

# ENSAFE – Business Plan Italy Appendix

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Date: 18-02-2018  
Revision: V1.3  
Dissemination Level: PUBLIC



*Project Acronym:* ENSAFE  
*Project full title:* Elderly-oriented, Network-based Services Aimed at independent liFE  
*AAL project number:* AAL 2014-1-112  
*With support of:*



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## 1 Introduction

This document provides detail for elements of the business model for ENSAFE in the Italy, it acts as an appendix to the main business plan document. Specifically, this document contains Market Analysis for Italy.

### 1.1 Background

#### 1.1.1 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:

1. low birth-rate and
2. 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%<sup>1</sup>.

#### 1.1.2 Public Spending

The healthcare model in Italy is universal and (almost) completely free, (It is mandatory only a small fee (called Ticket), with large exemptions based on income, age and need for treatment) characterised by the predominance of public spending (In 2016 the public spending has accounted for over 75% of the money spent on healthcare<sup>2</sup>. 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.

#### 1.1.3 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.).

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<sup>1</sup> Source: ISTAT <https://www.istat.it/it/archivio/80494>

<sup>2</sup> <http://www.sanita24.ilsole24ore.com/art/dal-governo/2016-04-08/def-2016-sanita-spesapil-calo-68-65percento-2016-2019-quest-anno-spesa-11337-mld-e-2017-11478-scontando-tagli-e-2015-il-personale-ha-perso-08percento-195324.php?uuid=ACsjh93C>.

Nevertheless, the eHealth offer in Italy is largely insufficient both for quality and quantity. The Politecnico di Milano<sup>3</sup>, 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 elderly 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 Market Analysis

The following sections outlines the results for the Italy Market Analysis.

### 2.1 Market Drivers

Desk research and insight gathered from potential partners across Italy provides us with a strong foundation to build the ENSAFE as a service offer. This PEST analysis is summarised below:

Political	Economic
<ul style="list-style-type: none"> <li>• Policy changes</li> <li>• Political forces</li> <li>• Accreditations</li> <li>• Personalisation</li> <li>• Normalisation</li> <li>• Integration</li> <li>• Early intervention</li> <li>• Increased regulation</li> <li>• Scandals (Winterbourne)</li> <li>• The move from residential models to community models</li> </ul>	<ul style="list-style-type: none"> <li>• Budgetary pressures</li> <li>• Supporting people funding cuts</li> <li>• The macro and micro economy</li> <li>• Wage cost inflation</li> <li>• European funding</li> <li>• Cuts in mental health services</li> </ul>
Social	Technological
<ul style="list-style-type: none"> <li>• Population demographics</li> <li>• Staff</li> <li>• Customer knowledge</li> </ul>	<ul style="list-style-type: none"> <li>• Advances in technology</li> <li>• Big data</li> <li>• The ‘internet of things’</li> </ul>

<sup>3</sup> (Source: <http://www.sanita24.ilsole24ore.com/art/dal-governo/2016-05-04/osseratorio-innovazione-digitale-l-e-health-vale-134-ml-d-ma-passo-e-lento--103853.php?uuid+ADGp0IJ>),

<ul style="list-style-type: none"> <li>• Increasing co-morbidities</li> <li>• Entrepreneurs</li> <li>• Collaborative design</li> </ul>	<ul style="list-style-type: none"> <li>• Inter-operability</li> </ul>
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### 2.1.1 Political & Legal Drivers

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 elderly, 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 8,000 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.

### 2.1.2 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.

### 2.1.3 Economic Factors

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 billion 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 billion 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 million euros/year to the Public Budget, and about 4.9 billion euros/year to

the citizens, without considering time savings (transfers, waiting's) 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%) recommend the use of such technologies, even if the main path to technology in Healthcare 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 development and *soft factors* like information and education of the citizens, without whom any effort will be doomed to fail.

#### 2.1.4 Social Factors

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 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.

### 2.1.5 Conclusions

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).

## 2.2 Market Structure

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:

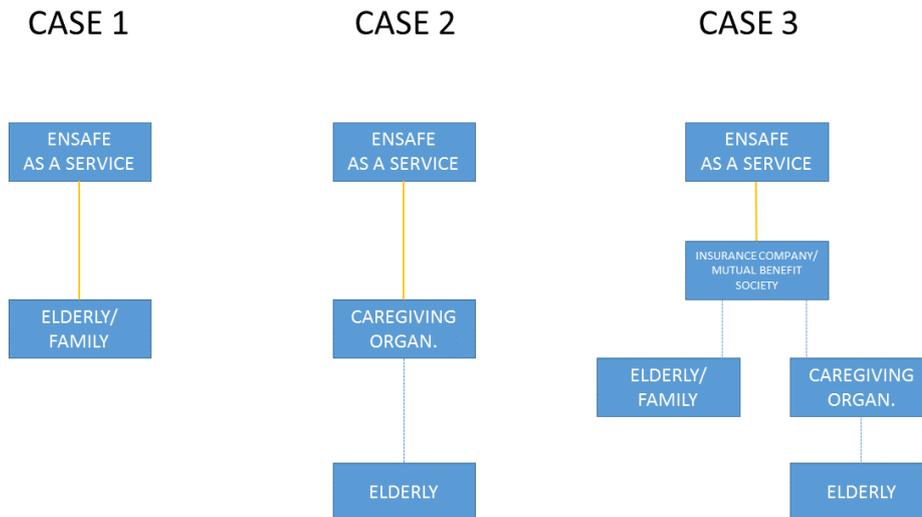
1. The one directed to the **private provider** of the healthcare services (mainly non-profit organisations), to whom it offers an upgrade of the outcomes and an opportunity to rationalize the resource outflow;
2. The one straightly aimed to the **end user** and to his relatives, leveraging the increase 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 play in any case an active role of di 'validator' and guarantor of the offered service.



### 2.3 Competitor Products & Services

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.