trento and Bolzano).

3 Market Structure

The complexity of the international markets at the current time provides us with the opportunity to consider multiple access routes for the ENSAFE as a service offer. Given that the majority of support for patients is delivered by National care organisations such as the NHS and there is a strong level of national pride in health services and the concept of ‘free’ care amongst the populations, it is unlikely that ENSAFE would achieve at scale adoption as a business to customer or direct sales model. Moreover, it is far more likely that it can be introduced as part of a ‘care package’ for specific patient groups provided by organisations directly responsible for commissioning or delivering care.

3.1.1 UK

The diagram below outlines the market structure for health and care as a result of national reform in 2012.



This structure offers us the opportunity to develop a proof of concept within a number of health and care settings to test and validate our business model.

It is expected therefore that we will work in partnership with the following organisations to test and reflect on the optimum route to market for ENSAFE and a Service in the UK:

- Wirral Council (older people’s parliament)
- Cheshire Council (Wellbeing)
- Liverpool Council (Riverside)

3.1.2 Netherlands

Since 2006, we have a new health care system in the Netherlands. More competition was introduced to the sector and health insurers & healthcare providers have more freedom in negotiating about the prices of a treatment for example. This freedom means that there are fewer rules; more has been left to the responsibility of the insurers and healthcare providers. Also, people can choose their own health insurance and healthcare provider, for which good and clear information is required. To regulate the entire process the right way, the Dutch Healthcare Authority (NZA) was established in 2006. The NZA acts as an independent regulator in the healthcare market. If certain consumer interests are at stake, the NZA will most likely intervene.

The diagram below outlines the structure for health and care in the Netherlands.

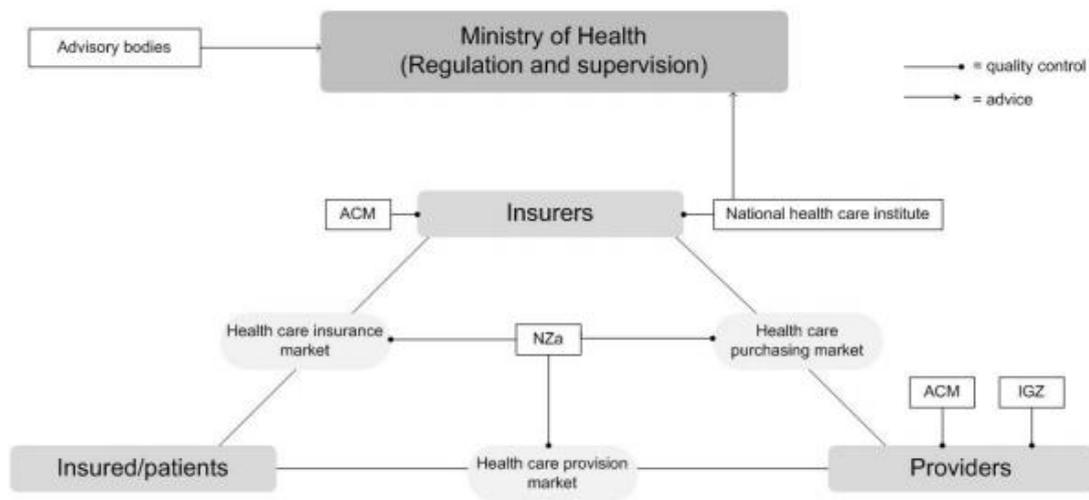


Figure 2 The Dutch Health System by Joost Wammes, Patrick Jeurissen and Gert Westert, Radboud University Medical Center (2014).

This structure offers us the opportunity to develop a proof of concept within a number of health and care settings to test and valid our business model. However, a business to consumer model is not included in this structure and needs further exploration as well.

3.1.3 Sweden

In Sweden today health care is provided by county councils and local municipalities. Medical care is conducted as both outpatient and inpatient care. At outpatient may be examined at a health center,

or in an emergency room, whereas inpatient care will be inscribed on a ward at the hospital, and cared for there.

In Sweden a physician, general practitioner or specialist, averages 900 patient visits per year.

There is a so-called health care guarantee, which means that you should receive care within a certain time. For example, you should never have to wait more than seven days to see a doctor at the health center.

The Swedish health care system is financed mostly by taxes, but patients pay a nominal fee for each visit to the hospital or health center. At private clinics or health centers that are part of the national health insurance system, patients pay the same patient fees as they would at the county council's health care facilities.

Exactly how much the patient fee is determined by each county, and will therefore vary depending on where you live. Most county councils provide free health care to those under 20 years.

If you go to hospital you have to pay a fee per day, which by law shall not exceed 100 SEK/day. Visits to hospitals and health centers are different depending on whether you get to see a doctor, a specialist, or a nurse. For a visit to the nurse is usually charges around 100 SEK, while visits to the emergency room and doctor visits are usually priced at about 200 SEK. For specialists, you pay 100-150 SEK more. For those who often need care, these fees can be very costly even though each visit does not cost so much. Therefore, there is a so-called high-cost protection, which means that during a twelve month period you won't pay more than 1100 SEK, regardless of the number of visits to the doctor.

Another way of looking at the Swedish health care market is to divide it into three main areas of activity - health promotion, sickness prevention, and post-care services. Health care recipients can also be divided into three main categories, depending on whether health care is delivered to individuals, groups or to whole organisations.

By far the most cost-effective solution is to work on health promotion at a group or organisational level, by following a carefully-structured health strategy. The least economically viable solution is carrying out rehabilitation on an individual level.

Therefore, it is a paradox that only a few percent of resources are currently spent on health promotion and health strategy, while 60-70% of expenditure is spent on health checks and reactive operations without a long-term health strategic plan.

Telia expects more than half of Sweden's 4.6 million households to be connected to health services in the home within three to five years. The company estimates that the market will by then be valued at "several billion SEK per year".

3.1.4 Italy

On the basis of these considerations, it's clear that, given those specific features of the Italian healthcare services market, any strategic approach to the market should be correctly positioned at different levels, each one with different audiences.

In a situation of forced spending review, Italian Public Administrations do not seem to be a likely buyer of the ENSAFE services.

Paths to follow to the service market are three at least:

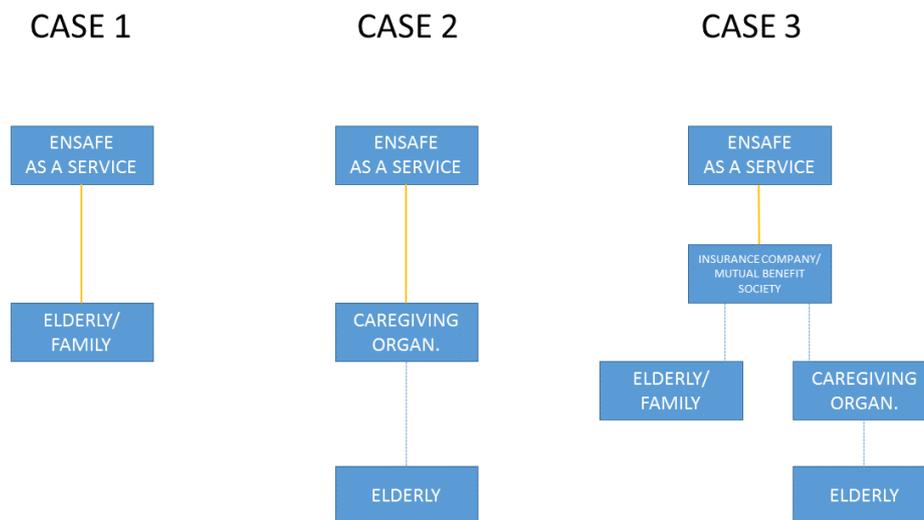
1. The one directed to the **private provider** of the healthcare services (mainly non-profit organizations), to whom it offers an upgrade of the outcomes and an opportunity to rationalize the resource outflow;
2. The one straightly aimed to the **end user** and to his relatives, leveraging the increase of self-security, health and independence;
3. The one looking at the growing intermediated services market: **insurance companies** and **mutual aid societies**, interesting in improving their services outcome.

The first path strategy lies on a clear explanation of the value proposition that ENSAFE offer represents in terms of increased competitiveness on the market and in terms of budget stretching (effectiveness, rationalization, interoperability, economies of scale, etc.).

The second path to market mainly aims for the increase of self-security perception, and for a competitive price.

The third path strategy synthesizes the other two, aiming both for an increased competition of the offer on the market, and for a small rise of costs for the customer of the service.

In this picture, Public Administrations (depending on the considered service: Health Agencies, Municipalities, etc.) should paly in any case an active role of di ‘validator’ and guarantor of the offered service.



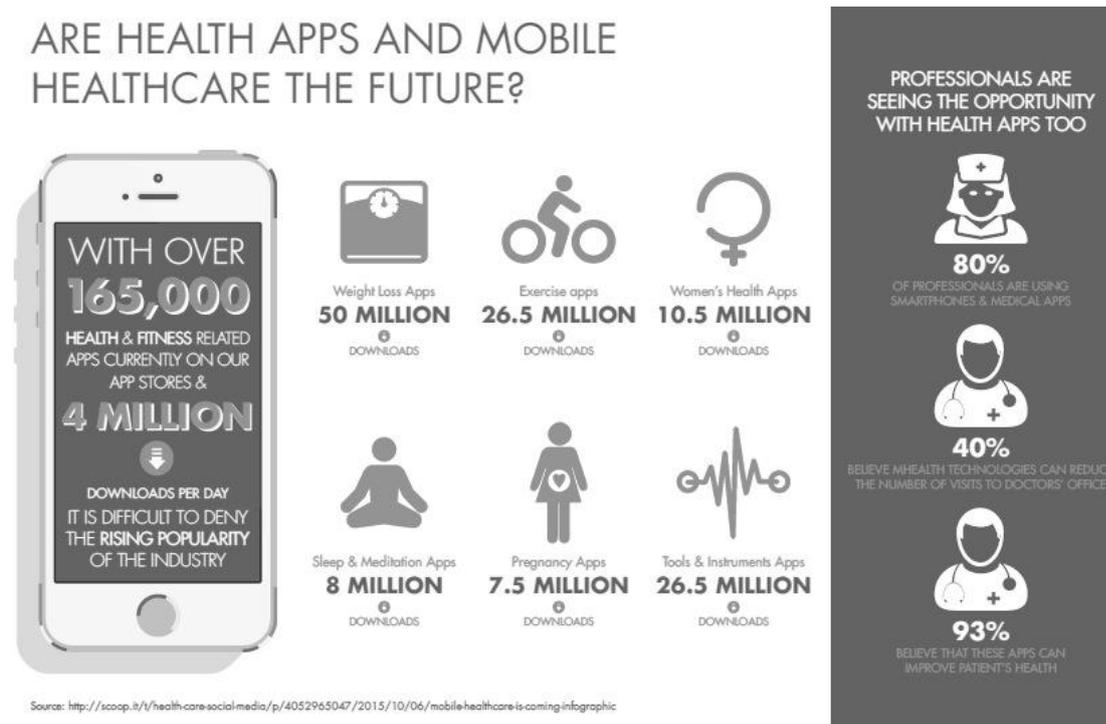
4 Competitor Products & Services

In a growing market, ENSAFE as a service will compete against a number of other products and services.

ENSAFE is able to position itself competitively within these markets due to the highly variable and mixed range of potential purchasers within these sectors, for example, housing organisations building assistive living properties or private domiciliary care providers. Following a successful trial, we will be able to offer a lower cost, comprehensive ‘plug and play’ system that is flexible to patients and citizens with variable needs within a health or care setting.

4.1.1 UK

This infographic highlights the wide range of products available:



ENSAFE 1-2 is competing with a large number of individual apps that help citizens to manage lower dependency levels of health and lifestyle. These tend to be relatively siloed around a specific condition of illness, for example reminders and trackers to support medicine management or mental health memory assistance. ENSAFE is able to offer a more sophisticated service because it will cover a wider range of features all in one place and linked directly to professional support.

Specific competitors include:

<https://www.canarycare.co.uk/> This service works to distinguish patterns and alarm in event of

emergency with a very competitive price point of £42 per month (compared with <http://www.justchecking.co.uk/> at £90 per month) and is based on mobile phone technology.

However, unlike ENSAFE, it does not offer:

- Any IOT devices
- Machine learning in the system
- Connections to the user's smartphone
- Medicines reminders
- Prompt for better health behaviours
- Support navigation
- Support connections to family
- Integration with a falls sensor.

<http://www.independence-telecare.com/true-kare/> is mobile phone based and integrates telehealth with a GPS locator. It also integrates with wearables and fall detectors and can screen nuisance calls. It also includes a diary system and a medication reminder function.

However, unlike ENSAFE, it does not offer:

- Any IOT devices
- Machine learning in the system
- Prompt for better health behaviours
- Support connections to family.

<http://www.docobo.co.uk/telehealth-solutions/docobo-products.html>

This is a telehealth-based solution that is also backed by an app. It has some intelligent algorithms that commissioners like that support patient management at scale.

However, unlike ENSAFE, it does not offer:

- Any IOT devices
- Machine learning in the system
- Connection to the user's smart phone
- Prompts for better health behaviors
- Support navigation
- Support connections to family
- Integration with a falls sensor.

ENSAFE 3-4 is competing with a range of residential providers and digital support products that are provided predominantly as part of wider domiciliary care options in places such as residential and care homes.

Hft's virtual Smart House - <http://www.hftsmarthouse.org.uk/> uses sensors and data to help support citizens with disabilities to live more independently at home. This is a more complex and expensive

version of the ENSAFE service and is less flexible. It also does not provide for wider healthy lifestyle or prevention factors.

‘Belong at home’ is a domiciliary care option for frail and elderly citizens that uses sensors in the home to help monitor movement and therefore alert carers. <http://www.belong.org.uk/what-is-a-belong-village/belong-at-home-.V58fhzkrJ68>

4.1.2 Sweden

Here follows a summary of some competitors within the Swedish market place.

HIP SDK

“Karolinska Institutet offers HIP SDK so that third parties can quickly and easily develop e-Health innovation solutions.

Our idea is that third parties will be able to produce high-quality IT solutions for patients and healthcare quickly using HIP SDK. HIP SDK has downloadable SDKs (connections) to all the county councils through the National Service Platform. HIP SDK has packaged, tested and quality assured data sets with experience from major national projects such as My Care Flows and New Patient Overview (NPÖ2).

HIP SDK is run by Karolinska Institutet Information AB, which is owned by Karolinska Institutet Holding.”

HIP.se gives small and large operators access to quality-assured code, which allows companies to quickly develop new solutions within the e-health area at a fraction of what it would otherwise have cost.

The HIP Forum exists to support companies and organizations to use the framework for application development with tools, regulations and development environments that are available on hip.se. During HIP Forum meetings, entrepreneurs and innovation operators receive information about the HIP SDK, participate in workshops, and get help from experts in the field, as well as getting individual consultation.

The target group for HIP Forum is operators who are planning or are developing new e-services and see HIP SDK as an opportunity to accelerate and facilitate development.

Telia

Telia is launching Sweden's first publicly available subscription service for online health services in the home. The idea is that Swedes should be able to measure everything from blood pressure and ECG to weight and lung capacity, from the comfort of their own homes. The information is sent automatically to a personal health account held by Telia.

The heart of Telia Home Care is a box that wirelessly communicates with caregivers through sensors in the home, and is entirely controlled by the user. Through Telia Homecare users gain control over what happens in their home and increase their contact with their caregivers. For example, users can get help with different types of services like blood tests or ECG measurement at home. The patient may also proactively monitor their health state to avoid illness, and share information with health professionals when they are ill. The system can also provide reminders when the user forgets things which are important in elderly care.

Telia Home Care is a scalable solution. Instead of the current requirement of a proprietary communications link for Security alarm, another for video communications, and a third for monitoring equipment etc. caregivers can use the same communication pathway for all services.

Telia Healthcare is built on open standards, which means that an organization that uses the platform is free to choose which device it wants to procure and install in the user's home. Telia also offers services over Telia Home Care.

Users may authorise that their health data be sent to a health center, a hospital or a relative. The data on the account is owned by the individual, not by Telia.

Telia is responsible for the health account and for the security, integrity and communication.

For this, Telia wants to charge 50 sek/month. In some cases, the service is paid for by the municipality or county council, sometimes by the consumer himself. The rental charge does not include the measurement equipment in the home, such as the electronic scales or the smart bracelet.

Telia's offering comprises a number of different services:

HomeCare – a sensor network in users' homes

ProCare – mobile work place for health care professionals

CareView – the display health related data via a mobile device

CareGuide – digital signage, web-based consultation, automated sign-in terminals

CareIntegrator - IT services related to the integration of existing IT solutions with Telia's solutions.

Inera

Inera is a limited company jointly owned by Sweden's county councils and regions. Inera coordinates, develops and implements e-health services, technological infrastructure and common standards for the benefit of residents, care staff and providers. Inera's mandate includes co-operation with other actors; municipalities, government authorities, private health care providers, research and development actors, NGOs and market players.

Inera has developed more than 40 digital services for use by Swedish citizens and local healthcare providers. As of 2017 the cost of these services will not only be borne by the government, local municipalities, regions and councils, but also by private health care providers and other commercial parties (e.g. developers)

Hälsa för mig (Health for me)

Health for me is a personal health account that will be available for anyone who wants to collect, view and share their health information. The personal health account makes it possible to subscribe to health information picked up medicines and vaccinations. Health for me continuously developed and eventually it will be possible to subscribe to additional information from health care, such as lab results and information from the account holder's medical record. Moreover, it will be possible to collect health information with the help of different applications, so called applications, which will be connected to the health for me.

The individual has full ownership and control over information in their personal health account. If you want, you can choose to share some of your information with the app that will be connected to the Health for me. This means that apps will be able to process your data and feedback to you.

Health for me is driven by Sweden's eHealth Authority (eHälsomyndigheten) on behalf of the Swedish government.

Health for me is a safe, secure and long-term storage of health data with the state as guarantor.

4.1.3 Italy

To date, on the Italian market there are many funded benchmark standards for eHealth services or devices. The current offer is mostly fragmented, not intraoperative and, above all, it is not conceived or presented *as a service*.

Mainly widespread products are technological devices, available on the retail market (i.e. the well-known Beghelli product line: <https://www.beghelli.it/it>), and on the other many ITC solutions (software, apps) implemented in single or isolated cases, without real interoperability and no connection to the whole welfare network.

In this situation, ENSAFE as a Service can represent the link and the connection between these two levels: a technological layout perfectly scalable and universal, ready to interconnect with the existing social and healthcare service network, thanks to direct involvement and the mediation of the caregiving organisations.

4.1.4 Netherlands

Sensara

Sensara focuses on the prevention, early detection and efficient management of treatable psychosocial and physical consequences of chronic diseases that are accompanied by progressive cognitive decline and an increased risk of straying and falling during the advanced stages of the disease.

The functionalities of the Sensara system can be summarised as:

- Monitoring of the activities of elderly persons with sensors.
- Generating alarms when unexpected/deviant (in) activities are predicted or detected (for example a fall).
- Generating warning when longer term deviations from the personal behaviour are detected.

Philips

Philips CareSensus is an unique home care monitoring solution consisting of connected, discreet, non-camera based sensors placed strategically in a senior's home to provide full-time monitoring of their daily activity, paired with a tablet-based two-way video engagement tool. Connected remote care teams such as in-home care providers or managed care organizations can spot changes from normal patterns and provide intervention before a more serious event occurs. The result is blended care—a combination of traditional hands-on care and remote care.

5 Product/Service Offer

It is expected that ENSAFE as a service will be introduced to the varying international markets as part of a package of support available to specific groups of patients within a fully integrated pathway, aligning professional and digital support as part of a seamless care service that will adapt to accommodate individuals' current state of dependency upon care services.

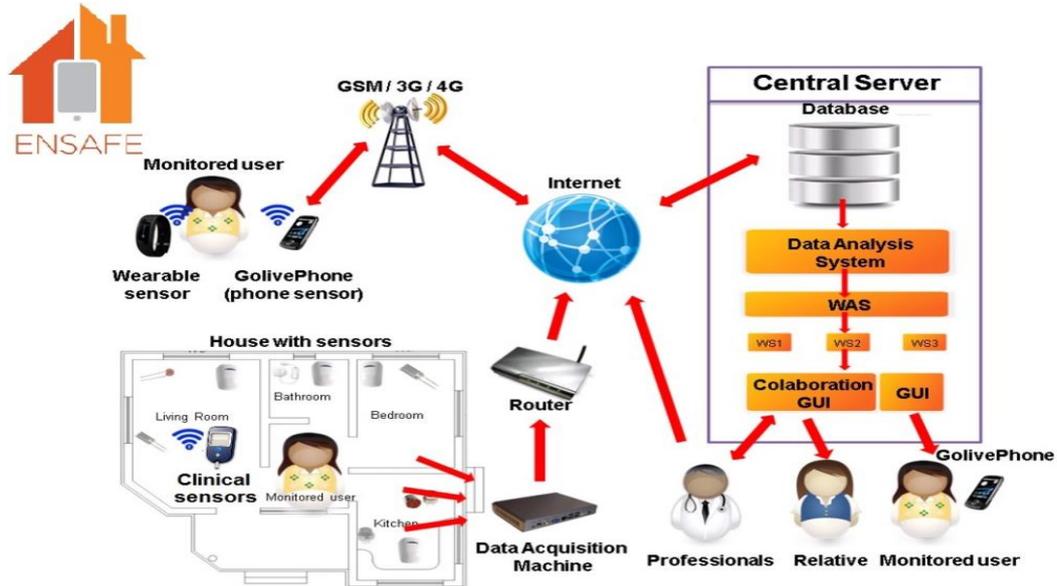
Purchasers will be able to bulk purchase either one level of the ENSAFE service or up to all four versions, depending upon the needs of their distinct patient groups. For example, a residential care provider with a mixed level cohort of patients/residents will be able to purchase level 1 support for patients who have lower care dependency as well as level 4 for individuals who have high care dependency and a greater need for additional remote clinical monitoring. In this way, the offer is multifaceted as it supplies support according into individual need, but also offers the opportunity to increase or decrease levels of support along a patient pathway.

Although the ENSAFE offer theoretically includes all 4 packages (*simple, comfort, safety, complete*), it is a spectrum of intensity. So, we can expect that ENSAFE I will not attract the Caregiving Organisations (Who will probably become more involved at ENSAFE II), whereas on the other side of the spectrum ENSAFE IV will not fit the expectations of a single elderly citizen in good shape with no need of care assistance. In any case, the customer will be free to change their choice (Package upgrade or downgrade) at any moment.

Package contents are as described below though not fixed in their state.

ENSAFE I (SIMPLE)	ENSAFE II (COMFORT)	ENSAFE III (SAFETY)	ENSAFE IV (COMPLETE)
GoLivePhone (normal functionality)	GoLivePhone (normal functionality)	GoLivePhone (normal functionality)	GoLivePhone (normal functionality)
GoLivePhone sensors	GolivePhone sensors	GoLivePhone Sensors	GoLivePhone Sensors
	Communication Hub (possibly smart phone)	Communication Hub (possibly smartphone)	Communication Hub (possibly smartphone)
	Wearable sensor	Wearable sensor	Wearable sensor
		Home and environmental sensors	Home and environmental sensors
			Clinical monitoring services (e.g. precision scale, BP monitor, glucose monitor, pulse monitor)
Web portal & apps			
	Web portal (IC)	Web portal (IC)	Web portal (IC)
Integration services - call centre, Gaia platform connections	Integration services - call centre, Gaia platform connections	Integration services - call centre, Gaia platform connections	Integration services - call centre, Gaia platform connections

The ENSAFE as a service offer provides for a flexible and innovative approach to apply technology across a wider system, fully integrated into the wider health and care ‘ecosystem’ as featured in the diagram below.



6 Market Positioning and Routes to Markets

ENSAFE as a service will be positioned in the market as the product of choice for:

- **Caregiving organisations** (profit and non-profit) that wish to improve services quality, patient outcomes and to reduce costs
- **Elderly in good health** who wish to improve their independence, their self-sufficiency, to prevent their decline or diseases' insurgence, to keep good and broad social relationship, to maximize security and safeness, to get early warning about trends and other health related-status
- **Informal caregivers** (relatives) who wish to improve their relative's independence, self-sufficiency, to prevent decline or diseases, to keep him in good and broad social relationship, to maximize his security and safeness, to get early warning about trends and other health-related status
- **Insurance Companies and Mutual Benefit Societies** who wish to enrich their offer
- **Public Administrations** who wants to improve service outcomes for the citizens and more effective network relationship in the welfare system

Due to the flexibility offered by ENSAFE 1-4, it is also expected that ENSAFE as a service will be made available to other technology partners who wish to:

- Integrate their personalised care record systems with mobile and sensor based technology so that they are able to offer additional services to care providers who wish to monitor patients more comprehensively (for example technology suppliers to the domiciliary care sector)
- Integrate patient self-management 'apps' within a wider more integrated offer.

It may also be possible for us to add this additional functionality within the existing ENSAFE offer in the form of a collaborative partnership, for example, with Puffell.com, a digital health and wellness platform that encourages self care, self-management and wider health and wellbeing support directly to citizens.

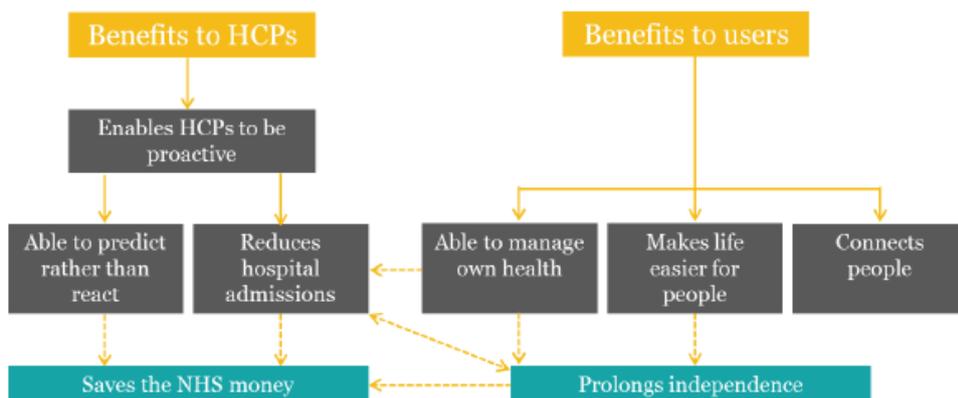
7 Value Proposition & USP

In February 2016, ICE Creates delivered focus groups with potential ENSAFE customers and health professionals. The insights gathered from these groups has helped to shape the overall value proposition based upon feedback from potential users:

Research Findings:

- Technology will not replace one-to-one care, but provide an alternative for when this is not possible
- Technology will make life easier for people to monitor and support their own health
- Technology will enable professionals to be proactive and identify problems earlier to prevent need for hospital admission/care
- Technology will prolong independence
- Health-related technologies are unlikely to be one-size-fits-all as patient needs will change over time.

These benefits for both patients and HCPs (health care professionals) are featured in the model below:



The overall vision for ENSAFE is to:

“Offer a seamless, complete healthcare experience to various customer groups, from prevention, to diagnosis and ongoing care”.

Therefore, the overall unique selling proposition for the ENSAFE offer is to *“connect every participant in the entire continuum of care using personalised technologies”.*

Within this, additional insights with potential beneficiaries has helped us to shape our offer as follows:



ENSAFE Value Propositions
Doc.doc

8 Target Audiences (Personas) & Key Messages

The following pages summarise the key findings from our value proposition document and canvases to describe our target audience for each level of service with corresponding key messages and benefits.

8.1 ENSAFE I

<p>End user: Elderly person, Relative</p> <p>Buyer: Elderly person, Relative, Insurance Company or Mutual Aid Society</p>	<p>Independence; Safety; Information; Health; Social Relationships; Services Offer Improvement</p>	<p>Stay Safe at Home;</p> <p>Stay in Health; Be Independent; Stay Connected To The People You Love; Take Care/Keep Informed About Your Relative; Improve Your Service Offer;</p>
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Our offer: A digital solution that seamlessly combines social interactions, self-management of health and wellbeing and digital connection to the end-user's health services all within one space; saving time, effort and confusion.

Persona 1



Annie Janssen



Age: 71
 Sex: Female
 Living situation: With partner at home
 Hobbies: Reading, cycling and Singing.

Personal needs:

She has a below average health / average health / above average health.

Condition: None
 Needs: Would like to see her family members and neighbors more and stay in touch, has sometimes trouble with walking (especially the stairs).

Technology usage:

She has no / low / medium / high skill in using technology

Technology owned: Desktop PC, Tablet, mobile phone and digital camera.
 These are used for: Online banking, email and browsing the Internet.

Barriers experienced: Can't keep up, sometimes I forget how something works and then I can't do it again on my own.

8.2 ENSAFE II

<p>End user: Elderly person, Relative, Formal and/or Informal Caregiver, Caregiving Manager</p> <p>Buyer: Elderly person, Relative, Insurance Company or Mutual Aid Society; Caregiving Organisation</p>	<p>Independence; Safety; Information; Health; Social Relationships; Services Offer Improvement; Service Outcome Improvement; Budget Stretching; Interoperability; Running Costs Effectiveness</p>	<p>Stay Safe at Home;</p> <p>Stay in Health; Be Independent; Stay Connected To The People You Love; Take Care/Keep Informed About Your Relative; Improve Your Service Offer/ Outcomes; Save Costs;</p>
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Our offer - In addition to the value delivered within ENSAFE I, the end-user is connected to an active Telehealth solution with access to rapid response or support at the press of a

button. Whilst this does not mean they are monitored or routinely supported, it does give them the option of calling for assistance if required.

Persona 2



David Gilroy



Age: 82
 Sex: Male
 Living situation: Lives Alone, Extended family visit often
 Hobbies: Browsing internet
 Chess
 Watching Rugby League
 Candy Crush

Personal needs:

She has a below average health / average health / above average health.

Condition: Poor Eyesight, Hearing Loss, Diabetes, Knee Replacement
 Needs: Risk of falls
 Reassurance needed
 Risk of self-neglect
 Daily care call to prompt medication, support with daily living tasks as required (Personal Hygiene Prompts)

Technology usage:

She has no / low / medium / high skill in using technology

Technology owned: Microwave, TV, Smart phone, Ipad, Telehealth, one touch kettle
 These are used for: Meals, Watch TV, Google, Chess, Check Rugby fixtures, Skpe, online shopping, Games, youtube, facebook, ebay

Barriers experienced: Poor eyesight
 Poor Hearing
 Poor Mobility
 Poor Manual Dexterity

8.3 ENSAFE III

<p>End user: Elderly person, Relative, Formal and/or Informal Caregiver, Caregiving Manager</p> <p>Buyer: Elderly person, Relative, Insurance Company or Mutual Aid Society; Caregiving</p>	<p>Independence; Safety; Information; Health; Social Relationships; Services Offer Improvement; Service Outcome Improvement; Budget Stretching; Interoperability; Running Costs Effectiveness</p>	<p>Stay Safe at Home;</p> <p>Stay in Health; Be Independent; Stay Connected To The People You Love; Take Care/Keep Informed About Your Relative; Improve Your Service Offer/ Outcomes; Save Costs;</p>
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Organisation		
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Our offer - ENSAFE III will directly benefit the care providers for the patient in question, as they will be given access to the data that is captured in a live state through the environment and wearable sensors. This will allow for interventions to be led more proactively and less reactively. In turn this additional level of support provides piece of mind to friends and family as well as the end-user, as they know there are suitable interventions in place to keep the end-user as safe as possible.

Persona 3



Stina Svensson



Age:

84

Sex:

Female

Living situation:

Lives alone, with homecare

Hobbies:

Walk in the city, sewing and knitting (used to solve cross-words, but not able to do anymore)

Technology Tree:



Use case narrative:

Stina has been living alone for the past 5 years in an independent apartment. She receives homecare visits twice daily, and her family visits her on a weekly basis. She pays daily visits to her local senior centre where she participates in social activities and eats lunch.

Stina has below average health and suffers from diabetes type 2. She has suffered a number of falls at home, and requires a frame to help her walk. Stina often requires help finding her way home as she becomes easily disorientated.

Stina also has below average technology skills. She values her independence, and unfortunately is not fully aware of her own cognitive limitations. Although she can answer calls, she seldom places calls to others. She often forgets to charge and turn on her phone.

Technology elements:

GPS Alarm Watch:

Stina's GPS Alarm Watch has no display, and any alarm activated is sent to the homecare provider.

Nokia Lumia 520 Mobile Phone:

Stina uses her mobile phone to stay in touch with her son. She seldom, if ever, makes outgoing calls, as she finds it increasingly difficult to use the phone's small keys.

8.4 ENSAFE IV

<p>End user: (Elderly person), Relative, Formal and/or Informal Caregiver, Caregiving Manager</p> <p>Buyer: Insurance Company or Mutual Aid Society; Caregiving Organisation</p>	<p>Independence; Safety; Information; Health; Social Relationships; Services Offer Improvement; Service Outcome Improvement; Budget Stretching; Interoperability; Running Costs Effectiveness</p>	<p>Take Care/Keep Informed About Your Relative; Improve Your Service Offer/ Outcomes; Save Costs;</p>
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Our offer: In addition to the value delivered in ENSAFE III, ENSAFE IV will provide the option for additional ‘Medical Sensors’ to be configured alongside the environmental sensors. For end-users with complex comorbidities or specific mental/physical health conditions, these sensors will act as a 24/7 monitor, ensuring any unusual patterns or behaviours are identified quickly and suitable interventions follow.

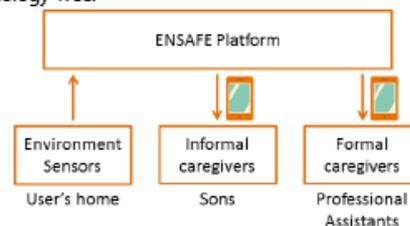


Adele, Polastri



Age: 87
 Sex: Female
 Living situation: Alone in an assisted apartment
 Hobbies: TV, Card Games, Knitting

Technology Tree:



Use case narrative:

Adele is a self-sufficient old woman, who lost her husband 5 years ago. Last year, despite her pretty good health, she began to forget facts and information, such as tasks or appointments. By agreement with her sons (Marco and Daniela), she decided to move to an assisted apartment in her city neighborhood. Marco and Daniela often visit Adele in her new house, and thanks to the assistants taking care of her, she feels better and less scared about her future.

She's still able to use her Mobile Phone to call Marco and Daniela, but she finds some increasing difficulties in following the right sequence of operation to do it. In the last months she often forgot to take her medicines, and she became to wander and wake up at night, so the assistants decided to implement new specific sensors to monitor her health, activity and mobility, in order to detect any danger and help her.

Technology elements:

Behavioural monitoring:

Using a set of environment sensors, the behaviour of Adele at home can be continuously monitored.

Her sons (Marco and Daniela) and Professional Assistants can evaluate her state of wellness, monitoring:

- how many times she gets up at night;
- how often she opens the refrigerator or the pantry
- how many times she enters in the bathroom and she uses the toilet
- if, and when, she opens the drawer of medicines
- ...

Key Messages

ENSAFE as a Service promotes independent lifestyle and helps the elderly to stay at home as long as

possible, keeping alive their social relationships. Technological devices are not conceived to replace the human factor or human presence in the elderly life: on the contrary, it gives simple and user-centred instruments to connect people and to avoid isolation, increasing personal safety and security.

Technology will also permit a better and more friendly control of the domestic environment.

Health & Wellbeing tracking and long-term trends detection offered by the ENSAFE sensors and apps will also provide a large amount of data, giving to the elderly and/or to their caregivers the opportunity to detect illness, diseases or needs changes, and to prevent physical and/or cognitive decline.

The ENSAFE app will provide information and suggestions about everyday life and activities (mobility, social relationships, lifestyles) and about health status.

The overall service will answer to a wide-range of needs, and fit a large audience, from the single person living independently at home, to the big caregiving professional organisations.

9 Pricing Strategy

Price elasticity will be fully scoped and testing during the trial and proof of concept stage in late 2016. It is expected that our pricing strategy in England will comprise of a 'unit' cost based upon the number of patients who will use the products and will also be made available as a range of pick and mix packages of levels 1-4, depending upon which level an organisation wishes to 'unlock' for users. Strategies will need to consider existing telecare providers with above 2000 current users (some providing free services and other charging £5.64/week and above). It will also need to consider housing trusts and nursing/residential homes as well as the potential market with retirement villages and extra-care facilities who have already unlocked the "silver pound".

10 Marketing Strategy

Subject to proof of concept testing, the marketing strategy to launch ENSAFE as a service into the UK market will focus upon a business to business promotional strategy to raise awareness of the range of services available as licences for cohorts of patient or citizen groups.

Marketing Aims:

To position ENSAFE as a service as the product of choice for health and care organisations wishing to maximise patient health and wellbeing, whilst minimising variation and care costs.

Awareness raising activities will include:

- Thought leadership events and conference speaking
- Attendance at health and care shows and events such as the Health+ Care Show in London each year
- A strong digital presence including social media promotion, paid for search and promotional website with patient and professional videos

Sales activities will include:

- Creation of a suite of sales materials and marketing collateral
- Demonstrator sites and testimonials
- Sales meetings
- Partnership arrangements to access funding streams.

11 Proof of Concept

The principles outlined in this business plan will move forward for proof of concept testing towards the end of 2016.

In order to have a marketable product, the functionality of ENSAFE system must be absolutely reliable. Even the interface with which the information concerning the behaviour of the end users are returned to the caregivers must be appropriately verified.

Further information about these trials is available as part of Work Package 3

11.1 UK

At present, the following partnerships are being considered with a view to testing the ENSAFE as a service offer directly with end users across product levels. It is expected that approximately 20 patients will take part in the trials. Insights from this testing will help us to validate our business plan and contribute to the project wide evidence base. The identified test locations are:

- Wirral Council (older people's parliament)
- Cheshire Council (Wellbeing)
- Liverpool Council (Riverside)

11.2 ITALY

The pilot experiences for the ENSAFE III and IV, are organized in two rounds, of about 3 months each, involving about 20-25 users in Italy, Sweden, Holland and England.

The first round will involve the development especially the technical issues such as:

- Reliability
- System integration
- Ease of use.

The results of this phase will determine any technical improvements. In the second round activity will be focused on the development of data and the return of information to users

11.3 Netherlands

The Netherlands will start with ENSAFE I and II and expand with both users and technology in ENSAFE III and IV. Insights from this testing will help us to validate our business proposition and contribute to the project wide evidence base. Besides this the pilot will focus on user friendliness and reliability. User input will be used for further development of the ENSAFE system and services.

11.4 Sweden

Sweden will start pilot testing with a group of 6 users in ENSAFE III and IV, in March 2016. The pilot

testing is organized in two rounds, of about 3 months each.

The first round will focus on user friendliness, systems integration, and reliability. Bi-weekly user group meetings will allow us to document the users' experiences, and feed this information back to the development team for further development of the ENSAFE system and services.

The second round of testing will focus on the development of data and the return of information to users.
