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Integrated Network for Completely Assisted Senior citizen's Autonomy

D2.1 Preliminary requirements investigation

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Executive summary

inCASA aims at developing a system that will support the aging population and facilitate them to stay well at their own homes. The inCASA technical platform will thus allow a flexible combination of components and services, for meeting the end-user's needs (independent living sensors, home automation, emergency alert systems, tele-and remote monitoring as well as home security and energy management), with a "check/act" approach.

This deliverable presents the inCASA pilot sites and the preliminary user requirements for the inCASA solution. The targeted inCASA end-user is an elderly person (+65 years) who lives at home alone and/or who suffers from a chronic condition, and who has a sufficient level of autonomy and self-care ability. The five pilot sites that participate in the inCASA project are targeted at the elderly (65+) who deal with either health or social issues, and who may thus benefit from participating in the inCASA pilots. inCASA will employ both telecare and telehealth solutions to meet the aims and objectives of the pilots.

The methodology used to collect the preliminary user requirements from the inCASA pilot sites included a qualitative questionnaire, a user requirement workshop, Skype conferences, and a focused interview with of one of the pilots (at the pilot site) which also aided to provide a structure for the other pilots.

Although the inCASA pilots have different target groups, aims and objectives, and different requests as to what parameter they wish to monitor, it is possible to extract some common requirements. For example, several pilots wish to monitor body weight, heart rate and movement. However, the frequency, data value definitions, alert systems etc. will then be configured to each pilot's and each individual end-user's exact requirement.

Several EU and regional policies, action plans, regulatory and standard requirements are relevant to inCASA and need to be taken into account in designing the inCASA applications in each pilot. This includes ensuring that inCASA technologies and applications will have the necessary security measurements in order to protect privacy and personal data, that the inCASA platform can support interoperability and that the medical devices used comply with safety regulations among other things. These requirements will also feed into the work to be carried out in WP3 Architecture Design.

The preliminarly requirements defined in the current deliverable will consolidated and prioritised in D2.2 Requirements Consolidation and Prioritisation Iteration 1. In addition, the variations in-between the pilot sites and the various regulatory requirements will contribute to the tehcnical work planned for WP3 Architecture Design.

Four out of the five inCASA pilots are described and analysed in this deliverable. A summary of each is provided below. The fifth pilot site, Fundación Hospital de Calahorra (FHC) in Spain has, due to various internal problems, not been able to finally define the clinical focus of the pilot and allocate the necessary resources to start the pilot in the first iteration and is therefore not included in the current deliverable. A further discussion of this issue will follow and the proposed solution will be provided in the next Progress Report.

Agenzia Territoriale per la casa della Provincia di Torino (ATC)
The pilot in Italy, ATC, manages 18.000 flats in the city of Torino. Approximately, 29% of the tenants are over the age of 65. The ATC pilot aims to integrate social housing and social services by employing telecare services enabled by inCASA. ATC is targeted at 20-25 senior citizens over 65 (living alone) who require some form of support.

In the first phase of the pilot, ATC will focus on monitoring behavioural parameters, e.g. movement and contact, and home environment parameters, e.g. gas/water leaks and room temperature. Participants' apartments will be equipped with the appropriate devices in order to establish and an alert system will be set up. The alert system will be based on the predefined User Habits or a Habits Model by first observing the end-user's behaviour for a week. Habit sensors (activity, motion or presence sensors, door and contact sensors) will be used to create a behavioural model for each end-user. Any significant deviations from the Habits Model will release an alert that requires a defined action by a designated person (e.g. case manager or social worker. A deviation that could trigger an alert/action could be that the end-user is not moving for several hours during the day, or is moving around during the night or is not getting out of bed in the morning.

The main objectives include: improving elderly people's quality of life, promote remote health monitoring, implement home automation services and improve relations with neighbours.

Chorleywood Health Centre (CHC)
Chorleywood Health Centre is a medium sized general practice based in an affluent area North West of London. The majority of its 6000 patients are elderly and patient care is well managed. End-users targeted for the pilot are frail elderly patients with chronic conditions, e.g. Chronic Heart Failure, Chronic Obstructive Pulmonary Disease or Dementia.

Each patient will be provided with a monitor in their home that will capture and transmit a number of different physiological measurements on a daily basis, e.g. blood pressure, body weight, blood oxygen saturation level, and habits/movements. The data will be viewed by the clinical team at Chorleywood Health Centre to determine if and when clinical intervention is required; thus an alert system will be configured. The patients will also be provided with environmental sensors that will monitor and capture trend information about the patient's movements while in the home in order to develop an activity template.

The CHC pilot will seek to compare variations the variations in the physiological parameters and in the activity template to identify patterns and to understand if and how environmental monitoring can aid and even predict clinical events and care. CHC's objectives include: improved clinical outcomes, improved quality of life and increased independence, more appropriate clinical interventions, and reduced hospital admissions.

Institut National de la Sante et de la Recherche Medicale (INSERM)
Institut National de la Sante et de la Recherche Medicale (INSERM) has long standing experience in the regulation of tolerability and efficacy of cancer treatments based on circadian rhythm. The pilot will involve elderly cancer patients who are at a stage in the course of their disease where they are not too ill and who are receiving chronomodulated chemotherapy at home.

The pilot will monitor and record the patients' rest-activity circadian rhythm, body weight, activity and self-assessed symptoms. The monitoring of these parameters will help to detect any disruption of circadian activity patterns or other behavioural abnormalities related to treatment toxicities or cancer disease, rapid weight loss resulting from gastrointestinal symptoms related to treatment toxicities or cancer disease, and/or the deterioration of other symptoms related to cancer disease or treatments, such as pain or loss of appetite.

The overall objective of the pilot is to set up a tele-healthcare solution which provides continuous information on the conditions of the elderly cancer patients at home, so as to detect early signs of alterations related to cancer or adverse events of cancer treatments, and to make rapid decisions to improve safety of home delivery of cancer chemotherapy in elderly patients. This early detection/intervention can thus improve safety of complex medical treatments at home and minimize disruptions of familial and social environment of the patient.

Konstantopouleio General Hospital of Nea Ionia (KGHNI)
KGHNI is a University Hospital in Greece that offers almost all medical specialties; the Department of Cardiology of KGHNI is participating inCASA. The KGHNI Pilot will address its services to elderly people that live alone and who mainly suffer from CHF. Also, concomitant problems will be a common factor for the target group. Concomitant problems include hypertension, diabetes mellitus, atrial fibrillation and other arrhythmias.

The following medical parameters will be monitored: blood pressure, heart rate, heart rhythm, blood glucose, partial prothrombin time[1] (INR), body weight, blood oxygen saturation level and movement. By monitoring these parameters KGHNI will be able to have a close follow-up of the patients, estimate the efficacy and safety of the medical treatment, make the appropriate regulation of the medication dose, detect acute changes in the patient's situation, and instigate early treatment of acute problems with either clinical or social means. In addition, KGHNI will install a video conference system to allow for visual communication between patient and doctor.

KGHNI's objectives include: improve the medical compliance of patients, improve medical therapy, increase quality of life for patients, reduce the need for re-hospitalisation and improve quality and cost effectiveness of delivered healthcare services.

[1] INR measurements are used to determine the clotting tendency of blood.

1 Introduction

The inCASA project aims to help elderly people to stay at home longer and to better monitor their chronic condition. This aim will be achieved by using state of the art Information and Communication Technologies (ICT). inCASA will enable the monitoring of end-users' health and behavioural parameters, as well as the collection and transmission of these data, in order to implement customized intelligent multilevel alerts/communication services.

Data will be made available to care services through a Smart Personal Platform with an embedded Behaviour Analysis Application which will include: access policies to preserve privacy; planning for day-by-day activities and therapies with multiple alerts; co-ordination of local public Social and Health Care Services; and help to deploy specialist community based services. The specification of end-user requirements is a complex but important endeavour. Meeting the end-user requirements is key for the project's success.

As the title suggest, this deliverable is concerned with investigating the preliminary requirements. The focus is particularly on the inCASA pilot sites' requirements, i.e. on each pilot site's specific needs and requirements to meet their individual aim and objectives. The pilots' aims and objectives are obviously closely related to the end-users' (i.e. the elderly) as the different pilots each seek to assist and support their target group by meeting their particular care and health needs. As such, the pilot sites already have an acute awareness and knowledge of their target group's needs.

Being aimed at elderly people, it is necessary to have a basic understanding of who the elderly are and the social and cultural meaning attached to this label. Age and ageing have social and cultural meanings and values, and when intercepted with ICT these meanings and values take on a specific shape. Thus, as a user-group, the elderly have specific needs, requirements, desires, capabilities and abilities in relation to ICT. The starting point always ought to be to adjust ICT to fit the elderly's needs etc. rather than the other way around.

Assistive and health care technologies and services, as those offered by inCASA, can be very beneficial to the elderly; monitoring chronic conditions at home thus providing better and more convenient care, providing new and easy ways of being socially connected, or offering remote control of electronic devices in the home.

This deliverable draws heavily on input from the individual pilot sites who have clearly defined aims and objectives for the services and care they provide for their end-users. With these aims and objectives in mind, the pilot sites have defined who their targeted end-users are and grouped these according to problem (e.g. health condition, loneliness, safety at home issues). The pilot sites have also defined which clinical and behavioural parameters they wish to monitor and use cases describing the anticipated scenarios.

The possibilities are vast but offering a service that the end-user does not feel the need for, cannot see any benefits in, or does not understand (learn) how to use has a great risk of rejection. The inCASA pilots have therefore carefully described and analysed their end-users' profiles in order to elicit their preliminary user requirements.

Four out of the five inCASA pilots are described and analysed in this deliverable. The fifth pilot site, Fundación Hospital de Calahorra (FHC) in Spain has, due to various internal problems, not been able to define the clinical focus of the pilot and allocate the necessary resources to start the pilot in the first iteration and is therefore not included in the current deliverable. A further discussion of this issue will follow and the proposed solution will be provided in the next Progress Report.

1.1 Purpose and content of this deliverable

The main purpose of this deliverable is to present each pilot site's end-user requirements by describing the end-users profile, including the problem(s) end-users have that may be helped by the inCASA project. As such, the current deliverable also presents the preliminary parameters that pilots wish to monitor, use case scenarios and the available/current infrastructure, thus providing the inCASA technical partners with a preliminary basic framework for providing the best possible technological solution, namely the integration of healthcare and social care services through one ICT solution. This work will be carried out in WP3. The preliminary requirements investigated here will be consolidated and prioritised in D2.2 Requirements Consolidation and Prioritisation Iteration 1.

Seeing that the inCASA target end-user is an elderly person, the current deliverable will begin by placing end-user requirements in their proper context, i.e. in relation to elderly people. It is important to be aware of some of the main issues regarding elderly people and ICT; elderly people as a group have different needs and requirements than say adolescents as a group. Obviously, we do not here intend to suggest that elderly people (or adolescents) constitute a homogenous group, but rather to point out that age is an important factor that should not be ignored when defining user requirements.

1.2 Methodology

The methodology used to collect the preliminary user requirements from the inCASA pilot sites included a qualitative questionnaire (referred to as the Pilot Instruction Sheet), which asked each pilot to compile information, e.g. describe the social and medical background, their target group, aims, objectives and challenges and the parameters they wish to monitor. Each pilot was also asked to provide a detailed description of the services that they wanted to install and the clinical and medical rationale for these services.

As it transpired that collecting the information was more complex than anticipated, a user requirement workshop was subsequently organised in Italy. The workshop gave all project partners a chance to discuss their objectives, wishes and needs for the project and was useful for gaining a better understanding of the pilots' requirements in particular. The information gathered has been used as input for this deliverable and some will also be used for deliverable D2.2 Requirements consolidation and prioritisation iteration 1.

Moreover, INJET and REPLY visited the Greek pilot (KGHNI) in order to discuss their objectives and user requirements from a clinical and medical perspective as a model framework for other pilots. Another aim for doing so was to structure the user requirements for the different pilots in a similar fashion in order to facilitate the subsequent consolidation and prioritisation in *D2.2 Requirements consolidation and prioritisation iteration 1*. Both clinical and technical staff from KGHNI and NTUA partners participated. Together, the pilot's objectives, parameters and use cases were defined. The focused discussion and interviews with the Greek pilot proved very useful. However, within the given timeframe it has only been possible to visit Greek pilot sites so far, but future visits and interviews are planned for the other pilots at a later stage in the project. This will be part of the second iteration of user requirements planned for the second year of the project.

Finally, we have been in continuous contact (via email and Skype) with the pilot sites in order to clarify any questions about the information and input from them.

1.3 Outline of this deliverable

Chapter Two will situate healthcare and assistive/social care ICT in their proper context in relation to the inCASA project; namely in relation to elderly end-users. To do so, a brief analysis of age and

ageing in relation to ICT and a description of main healthcare and assistive technologies for the elderly is presented. The concepts of telecare and telehealth are also explained. Finally, this is placed in relation to the elderly and their special needs and issues.

Chapters Three to Six present the inCASA pilot sites, their aims and objectives, and their end-user profiles. This chapter builds on information provided by the pilot sites.

Chapter Seven gives an overview of relevant policy, regulatory and standards requirement on EU level.

Chapter Eight gives a summery, including a table of the parameters the pilots wish to monitor.

2 Elderly users and ICT

The inCASA project will bring elderly people in to close contact with innovative information and communication technologies (ICT) and this is an issue which has generated a lot of interesting research in very recent years. In the light of the *e*-inclusion debate and initiatives, such as the Riga Declaration [1], Aging well in the Information Society [2] and i2010 [3] (to name but a few), it is important to understand some of the issues that may hinder a fruitful "relationship" between elderly citizens and ICT.

The development of ICT and the increasing digitalisation of our societies have meant that ICT skills, or lack thereof, have become a type of signifier of age. In other words, individual purpose, needs and skills in relation to ICT is often age-determined.

In this chapter, a brief discussion on age and ageing is first presented which will place these notions in a more theoretical framework, thereby demonstrating that being classified as an elderly person has a social and cultural meaning. Also, as when analysing end-user requirements, it is important to be aware of how age and ageing is embedded in specific cultural and social contexts, rather than being a question of simple chronological or biological age. To really understand and accommodate the end-user's needs and requirements it is important to have an understanding of where the end-user is coming from, i.e. the socio-economic, cultural and health context.

Next, the overall demographic situation in Europe and how ICT may provide some of the answers as to how Europe is going to accommodate to its ageing population is described, followed by a summary of the main features of the inCASA solution. Finally, keeping notions of age and ageing and the possibilities of assistive and healthcare ICT in mind, a short description of elderly users' needs and requirements will be presented.

2.1 Age and ageing

The lives of elderly people, today as well as a hundred years ago, are affected by the attitude or mentality of a given society towards what is 'old'. Ageing is more than simply a biological process. In other words, it is not a simple matter of defining what is old, or who is old, in terms of chronological age. Ageing is embedded with social and cultural values, and as such the meaning of ageing is affected by social changes and developments.

The scientific study of age – Gerontology – studies the social, psychological and biological aspects of ageing. Among other things, it includes the investigation of the physical, mental and social changes in people as they age, the ageing process itself (bio-gerontology), and the effects of our ageing population on society, including the economic effects of pensions, entitlements, life and health insurance, and retirement planning.

Theories of ageing have often focused on varying notions of 'adjustment'. Disengagement theory argues that, as a natural consequence of ageing, senior citizens wish to withdraw from society and thus become disengaged. The theory assumes that all senior citizens wish to withdraw and it neglects to consider the social structures that force (directly or indirectly) seniors to disengage, e.g., obligatory retirement. In contrast, engagement theory argues that it is crucial to secure continued engagement with society through the replacement of lost roles (work, looking after children) if senior citizens are to be well-adjusted and age optimally. More recently, theories of ageing have focused on participation in social networks as key to ensure continued well-adjustment and engagement in society.

Both theories have a specific gender perspective, where activity has different meanings for men and women. Male activity was associated with work, whereas female activity was associated with

the family. Consequently, their roles were likewise associated with these two different realms and loss of these roles was caused by retirement for men and changes in family situation (the 'empty nest') for women.

Whereas disengagement theory sees retirement and change in family structure as positive, activity theory argues that it is essential to replace the lost roles, thus maintaining a level of activity for older people who would then adjust and age more positively. Roles would not simply disappear but rather change as one became older. Older people who are engaged in productive activities and have social networks are less likely to be depressed than those who are not engaged [4].

It is important here to consider the notion of roles further. The problem with senior citizens' loss or change of roles is the social status and value attached to work, i.e., to monetary productivity. Retirement as opposed to work suggests non-productivity. In order to counter this negative view of ageing, we may use the term 'productive ageing' to emphasise the importance of non-monetary contributions to society, e.g., voluntary work and independent living. Notably, living independently is considered productive in the sense that it relieves family and/or society from providing care and from giving support.[2]

It is in this context – living independently – that ICT can be of great benefit for both the individual and society as a whole. However, one needs to be acutely aware that elderly people have specific needs, skills, capabilities and desires in relation to ICT. This will be discussed further below (section 2.3). First, a brief look at who are the elderly in Europe today and what does the future look like?

2.1.1 Europe is ageing

Europe is ageing and it is predicted that by 2020, 25 per cent of the EU's population will be over 60 [5]. This demographic development will have serious social and economic impacts on Member States, in particular, on healthcare and the workforce. The growth of the population aged 80 or more will be even more pronounced in the future as more people are expected to survive to higher ages. The proportion of very old people (aged 80 and more) is expected to almost triple in the EU-27, from 4% in 2005 to 11% in 2050, with the highest proportions expected in Italy, Germany and Spain. It is worth noting that the population aged 55 to 64 will also grow considerably over the next fifteen years.

Demographic ageing may generate a high number of situations in which the caring needs of older persons are unmet [6]. Up to two-thirds of people over 75 are today dependent on informal care, which is mostly provided by the immediate family, especially women. Today, however, many elderly persons (28% of the population over 70) live alone. Financial means also vary. In Europe the risk of poverty is higher among older people[3], with elderly women particularly exposed to low pensions as a result of incomplete careers. Family structures are also changing; marital break ups, single parenthood, weakening bonds of extended family, shifting work/life balance and care responsibilities, and higher risk of unstable employment all have an influence of these structures.

2 Robert N. Butler, the first director of the National Institute of Ageing in the US, coined the term 'productive ageing' in order to emphasise that productivity and ageing are not contradictory. Living independently is considered productive in the sense that it relieves family and/or society of care-giving and/or support. See Butler, Robert N., The Longevity Revolution: The Benefits and Challenges of Living a Long Life, Public Affairs Press, New York, 2008.

3 'Elderly people also face a higher risk of poverty than the total population. In 2008, the at-risk-of-poverty rate for those aged 65 years and over was 19% in the EU27. The highest rates were observed in Latvia (51%), Cyprus (49%), Estonia (39%) and Bulgaria (34%), and the lowest in Hungary (4%), Luxembourg (5%) and the Czech Republic (7%).' Eurostat, Living conditions in 2008, Brussels, 18 January 2010. It should be noted that the 'at-risk-of-poverty rate' is a relative measure of poverty, and that the poverty threshold varies greatly between Member States.

These conditions affect millions of middle age Europeans today and may become source of social exclusion in few years time.

Overall, ICT are considered as key to the ageing challenge; assistive technologies may help seniors and people with health problems to remain independent and at home, thus providing a tool for enhancing the quality of life as well as for controlling spiralling healthcare costs and making up for the shortage of healthcare personnel.

2.2 Assistive and health care technologies

The future diffusion and widespread use of innovative, context-aware services based on ubiquitous communication and massively distributed networks is very well demonstrated in different EU funded initiative, which have turned into a specific inter-linked programmes promoted by the European Commission programs, such as Ambient Assisted Living (AAL), Competitiveness and Innovation Program (CIP)

The action plan of the CIP-ICT objective “ICT for ageing well/independent living” as well as AAL programme is to enhance the quality of life of older people and strengthen the industrial base in Europe through the use of information and communication technologies (ICT).

The motivation for those new activities is in the demographic change and ageing in Europe, which implies not only challenges but also opportunities for the citizens, the social and healthcare systems as well as industry and the European market. The aim is to:

- extend the time people can live in their preferred environment by increasing their autonomy, self-confidence and mobility,
- support maintaining health and functional capability of senior citizens,
- promote a better and healthier lifestyle for individuals at risk,
- enhance the security, prevent social isolation and support the multifunctional network around the individual,
- support carers, families and care organisations, and
- increase the efficiency and productivity of used resources in the ageing societies.

The idea is release innovative products, services and systems for ageing well at home, in the community and at work, thus improving the quality of life, autonomy, participation in social life, skills and employability of senior citizens and people with disabilities, all of which should contribute to a reduction in the costs of health and social care.

The deployment of services for ageing well will be critically dependent on a coherent European framework for developing common approaches, including common minimal standards, and facilitating the localisation and adaptation of common solutions which are compatible with varying social and ethical preferences and regulatory aspects at national or regional levels across Europe.

In order to describe assistive and health care technologies already available on the market, it is necessary to first define the range of products and initiatives that suit ageing well requirements. Up to now, there is no common definition of ICT-enabled ageing well products for elderly people. The term AAL or comparable expressions are today used in the research community, but they are neither established in the corresponding market nor for the communication with the customers. Therefore, it happens that products, systems or services may be designed for elderly people, but are not explicitly declared as such.

A classification problem arises from the differentiation between the system parts and the integrated solution. ICT products for elderly people very often integrate a wide range of technologies, comprising e.g. sensor technology, internet technology, innovative computer interfaces, bus

systems and control systems. Although several different technical components often are part of assistive and health care products or systems, these components have not particularly been developed for ageing well solutions.

Recent technological developments in the field of e-health allow elderly people with chronic diseases or certain impairments to be treated and monitored within their domestic environment. The great advantage of tele-monitoring applications is that the patients do not have to move to a medical institution to be monitored and treated appropriately. Information on vital parameters can be taken from the patient by (portable) devices and transmitted to medical institutions in order to control them and to interfere if necessary. Overall, e-health solutions and tele-monitoring products guarantee more autonomy for elderly patients.

Although a market for ICT-enabled products and services for elderly people is only just emerging, some ICT products for the independent living of elderly are already available in Europe.

From a preliminary analysis of the state of the art of European initiatives, including ICT products with a registered patents and European funded projects, it results that several institutions, Universities, public bodies are making many efforts for improving life quality of elderly people, however there does not exist yet one initiative taking into account all possible aspects, problems and target user needs. The inCASA goal is to integrate and reuse pre-existing solutions/services for human/environment monitoring, in order to collect and analyze data to profile user habits and implement customized intelligent multilevel alerts/communication services. The main project purpose is then applying ICT for improving elderly life quality.

A brief overview of the state of the art follows:

Assistive and health care ICT-based patents

The proposed patented ideas deal with some specific aspects of ICT applications to e-health, particularly they can be implemented in assisting elderly people, but they are not comprehensive of all technical aspects, social and medical needs, that are tackled in the inCASA project.

A method for controlling and monitoring process flow and tele-medicine service using data processing devices has been realized by SIEMENS AG and patented on 2002 (Publication number: EP1267297 - A2)[4]. It is named *Method for controlling and monitoring the process flow to determine the performance of a telemedicine healthcare service.* It includes a data processing device that furnishes at least one part service from its health service provision service. The central data processing device monitors the process to ensure the part service is provided within a given time and fulfils qualitative requirements.

Another monitoring idea is named *Method for monitoring telemedicine healthcare services* (Christ Tilo [DE]; Prihoda Heinz[DE]; Schmidt Volker [DE]; Schneider Siegfreid [DE]; Schull Hans-Dieter [DE]; Striebel Werner [DE]; Zahlmann Gudrun [DE])[5], and patented on 2004 with code US2004153340 (A1). This invention proposes a method for automated monitoring of the service quality, by recording and/or evaluating medical data sets as part of a telemedicine healthcare service. The number of medical data sets received and/or evaluated by the person and/or the data characterizing the quality of the recordings and/or evaluation is/are compared with predetermined data and the service quantity and/or service quality of person receiving and/or evaluating the data is calculated.

[4] http://www.wikipatents.com/CA-Patent-2390135/method-for-controlling-and-monitoring-the-process-sequence-of-a

[5] http://www.wipo.int/pctdb/en/wo.jsp?WO=2002101667

A framework named *Apparatus and system of Internet-enabled wireless medical sensor scale,* proposed by Chen Thomas [US] and Chen Connie [US], patented on 2007 with code US2007010721 (A1)[6], proposes a system, internet enabled, for communicating with personal health and medical care monitoring systems through wireless communication network and Internet connection. It includes a plurality of Wireless Medical Sensor Scale apparatus that can be placed in any location where a wireless communication network is reachable and a system including microcontroller, system memory, LCD display for processing vital sign related data, and a plurality of active health sensing substrate for sensing substance from human body. Moreover, a Web-based Personal Health Monitoring System and a Web-based Medical Care Monitoring System for communicating with personal health and medical care monitoring systems through wireless communication network and Internet connection.

Assistive and health care ICT-based EU projects

HomeSweetHome[7] (Health Monitoring and Social Integration Environment for Supporting Wide Extension of Independent Life at Home) is a running Pilot B project funded under the EU CIP-PSP programme, started on 2010. Its aims are improving quality of life of elderly people by extending their independent life (if they wish so) while providing a level of safety equivalent or better than that enjoyed in elderly homes; breaking the isolation of elderly people living alone, through an intuitive videoconferencing system which is based on the familiar combination of a TV set and of an infrared remote control. The project involves 18 European partners, including 4 pilot sites and 105 end users.

The *HEARCOM*[8] project (Hearing in the communication society) aims at reducing limitations in auditory communication of people who suffer from a hearing impairment in order to allow them to keep on being a member in a communication society. Although this project is not explicitly related to elderly people, it has been integrated into the AAL project list because hearing impairment is a typical disease of elderly people.

The project consists of 30 partners from 13 nations. The project consortium integrates various scientific disciplines in the fields of audiology, acoustics, speech technology and ICT.

HEARCOM had a total project time of five years (2004 - 2009) and had been carried out within the scope of the e-Inclusion segment of the IST priority of FP6.

Western world cardio-vascular diseases (CVD) are the main cause of death today. The main objective of the project *MyHeart*[9] is to support citizens in preventing cardio-vascular diseases by an appropriate lifestyle and an early diagnosis. The approach is to integrate system solutions into functional clothes with integrated textile sensors (“biomedical clothes”). The process consists of performing diagnoses, detecting trends and reacting to them. Together with professional services, the biomedical clothes create the MyHeart system, which will help citizens to fight major CVD risk factors and to avoid heart attacks.

The MyHeart consortium is very interdisciplinary: it brings together 33 partners from 11 countries, ranging from (textile) industry, research, academics and medical hospitals. The consortium thus covers the whole value chain from textile research to fashion and electronic designers and is strongly user-oriented.

[6] http://www.freepatentsonline.com/y2007/0010721.html
[7] http://www.homesweethome-project.be/Home-Sweet-Home/Publicatiekanalen/Overig/Home-Sweet-Home/Website-Home-Sweet-Home/Home-Sweet-Home-Hoofdnavigatie/General-information.html
[8] http://hearcom.eu/main.html
[9] http://www.hitech-projects.com/euprojects/myheart/

SOPRANO (Service-oriented programmable smart environments for older Europeans) is an integrated project under the European Commission's 6th Framework Programme (i.e. IST Priority 6th Call on Ambient Assisted Living -AAL). Its purpose is to develop a home environment to support assistive technology by "unobtrusive components seamlessly linked to external service provision". The platform is developed through a service-oriented architecture (SOA). The main objective of SOPRANO is the development of "affordable, smart ICT-based assisted living services with interfaces which are easy to use for older people…" Thus, the project also tackles the problem of how to convince elderly people to accept technology-based monitoring systems. The SOPRANO consortium consists of 25 partners, including various organisation types ranging from SMEs to multinational companies as well as public and non-profit organisations.

The aim of the *REACTION*[10] project is to develop an integrated ICT platform that supports improved long term management of diabetes based on wearable, continuous blood glucose monitoring sensors and automated closed-loop delivery of insulin. The REACTION platform will present an interoperable peer-to-peer communication platform based on Service Oriented Architecture (SoA) using cloud-enabling midddleware. It will feature a Model Driven Application Development environment based on extensive use of dynamic ontologies. The REACTION platform will provide integrated, professional, management and therapy services to diabetes patients in different healthcare regimes across Europe, including 1) professional decision support for in-hospital environments, 2) safety monitoring for dosage and compliance, 3) long term management of outpatients in clinical schemes, 4) care of acute diabetic conditions and 5) support for self management and life-style changes for diabetic patients.

The above (non exhaustive) list of EU projects highlights that most of the EU initiatives introduce technologies able to handle particular aspects of assistive and health care needs.

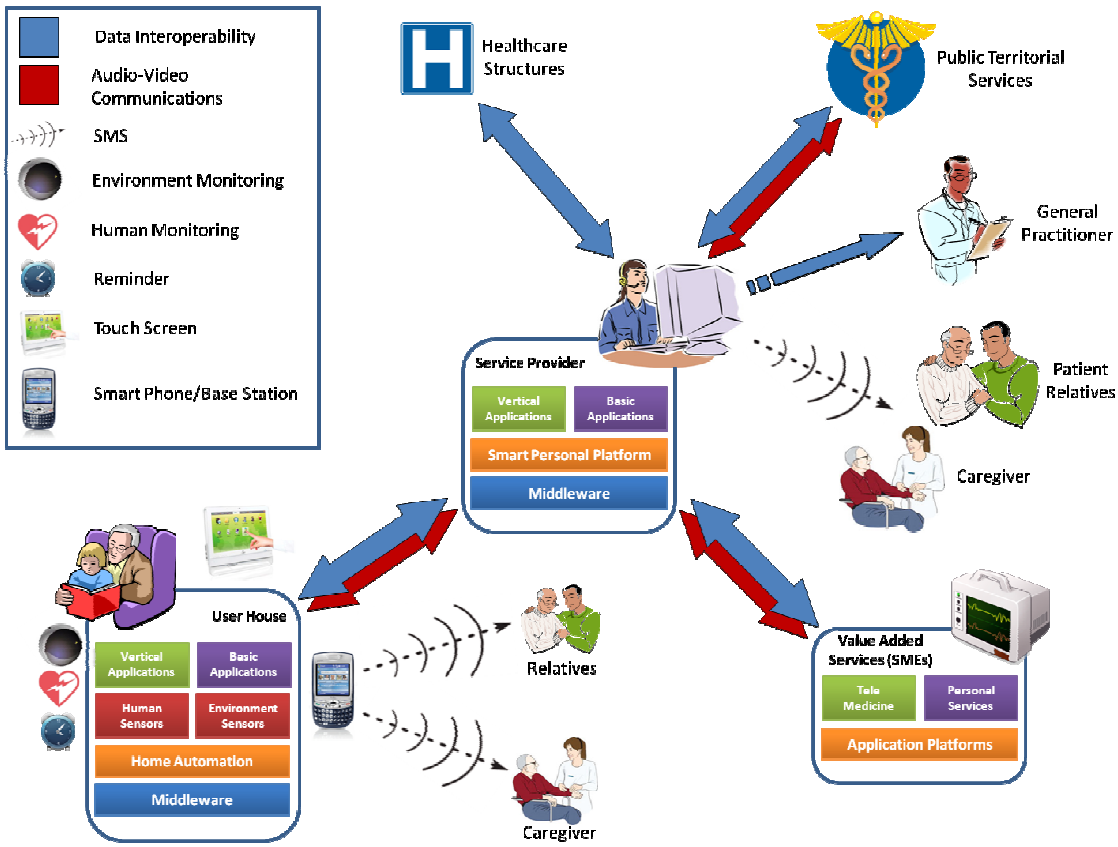
2.2.1 The inCASA Solution

inCASA aims at developing a system that will support the aging population and facilitate them to stay well at their own homes, by mean of these specific objective:

- Providing elderly people with means to profile their habits, while they are at home,
- Providing elderly people (and patients with special needs) with means to monitor their health conditions outside traditional healthcare environments,
- Providing doctors and health professionals with more comprehensive monitoring data for understanding remote user's social/physical conditions and diagnostics.
- Enabling continuity of care through a wider interaction between elderly people and caretakers, especially including not just health specialists but also relatives or people who has close social relations with the user;
- Integrating home automation in a system permitting remote control of electronic devices in the immediate surroundings.

In order to reach the described goals, inCASA proposed solution will be based on a complete set of common specifications for technology and services agreed by the whole actors' value chain. The technical platform will allow a flexible combination of components and services, for meeting the end-user's needs (independent living sensors, home automation, emergency alert systems, tele- and remote monitoring as well as home security and energy management), with a "check/act" approach. Medical device and mobile handset manufacturers are investing in e-health direction and associated services. The following picture summarizes "at a Glance" the inCASA Solution:

[10] http://www.reaction-project.eu



The inCASA architecture allows a wide-range of applications in home-assistance (not only on Health care area), including a great variety of targets (e.g. private houses, schools, social housing, etc.), and using it as a full-size solution, vice versa as few-components implementation, thanks to its scalability and modularity.

The proposed application will monitor biometric data and track environment parameters of elderly users in their own home, integrating collected related data into a new lifestyle model. The solution will also integrate social and healthcare Territorial Services available through local authorities (via a Service Provider).

2.2.2 Telecare and Telehealth

As described above, inCASA will enable a variety of applications to support the elderly person at home. As such, inCASA pilots offer both telecare and telehealth applications and services. The distinction between telecare and telehealth is often a bit vague and we will therefore briefly describe here how we define the two below.

Telecare

Overall, the main objective of telecare is to allow people to live independently in their own home for as long as possible. As such, telecare can reinforce or improve existing social care services or implement completely new social care service. Telecare refers to non-medical remote monitoring services installed in people's homes, such as fall sensors, behaviour patterns (movement) and environmental monitoring (e.g. gas leaks or fires). It includes an alert or alarm service if the defined monitoring parameters are abnormal. Telecare thus aims to respond to instant and real-time needs but also has a real value in providing preventative care, e.g. through the monitoring of a person's lifestyle so as to detect any deterioration of the person' health or well-being. The application and services must be personalised to fit the individual's particular needs.

Telehealth
Telehealth is here seen as form of telecare which focuses on medical or clinical aspect of remote monitoring. It covers the remote monitoring of physiological data or vital signs, e.g. temperature and blood pressure that can be used by health professionals for diagnosis or disease management. Telehealth is thus a compliment to health care and is particular useful for improved management of chronic diseases. The clinicians will define medical parameters for the individual and thereby monitor the individual's health status; if the individual's vital sign moves outside the normal parameter it will trigger a response.

2.3 Elderly users' needs and requirements

As a group, elderly people are at great risks of exclusion in the digital society. Elderly people are generally less familiar with communication and information technologies and may have less access to computers and the Internet. They are thus at risk of e-exclusion. Implementing telecare and telehealth technologies aimed at the elderly therefore face a particular challenge; the elderly's lack of experience and confidence with assistive technologies may be a barrier for their use and as a result the elderly may be excluded from the advantages and benefits of telecare and telehealth services. It is therefore crucial to consider the elderly users' specific needs and requirements when developing and designing these services and applications.

When talking about elderly users' special needs and requirements in relation to ICT, we are here not only talking about specific elderly user-friendly interfaces and devices (e.g. large buttons on devices, big letters on screens) or easy and simple to follow commands/instructions. We are here also concerned with some of elderly users' special needs and requirements in relation to how ICT can be of assistance to improve the quality of life. This may be in the form of improved monitoring of a health problem, home automation possibilities, and/or of providing new ways to connect socially with others. In this sense, it can be very useful to focus on the elderly's fears and concerns when trying to define their needs; e.g. fear of falling can be translated into a need for monitoring movement in the user's home.

Existing research show that in general, elderly people's expectations of ICT depend on the personal benefits (e.g. in relation to health, social contact, alarm services etc.) they can immediately see. This of course also depends on the specific technology in question and its purpose. In general, older people generally perceive ICT (e.g. in the form of smart home technologies, AAL products, and/or assistive and healthcare technologies) as useful and helpful. For example, ICT can provide people with dementia social memory aids to remember faces or with continence reminders to avoid accidents thus encouraging self-confidence. It is, however, important to be aware that technologies assisting with basic skills may also produce dependencies and de-skilling. People with dementia should not have to use technology when they can manage without it. Assistive technology should be designed so that it allows people to perform without it when they are able to do so.

Assistive and healthcare technologies for senior citizens often raise some complex, and often conflicting, questions. A balance needs to be struck between the perceived pros and cons of monitoring technologies, which should be situated in their proper context. For example, this means taking into account of where the person lives (in an urban or rural area) and his/her social and family situation, as these factors will undoubtedly affect how the person perceives the pros and cons of monitoring, assistive and healthcare technologies, e.g. in relation to security and assurance, user control and severity of consequences. Acceptability takes on a specific meaning for a healthy widow who lives in a rural area with a large but distant social and family network, and another meaning for the disabled elderly couple who live in an urban area with a small but nearby social and family network.

Another issue is the question of intrusion versus ambience. Some technologies that are installed in the home are often intrusive simply by their design (disrupting the home aesthetic), which may lead some people to reject the technology despite their need for it. On the other hand, if technologies become too ambient and invisible they may cause confusion. For example, a disembodied voice giving instructions, particularly to someone with dementia, can cause great confusion and anxiety.

Successful ageing is not simply a question of physical health but depends also on the psychological health. For many seniors, this means staying active and engaged in society. ICT can support continued social engagement by providing access to new types of personal and social networks (e-mail, virtual communities, etc.), and healthcare and assistive ICT can support an independent lifestyle.

Often, the ICT that enable seniors to live independently at home are sometimes thought to foster isolation by replacing human-to-human contact with ICT. It is important to move away from this either/or viewpoint and instead see ICT as a support not a replacement, whether as a support to stay at home or (re)or as stimulating social networks. Intelligent technologies should be designed to empower and suggest rather than to police or replace. To achieve this end, it is crucial to consult with the elderly end-user to find out what his/her particular needs and requirements, as well as fears and concerns, are and together define the best ICT solution available.

2.3.1 The inCASA elderly user

The target group for inCASA is elderly people who would benefit from telecare and/or telehealth applications enabled by the inCASA platform. This elderly user is typically someone who suffers from a chronic disease such as diabetes, chronic heart failure, chronic obstructive pulmonary disease, cancer or hypertension and/or someone who suffers from loneliness or is in need of practical assistance in the home (home automation technologies) in order to increase their home safety and autonomy.

As a group these users are at risk of e-exclusion based on their age; their IT skills and experiences are typically lower than average. Living alone and being on a low income (which also described the typical inCASA end-user) have also been found to be a factor for e-exclusion [7]. To overcome the risks of e-exclusion, inCASA is dedicated to develop services and applications that meet the end-users' needs by using accessible design and interfaces and by developing the services through testing at the pilot sites. There are thus three iteration steps which allow for a continued evaluation, prioritisation and modification of the inCASA services to meet the users' requirements as best as possible.

Supporting an independent lifestyle including better management of chronic diseases can effectively support the social inclusion of the target group. The pilot sites foresee that by allowing the end-user to establish easy access to either their health- or social care provider, i.e. via email or text services or simply by knowing that their health status and/or safety at home are being monitored, the elderly user will feel less isolated. Existing research has demonstrated that feeling isolated or socially excluded may affect negatively the effect and process of ageing; successful ageing is not simply a question of physical health but depends also on the psychological health. For many seniors, this means staying active and engaged in society and living at home independently [8].

3 Agenzia Territoriale per la casa della Provincia di Torino (ATC), Italy

More than 14.000 people over the age of 70 are currently living the flats that ATC is responsible for. Approximately, 5.000 people live alone. As the number of elderly people is increasing the demand for social housing is subsequently growing. In the next 10 years, it is estimated that the demand for assistance of the elderly people in social housing will rise up to around 36%. ATC plan to increase our focus on linking housing assistance programs to support tenants over 70 in order to give them the opportunity to maintain independence in their flats where they are living.

ATC manages 18.000 flats in Turin. Approximately 39.300 people live in flats, with 11.233 of these over the age of 65 (of which 3069 are over the age of 80).

Figures from December 2009 show that 910.504 elderly people live in Turin of which 79.609 live in District 1 (Centro – Crocetta). In percentage, this means that 24.5% of elderly people (over 65) live in Turin, with 30% living in District 1. Looking at how many elderly people live alone the figures in percentage are:

- Age 65-74: 33.5%
- Age 75-84: 44.8%
- Age 85+ : 61.7%

By working in partnership with public authorities, private and voluntary sectors, public housing authorities and housing agencies, ATC can improve the quality of life for tenants by offering housing and services adapted to their needs.

The main tools that ATC has available include:

- Social master plans and governance white papers
- Policies for elderly people
- Policies for social inclusion of foreigners
- Promotion of urban regeneration
- Moderation of neighbourhood disputes
- Mixing social housing, affordable and private tenancy
- Policies to improve social security in our district (with country police).

3.1 Medical and social background for the pilot

Italy is one of the “oldest” countries in the world, with a high percentage of elderly people in its population: indeed, it is estimated that 1 out of 3 families have an elderly person (over 65) within their household [9]. The ageing of the population has caused a significant increase in the demand for care services. In 2004, the number of families in need of care and assistance services for the elderly and for children amounted to 950.000, as public services are not able to meet their needs. The Italian care service system is based on a mix of public and private supply and on vast assistance work performed by the families themselves. Medical and social care is developed at regional level.

The mission of the public social housing system is not to provide social assistance, even if the mission is strictly a social one. Rather, the public social housing system plays an important role in the localization and “geo-differentiation” of social services. The area surrounding a property should work as a link to the rest of the community. Parking spaces and rubbish disposals are examples of things that should be present within this area, i.e. close to the property. In addition, parks, communal gardens with meeting facilities, and places that provide a platform for social activities

should also be present. Other important aspects are feeling safe and secure, closeness to (public) transport, and access to other public services such as, shops, restaurants, health care and a pharmacy.

Quite often older people live by themselves and do not have immediate family close by to help them. The housing companies have an important role in providing this service, but also in working with other organizations, both in the private and public sector. In addition, consideration should always be made as to who provides the best service for each occasion. The current cooperation between the different stakeholders is very important and will continue to be so in the future.

The main task of the public housing authorities is to provide accommodation, respecting three main issues:

- Social mix; i.e. to avoid creating of “ghettoes” for elderly people
- Reversibility of the intervention
- Economical sustainability.

The management of social housing estates is dealt through development of integrated policies discussed directly with the stakeholders:

- social providers and health care authorities
- networks of charity work
- networks of social associations and welfare co-operation agencies.

On 15th of April 2009, the ATC-board deliberated new orders to improve elderly (and disabled) tenants’ living conditions; item 4 is of particular relevance to the inCASA project:

1) ATC shall develop clear guidelines for best practice design of social housing to improve suitability of housing to meet the needs of elderly people.
2) ATC shall Training suitable employees by organizing courses where it is explain the proper manner to have relation with elderly tenants (communication and social accompaniment)
3) ATC shall focus on maintenance of existing and design of new buildings oriented to consider the needs of ageing and disabled tenants (architectural barrier)
4) ATC shall focus on technological choices to be oriented on simple and user friendly devices, suitable for ageing people (home automation)
5) ATC shall improve co- ordination between the Department of Housing and other Local Authorities (Welfare and Health Services Departments) to monitor constantly the needs of elderly tenants.
6) ATC shall explore partnership with other organizations in order to provide social housing in conjunction with facilities of support for the elderly (home services)
7) ATC shall provide flexible services such as for 24 hour call service to resolve urgent maintenance issues.

3.2 Objectives of the pilot

One of the objectives is to integrate social housing and social services by employing telecare services enabled by inCASA. The main part of this task has to be developed in cooperation with the offices of the Municipality of Torino which is the main authority responsible of the Social Services District 1.

Objectives include:

- improve a new model of local welfare (issues integration of social services, health

services and social housing)
- improve quality of life (solitude/safety)
- promote remote health monitoring of people living alone
- implement new services (home automation)
- improve relations with neighbours (social neighbourhood)
- integrate a free number to ATC (24 hour call service) with network social services.

As a final output of this activity, an agreement with the Municipality of Torino will be signed in order to define and describe the common activities to be carried on to fulfil the goals of the project.

It is important to highlight that ATC Torino is only responsible for the management of housing and actually does not have the skills, competences and/or authority to deal directly with the tenants in matters of social care.

3.3 Pilot setup and challenges

3.3.1 Target group

ATC has chosen District 1 as the pilot site based on an evaluation of the following factors:

- The demographic conditions
- Good integration with social and health services
- Age of the buildings
- Number of elderly people

District 1 includes over two thousand flats, often situated in old buildings without lifts. The final pilot site will be composed of about 20 flats.

The inclusion criteria for ACT residents who will participate in the inCASA pilot are:

- Senior citizens over 65 self-sufficient that require light support by professional to improve their autonomy in addition to or in replacement of the family network (where absent)
- Senior citizens over 65 partially self-sufficient or non self-sufficient who require support by professional to improve their autonomy in addition to or in replacement of the family network (where absent)
- Different situations where a coexistence of the matters above is present
- An already well established and good relationship with his/her social worker.

Exclusion criteria:
- Residents who do not require social support
- Residents who do not have chronic health conditions.

The tenants/users will be able to freely choose they want to participate or not, and may withdraw at any time. They will be clearly informed that they will participate exclusively on a voluntary basis. They will also sign the Informed Consent form provided by the project before they participate in the pilot.

3.3.2 Pilot setup and resources

The following preliminary activities will be carried out:

- Holding meetings between operators of ATC and social services professionals to identify potential lines of action
- Crossing ATC internal data analysis with databases of the Social Services of District 1

(Municipality of Turin Welfare Department)
- Focusing on issues such as: improve conditions autonomy and work against loneliness.

Working methodology:

- The pilot site will use focus groups for needs analysis of the elderly (as the first step of the project)
- The pilot site will plan for multidisciplinary team meetings (social housing and social services)
- A pre-pilot will be planned in order to define priorities and to assess the process
- The pilot site will prepare communication tools to explain easy the project (motivational welcome kit).
- Using user-friendly communication tools are a priority.

The social conditions of the tenants:

- Low income and often low education
- Unfamiliarity with information and communication technology (ICT)
- Poor family network.

3.3.3 Pilot execution

We aim to select 20 to 25 end users among a group of 50 people indicated by the social services as representatives of the social characteristics indicated for the project:
- senior citizens over 65
- partially self-sufficient or non self-sufficient
- require support by professional care workers.

It is important to mention that our end users are not patients under the care of hospitals or residences for elderly people, but tenants who are living independently in social housing dwellings.

ATC will interview 50 potential end users and select among them 20-25 final end users.

ACT will present the inCASA project to each of the 50 selected residents and inform them of the purpose and scope of the project. This includes the fact that ATC Torino will install a number of electronic devices in their home to monitor their day to day routine in addition to the normal monitoring performed by vis-à-vis by the social workers.

In our experience we are certain that only about 50% of the 50 social housing residents will respond positively and agree to participate in the pilot.

The 20-25 selected residents will be individually monitored and the services provided will be adapted not only to their health and social needs, but also to the configuration of their home. In this instance it is important to underline that we are interacting with different house types and this is why we will create a personalised service for each user. The housing blocks where our end users live are quite different, e.g. in terms of date of construction, size of dwelling, facilities and disability barriers.

The only common characteristic of the end user's housing blocks is that they are located within the same geographical area, i.e. District 1 of the City Centre of Turin (an area of 7sqKm of radius).

The group end users will be followed by the social workers monitoring their behaviour al patterns throughout the duration of the project. We plan to have a review for each user every 4 months (each season) to verify also how their behaviours change.

ATC plan to adapt the devices not just to the users but to their houses.

3.3.4 Challenges

Cultural divide: We intend to involve our residents who are not used to interact with technology in their dwelling. We plan to prepare a strong communication plan paring with a good knowledge of social services to involve positively the residents and overcome the cultural divide.

Complexity of construction of a model behaviour: We are aware of the difficulty to create a standard of personal behaviour: every individual is different and behave differently during the day. We plan to use interviews and focus group to create a model.

Having 25 different dwellings and 25 different people: We are aware of the fact that we are dealing with 25 different home environments. We believe we can overcome this challenge by dividing the day in different parts and analyse them separately.

3.3.5 Ethical requirements in Italy

With reference to the following Agreements between the Municipality of Turin and the Local Health Board Authorities DGR 51-11389 23 December 2003 and DPCM of the 29 November 2001 (Law 328) an ethical approval from an ethical committee or other authority is not required for the pilot.

The main legal and deontological frame to be taken in account and referring to the activities are:

1. ACT 31.12.1996 n. 675 followed by DLGS 30 giugno 2003, n. 196, so called “Codex for the protection of personal data”.

The principles of ACT 675/1996 that apply to inCASA project are as follows:

a) to be processed lawfully and fairly;
b) to be collected and recorded for specific, explicit and legitimate purposes and used for further processing operations in a way that is not inconsistent with said purposes;
c) to be accurate and, when necessary, kept up to date;
d) to be adequate, relevant and not excessive in relation to the purposes for which they are collected or subsequently processed;
e) to be kept in a form which permits identification of the data subject for no longer than is necessary for the purposes for which the data were collected or subsequently processed.

To process personal data for historical, scientific research or statistics purposes shall be consistent with the purposes for which the data are collected or subsequently processed and may be carried out even after expiry of the period that is necessary for the latter purposes.

The person who shall provide his/her personal data shall be preliminary informed about:

a) the purposes and modalities of the processing for which the data are intended;
b) the obligatory or voluntary nature of providing the requested data;
c) the consequences of no reply;
d) the nature of the entities/persons to whom the data will be transmitted, that can process the personal data and the contest in which the data may be disseminated;

The Article 13 of ATC n. 675 regulates the right of all parties involved.

2. The Code of Conduct and Professional Practice applying to the processing of personal data for statistical and scientific research purposes within the framework of the national statistical system

(Published in the Official Journal no. 230 of October 10, 2002): regulates the treatment of scientific, medical and statistic data.

3. The internal ATC Torino Ethical Code of ATC Turin approved by the Board of Directors n. 206 _2008 of the 27 of November 2008 (available at request). This regulates the behaviours of the employer and the employees in matter of ethical conduct.

4. The Regione Piemonte Law n.3_2009 **(**available on request) regulates the ethical relationship between ATC Torino and the Public Authorities, the treatment and the use of Public Finance, the internal management of the Agency.

3.4 Scenarios and use cases

The aim is to describe the social services scenarios that will be typical for pre-pilot and pilot patient groups. Starting from here, we should define what is to to be measured (parameters, when and how often), the use cases and the corresponding workflows that will be useful to start up the service.

In the expanded use cases, we will also provide what combination of services the pilots should offer and how these will be integrated into the current ATC home/social care services.

3.4.1 Social services scenarios

The typical target group consists of single elderly people over 65, living in social housing, which require a light support from social services. The average person of the pilot group requires one weekly visit from the Healthcare Services/Social Services providing him/her with low or mild impact assistance.

Monitoring by a social/healthcare worker, is included and aims to give an weekly image of conditions and trends of the user's home conditions, future requirements of domestic support if apply, state of the autonomy of the subject and conditions of loneliness if may apply[11].

The scenarios are based on the theory, verified during the development of inCASA, that elderly people are subject to progressive loss of independence, decay of mobility within their home or short distance mobility, and that their daily life is dominated by repetitive sedentary habits: any deviation from established habits may create the need of additional support which is sometimes not fully perceived by the person who requires assistance.

Despite the need, social services are often not able to monitor the health and social condition of the elderly person through the existing family network / social network. Many elderly people are not able to take proper care of themselves and do not have a family/social network who can support them. In these cases, the timely action of the social services is essential to avoid critical situations. Moreover, given the fact that the cost of assistance is very high, the interventions should be concentrated at home and studied case by case to determine the essential requirements.

Every apartment shall be equipped with a set of devices that monitor the movements and contact and the input data shall be elaborated. This will allow us to:

Phase 1 – Establish the habits and behaviours of the assisted person.
A “User Habit” is defined as the repetition of a single or complex action (like sitting on a chair or leaving the home) or a pathway (a sequence of actions like leaving the bedroom to go to the toilet every day after getting up from bed) for several times at about the same time during a week.

11 However, in situations of potential further loss of autonomy, it is very difficult to identify the critical point that Action is required to support more intensive.

During this phase, the system should register all single actions in the end-user's house for a week (the time frame should be configurable), including the time stamp of the events. The system should then organise the data per time/per day/per week and create a profile of actions and pathways defined as a Normal Habits Model by measuring and profiling the next actions/pathways:

Phase 2 Habits monitoring alerts: to manage alerts and emergencies related to habit models
An Alert is defined as a message induced either by an event different from the Normal Habits Model or by an Emergency Event and which needs action. The system should describe alerts by identifying name, description, priority and severity. A user file should then open where each single alert is described and a SMS should be sent to the appropriate person(s) who will take action (e.g. relative, caregiver, neighbour, social worker, clinician, etc.).

A. Work flow in normal situations:
The professional workers involved are: A social worker from the Municipality of Turin, who is in charge of the users, and the case manager. Both are informed of the process and of the activities involved.

Actions:

- During the week, the social worker follows his/her routine, visits the assisted person and verify the continuation of normal behaviour (the user's)
- The normal routine is corroborated by the direct action of the assisted person that interacts with the sensors.

B. Work flow in the case of abnormal situation:
The professional workers involved are: A social worker from the Municipality of Turin, who is in charge of the users, and the case manager. Both are informed of the process and of the activities involved.

Actions:

- The anomaly is detected and processed by call ATC Call Centre.
- The Call Centre operators, depending on the type of event and its severity, forward a warning to the social services officer or ATC technical staff in case of leakage of gas or water.
- ATC technical staff or the social services resolve in situ the emergency/anomaly
- The social worker checks if the anomaly persists or if normal conditions are reinstated and resets the sensor to original conditions or actively sets the sensors in such a way that the "anomaly" becomes a new normal behaviour of the user that does not originates an emergency.

Currently, the parameters to be measured include:

- Movement
- Contact
- Temperature
- Humidity
- Gas leaks
- Water leaks

3.4.2 Basic use cases of inCASA services

On this basis, we are able to define some use case scenarios and to exemplify workflows related to specifics patterns, which would need automatic workflows or operator quick response. All the parameters and ranges should be customizable by operators through a specific Service User Interface.

Use case 1: The front door (contact/movement)
Overview: The service will monitor if there is an abnormal opening/closing of the front door of the flat.

Purpose: To show if the door is closed or open, in order to verify if there is an abnormal gap referring to the habits of the tenant.

Procedure: To reveal possible different patterns (user opens/closes the door; user goes out/stays in; user opens the door, goes out and closes the door; user open the door, goes out without closing the door etc).

Analysis: Evaluation of the time of gap concerning the user's habits.

Data fusion: The data will be sent and processed.

Alerts: If the user forgets to close door, after going out or staying in, a text message/alert will be sent to the neighbour/relative/social worker. If the alert is not responded to an operator will be sent to close the door and to do a survey of the situation.

Feedback to patients and relatives: Patient/relatives will be notified that the situation occurred.

Personalisation: Yes, all the users' habits are customized.

Devices: Contact sensor.

Use case 2: Indoor movement (movement sensors)
Overview: Through the data coming from the user's movements indoors, the use case will define a system of alerts. The movement sensors will be placed in strategic and relevant places in order to capture the user's habitual movements.

Purpose: The service will monitor the user's indoor movements in order to identify gaps and anomalies and to send alerts to the appropriate care worker.

Procedure: The user is not moving for several hours (> 50% of usual movement), or is moving abnormally inside his/her home, or is moving during the night when she/he usually sleeps, etc: the corresponding signals will be processed and send to verify the level of warning.

Analysis: Analysis of the gap between the user's habits and actual monitored movements.

Data fusion: All data are stored in a database connected to the system.

Alerts: Text message sent to the appropriate care worker.

Feedback to user and relatives: Yes.

Personalisation: Personalised to each user.

Devices: Movement sensors.

Use case 3: Bed permanence (contact/movement sensors)
Overview: A contact sensor will be placed in a way to enable it to detect when the user goes to bed and gets out of bed.

Purpose: Staying too long in bed or getting up too many times during the night could be a warning of illness or uneasiness that could necessitate an intervention by the social worker.

Procedure: The system will process some inputs such as: the user goes to bed; the user stays in bed; the user gets up from bed; the user doesn't go to bed. These different patterns will be processed in order to generate alert messages.

Analysis: Analysis of the gap between the user's habits and actual monitored movements.

Data fusion: All data are stored in a database connected to the system.

Alerts: Text message sent to the appropriate care worker.

Feedback to user and relatives: Yes.

Personalisation: Yes.

Devices: Contact/movement sensors.

Use case 4: Comfort of the home (sensors for temperature-humidity)
Overview: Sensors of temperature and humidity will be placed in appropriate locations; the data will be processed and compared with the defined normal parameters.

Purpose: By processing the data coming from the homes it will be possible to assess the comfort level in order to avoid critical situations with potential dangers for user's health (i.e. dehydration during hot summers).

Procedure: It is important to underline that every sensor is set with initial data for temperature and humidity different from each season. The sensors receive the data from the environment and indicate discrepancies from the seasonal average temperature/humidity. The data are received and processed in order to generate alert messages in case there is a difference from normality.

Analysis: The data are analysed by the system using an algorithm that compare the average situation (seasonal) from the day to day pattern.

Data fusion: All data are stored in a database connected to the system.

Alerts: Phone calls, text messages and/or e-mail will be sent to the user and relevant care worker.

Feedback to user/relatives: Yes.

Personalisation: Yes.

Devices: Sensors of temperature ad humidity.

Use case 5: Technical emergency
Overview: The service shall provide an automatic set of alerts in case of water or gas leaks or accidental fires in order to prevent acute dangerous situations in the tenant/user's home.

Purpose: Domestic accidents caused by forgetting to close the water or gas taps and accidental fires happen quite frequently in elderly people's homes (when living alone). The service will help to avoid severe dangers from developing.

Procedure: If an emergency event is detected (water or gas leaks and/or smoke) an immediate alert will be sent through to the Call Centre and forwarded to the closest team of intervention or fireman service.

Analysis: No.

Data fusion All data are stored in a database connected to the system.

Alerts: Yes

Feedback to patients and relatives: Yes.

Personalisation: No.

Devices: Specific sensors.

3.4.3 Expanded use cases: Phase 2

During the second phase, a pilot with around 25-30 users will be set up. The follow up of the project involves the implementation of an integrated system on a wider territorial scale to provide remote monitoring and support for a larger number of older and frail people living in social housing.

This will be done with a view to promote prevention, cost savings and integration of response to frail people needs. The aim is to increase the autonomy and independence of elderly people and improve the quality of their life. The goal is to contribute to the reduction of welfare costs through IT integrated systems and research and the networking between the ATC Call Centre and the Local Social Services (social workers, volunteers, health care system).

3.5 User Profiles

End-user/resident

The end-user/patient is the person who will have the monitoring equipment in their Social Housing home. The end-user has specifically accepted (through informed consent) that a certain type of his/her movements at home will be monitored and processed as part of the overall aim to improve social care and housing care services. He/she is a senior citizen over 65 with particular home assistance needs and thus receives services provided by the health and care system.

Carer/family member/neighbour/friend

The group of end users is composed by a very heterogeneous mix: some of the end users have a family network while others do not. The family member is the person nominated by the user who may also view user data, assist the user in taking measurements and when doing activities. This user cooperates with social services workers (case and care manager) and receives the alert messages if necessary.

If the family network does not exist we rely on the reference person indicated by the end user. This may be a neighbour or a friend who will cooperate in the same manner as the family member.

Case/care manager

First line Case/Care Manager responsible for user. He/she is a social worker in charge of the end-user or someone who will liaise with the social worker, the carer / family / neighbour / friend, with the admin support, and with the local administrators of ATC who are in charge of residence maintenance, in case of warning messages regarding gas and water leaks.

Social worker

The second line professional responsible for providing social support to the end-user is the social worker employed by Social Services. These social workers may have different professional profiles according to their special work area. The professional profiles of the social staff are:

- Team leaders who employs other professional staff
- Social workers who take care of preliminary interview with the users, and deal directly with complex situations from a social perspective;
- Educators involved in educational projects especially disabled;
- Caring Instructors who care for not self sufficient elderly people with family network;
- Social care professionals dealing with cases of elderly self sufficient in a family with a focus perspective to prevention and network ;
- Administrative employees who take care of the economic issues.

The Social Services provide also for a service called “Staying-at-home social services” that comprise:

- At home assistance (OSS or family assistance)
- Tele aid
- Family care
- Day care or residential assistance
- Home delivery of food.

The above indicated duties are provided by the Social workers, the Educators, the Caring Instructors and the Social Care Professionals.

The PAI (Individual Assistance Plan): The Social Services design for each user (over 65) an individual home assistance plan. To resolve the issue of loneliness, the Social Services include in the individual plan a series of collective activities in addiction to the ordinary individual interventions. The PAI is the responsibility of the Care Manager / Admin Support.

Installer

The Installer is a professional electrician instructed by an electrical and electronic engineer selected by Reply. The electrician is responsible for the mere installation of the sensors within the dwelling and the electrical engineer is responsible for the correct installation of the sensors, the training of the end users, and the correct transmission of the data to the main system.

Admin Support

Will be responsible for providing support / answering calls from users and support all professional actors. Will be the Case/Care Manager, in the pre-pilot phase, who is in a charge of the ACT call centre during the final implementation phase.

3.6 Infrastructure and service provisioning

3.6.1 The inCASA architecture

From the point of view of its architecture, the ACT pilot’s network model is as follows:

- Sensor devices to measure mobility/contact data.
- Hydra proxies to establish communication between the home gateway and each device
- Home Gateway / Hub/
- Transformation of the signals into alpha-numerical data

- Backend system and alert management hosted by ATC server and managed by the Call centre via Short Message System.

The system should output data coming from habits monitoring highlighting differences from normal habits related to a time frame (one week – two weeks – one month).

If the dashboard is present, the System should allow the social worker to log-in as user through the Web service GUI.
If the report is chosen, the System should be able to send an encrypted e-mail to the social worker containing the report. An overview of the system requirements is as follows:

- Repository where store the data (SPP)
- Reasoner for building habits models (SPP)
- Data transfer via Web Services (Hydra) User Interface to display and manage data
- E-mail engine to encrypt and send reports.

The communication shall be over ADSL lines, if such lines are already present in the end-user's home, or through a SIM card, regardless of the availability of ADSL.

An external inCASA database will be set up for extracting data for later transferral to a permanent service installed after the pilot.

3.6.2 inCASA pilot service installation

The service will be installed and configured in the users' homes with the appropriate devices and infrastructure.

Basing on the number of involved users (5 for the pre-pilot phase and 30 for the pilot phase), ATC Torino has selected the devices shown in the next table:

ATC Pilot Device committment		
Description	**Number**	**Specific Requirements**
Personal Id	30	Watch
Door	30	with beeper/buzzer for Alert
Movement	120	
Bed	30	not wired
Chair	30	not wired
Device	15	
CO	10	
Gas	15	
Water	15	
Temperature	15	
Humidity	15	
Gateway	30	

Habit sensors (activity, motion or presence sensors, door and contact sensors) will be used to create a behavioural model of the monitored person. Preferably, the sensors shall be available out of the shelf, as proven hardware is widely available from home automation or smart metering solutions. Amongst these, only standard products shall be regarded providing long-term availability of compatible hardware. To ease the sensors' installation, they are meant to communicate wirelessly.

Preferably, human movements are not to be monitored directly using distance calculation to anchor points, but indirectly, person's activity is measured using environmental sensors. Based on this approach, the modelling has a chance to work even if the monitored person forgets to wear the radio tag. This approach comes with the drawback that identification is not possible, and if there are multiple persons in a household, differentiation and behavioural model creation is a very difficult task. In those cases, sensors that are directly worn may permit the differentiation of different persons in the same environment.

The ATC Pilot site will not perform direct telehealth monitoring during the inCASA project. It will derive healthcare information thanks to the comparison of Habits Monitoring data (telecare).

4 Chorleywood Health Centre (CHC), UK

Chorleywood Health Centre is a medium sized general practice based in an affluent area North West of London. The majority of its 6000 patients are elderly and patient care is well managed. The practice achieves high QOF scores, taking 96.4% of the total points available – 0.7% above national average.

The health centre uses the iSoft Premiere clinical system to store its electronic patient records. This system is connected to Contract+ which is used to manage information required for the GMS contract.

The health centre is staffed by a multi-disciplinary team, including GP's nurses and on site physiotherapist and counselling services. In addition a Diabetic Retinopathy clinic is held at the centre.

The practice is housed in a purpose built building which replaced its predecessor after a flood in 1997. The building was developed specifically to exploit technology and telecommunications to deliver health care and the team has been using technology as tools to help them with their work for some time. In addition to providing sufficient power points, network outlets, ISDN and telephone lines in each of its rooms, the practice also has a purpose built telehealth room which houses video conferencing and digital imaging equipment. The practice runs a regular vascular clinic and uses the video conferencing equipment to link with the John Radcliffe Hospital in Oxford. It has a similar program for heart disease linked with Watford General Hospital.

4.1 Medical and social background for the pilot

The population of those aged 65 years and over in the UK has increased from 15 per cent in 1984 to 16 per cent in 2009, an increase of 1.7 million people. By 2034, it is estimated that 23 per cent of the population will be aged 65 and over. Of these the biggest increase has been of those 85 and over with numbers almost doubling since 1984 from 660,000 to 1.4 million in 2009. This increase is set to continue further and numbers of people aged 85 and over are expected to reach 3.5 million by 2034, accounting for 5 per cent of the total population [10].

Many amongst this aging population are living with one or more chronic diseases. It is estimated that there are more than 17 million people living with a chronic disease in the UK. They account for more than 80% of consultations with general practitioners.

While these older people, many of whom have significant support needs, make up a large proportion of the UK population, they have often been left out of advances in innovative service funding streams and practice developments.

There is an increasing amount of evidence to support the use of telecare, telehealth and other assistive technologies. The benefits of such services include the ability to:

- Reduce risk for those living at home
- Provide fast and appropriate response to emergencies
- Manage specific conditions
- Educate and enable individuals to manage their own conditions
- Delay admission to residential or nursing care
- Enable safer discharge from hospital or care

Examples where the use of such technologies has shown to provide significant benefits include: DOH, (2010), Implementing Telecare to achieve efficiencies Care Services Efficiency Delivery: supporting sustainable transformation. [12]

North Yorkshire County Council (NYCC) has introduced telecare as part of a range of personalised solutions for everybody requiring Adult and Community Services support. In the first year NYCC saved over £1 million on domiciliary or residential care costs (38% reduction in care costs).

Essex County Council invested £4 million pounds on telecare equipment with initial indications showing that for every £1 spent on telecare, £3.82 has been saved on traditional care.

However, despite the increasing amount of evidence, residential care is often regarded as the best option for older people. As a consequence the uptake of such technologies remains limited and its value in delivering more efficient and cost effective services remains under exploited.

4.2 Objectives of the pilot

The project will seek to compare variations in the activity template and the variations in the physiological parameters to identify patterns and to understand if and how environmental monitoring can aid and even predict clinical events and care.

- Build the technical and clinical service to deal with the data from both remote patient monitoring and environmental monitoring.
- Evaluate the value of such a service to both the frail elderly person and the clinical services that care for that person.
- Understand and measure the impact of such a service to a patient's quality of life.

The CHC pilot hopes to achieve the following outcomes:

- Improved Clinical Outcomes
- Improved quality of life
- More appropriate clinical interventions
- Reduced Hospital Admissions
- Increased independence
- Improved Patient Education
- Improved Clinician Education

4.3 Pilot setup and challenges

4.3.1 Target group

The project will aim to monitor elderly frail patients who are currently on the chronic disease register at Chorleywood Health Centre for one or more of the following:

- Chronic Heart Failure (CHF)
- Chronic Obstructive Pulmonary Disease (COPD)
- Dementia

Patient inclusion criteria:

- The patient must be registered with CHC
- The patient must be on the Chronic Heart Failure, Dementia, COPD disease register

[12] http://bit.ly/ct18t6

- The patient must be determined to be Frail as defined by the Edmonton Frail Score (see table below)
- The patient must have a basic level of literacy
- The patient must have broadband or live in an area with strong mobile signal strength.

Edmonton Frailty Scale[13]:

Frailty Domain	Measure
Cognition	Basic Cognitive Test
General Health Status	Hospital Admissions
Functional Independence	Ability to go shopping etc
Social Support	Has support structures
Medication Use	No's and Compliance
Nutrition	Weight Lose
Mood	Depression / Anxiety
Continence	Frequency
Functional Performance	Basic test

Patient exclusion criteria:

- Cognitive impairment

4.3.2 Pilot setup and resources

Each patient will be provided with a monitor in their home that will capture and transmit a number of different physiological measurements (see table below) on a daily basis. The data will be viewed by the clinical team at Chorleywood Health Centre to determine if and when clinical intervention is required. (Intervention will be determined, when patient's data is outside of predefined parameters).

In parallel to the clinical monitoring, the patients will also be provided with environmental sensors (see table below) that will monitor and capture trend information about the patient's movements while in the home in order to develop an activity template. We will not be monitoring for alerts. Intervention will be determined when data indicates a change from the patients "normal" routine.

User Group	BP	Weight	Spo2	Chair Sensor	Bed Sensor	PIR	Wrist Movement
CHF	X	X		X	X	X	X
COPD	X		X	X	X	X	X
Dementia	X			X	X	X	X

4.3.3 Pilot execution

Those participants meeting the inclusion criteria will be sent a letter of invitation, a demonstration information Form and the inCASA press release, which will describe the project and invite the patient to an induction meeting to be held at CHC. Letters will be sent out in batches of 50 by 2nd class post.

[13] Source: Petty D et al, Validity and reliability of the Edmonton Frail Scale, Age & Ageing doi:10.1093/ageing/afl023 Published electronically 11 May 2006

2 days after the letters have been sent, a follow up phone call will be made to each patient who has been contacted. The call will be used to:

- Further explain the demonstration
- Describe what the impact will be on the patient e.g. time / disruption during installation as well as monitoring requirements
- Answer patients questions
- Confirm whether the patient is willing to participate and can attend the demonstration induction meeting.
- Confirm dates / availability for induction meeting.

Details and results of the phone calls will be recorded on the Recruitment Control Form. Responsibility for the follow up calls will be with the CHC Research Team.

The recruitment process described above will continue until 45 patients have agreed to attend the induction meeting at CHC. The additional 10 will be invited in case of drop outs during the demonstration start up phase.

All participants will be invited to attend a Patient Induction Meeting. This meeting will be held at CHC. This meeting will last approx 1 ½ hours and will be used to:

- Describe the demonstration – Power Point Presentation
- Introduce the demonstration team. Team members to be present will include:
  - CHC Research Team
  - Dr Russell Jones
- Describe the patients role in the program and any benefits to the patients
- Demonstrate the technology
- Provide an opportunity to “have a go on the technology”
- Describe Data Sharing Issues and Consent form
- Answer any questions

Patients will be asked to sign a consent form[14], confirming their agreement to participate in the demonstration.

Withdrawal of Patients
Patients will be informed at each stage that they have the right to withdraw from the demonstration at any time. Patients who deteriorate during the monitoring phase of the demonstration will be withdrawn from the demonstration. Should a patient withdraw voluntarily or due to deterioration within the first 2 weeks of the start of the demonstration they will be replaced.

4.3.4 Challenges

We envisage that there will be a number of key challenges around the development of the inCASA platform itself which may affect the clinical pilot sites. In particular the bringing together of the different technologies so that they are able to be used effectively and efficiently together e.g. habits monitoring devices and telehealth monitoring devices. We anticipate that any problems will be eased by having a clear roadmap of technology development and timelines of what and how advancements in the inCASA platform will be rolled out to the participants (clinicians and patients) during the pilot. This will need to factor in sufficient timing for training for all users.

14 Deliverable D2.3 European country policies and Ethical package will include the consent form to be used by the inCASA pilots.

In addition to the platform challenges, we envisage a number of challenges that could arise out of running the service. These include organisational challenges, recruitment, drop outs and technology phobia.

Organisational
Any change to "normal" working practices, especially in such an organisation as health care where there are increasing daily pressures, can prove a challenge. While all those involved in the pilot are used to working in a "research" environment, it is extremely important to ensure that processes and protocols support working practice needs and requirements. We have developed a set of clinical protocols for this pilot that enable timely access to relevant information for the clinicians and that support them in responding to that information. These practices include: Standard monitoring protocols, alert protocols, case conferences to aid the understanding & interpretation of the information, response protocols as well as support for when things go wrong.

Recruitment
With any study recruitment of participants can be a lengthy and difficult process. This may be in part be due to a lack of understanding of the project by the participant, concern over what they would need to do during the study e.g. increased burden or because they feel they are not able to cope because of their illness.

In order to reduce the risk of these and other barriers that may stand in the way of a person participating in the study we have developed a tried and tested project and recruitment process. This involves carefully considered inclusion criteria, project letters and information sheets that clearly describe the project in detail and what would be expected of the participant as well as providing each participant to attend an induction presentation which demonstrates the technology and allows the participant to have any questions answered.

Drop outs
Again participant drop out can be a large problem within a project. Drop outs may occur for any number of reasons including: Illness, unplanned trips, unplanned admittance to hospital, change in circumstances and family pressures. We have built in to our program a protocol for managing drops outs and for recruiting replacements within a predefined time period.

Technology phobia
On some occasions we have found that participants, especially the elderly, can be concerned over the use of technology within their home and their own ability in using it. Again this is something that with careful management at the recruitment and induction stage can be overcome with as well as providing ongoing support and reassurance during the study period.

4.3.5 Ethical requirements in UK

As this project involves clinical aspects it will require ethical approval. In the UK, review by an ethics committee is one of a series of safeguards intended to protect the people taking part in the research. These safeguards are set out in a series of documents and guidance:

Declaration of Helsinki (World Medical Association, as amended 2008).

Sets out ethical principles for medical research involving human subjects, including research on identifiable human material and data.

Research Governance Framework for Health and Social Care (2nd edition) (Department of Health, published 24 April 2005).

Establishes a framework for the governance of research in health and social care. It applies to all

research that relates to the responsibilities of the Secretary of State for Health (that is, research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-departmental public bodies and the NHS), and research undertaken by or within social care agencies.

It includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and universities within the health and social care systems that might have an impact on the quality of those services.

Governance Arrangements for NHS Research Ethics Committees (GAfREC) (Department of Health, published July 2001).

Provides a standards framework for the ethical review of all NHS and social care research proposals which is efficient, effective and timely, and which will command public confidence. It sets out general standards and principles for an accountable system of Research Ethics Committees (RECs) working together to shared high standards of review and operating process throughout the NHS. It should be read in conjunction with the Research Governance Framework for Health and Social Care, above.

Source: http://www.nres.npsa.nhs.uk/aboutus/protecting-participant-safety/

4.4 Scenarios and use cases

The following section provides a description of how we envisage the inCASA platform to support the clinical management of the patients. We begin by providing a brief description of how the patients are currently being managed for their condition before describing what changes the inCASA platform will be bring to current service provision. An overview of the devices that we plan to use is given together with a description of how we would like them to be used by the patient and what clinical use this information will provide. Finally we provide a more detailed Use Cases that describe some of the main scenarios.

4.4.1 Clinical scenarios

We are focusing on patients from three specific disease groups, COPD, CHF and or Dementia who are also deemed to be fragile as defined by the Edmonton Frail Scale. However it is expected that these patients may have one or more co-morbidities which we will need to take into account during the monitoring period.

Traditional Management of Patients

A “normal” non-telehealth pathway for a patient with any one of the above conditions would be to visit the GP and or nurse as and when required. This may be as a result of a care plan e.g. pre-planned appointments to monitor the individuals clinical condition (s) or because of a deterioration or new condition. During the visit the clinician would view the patient’s history, test results, medications on the patient’s electronic patient record (EPR). The outcome of those visits would be recorded together with any new test results, changes to medication or observations. These visits may occur once a week or once a month and is often disease, co-morbidity variable. Where necessary and when the patient may not be well enough to attend the Health Centre in person, they may request a home visit, this visit maybe undertaken by the Nurse or General Practitioner dependent on the reason (if fully known). While the clinician will currently enquire about lifestyle habits and if there has been any change, in reality very little information is available to them, only what comes direct from the patient during the visit.

Management of Patients within the inCASA Platform
The main objective of introducing the inCASA platform to patient management is to enable the clinicians to have access to more timely information. Physiological and habits monitoring data will be "pushed" to the clinicians as opposed to the traditional method of "pulling" information via a traditional face to face consultation. Specifically with the aim of:

- Improving Clinical Outcomes
- Improving quality of life
- More appropriate & targeted clinical interventions
- Reduce Hospital Admissions
- Increase independence

Each patient will be provided with a monitor in their home that will capture and transmit a number of different physiological measurements based on their condition(s). Patients will be asked to take these measurements once per day. In addition, we may wish to ask some disease specific questions. These will be displayed to the patient via the monitoring equipment and the patient will be able to enter their responses onto the screen.

The patients will also be provided with environmental sensors that will monitor and capture trend information about the patient's movements while in the home in order to develop an activity template. This monitoring will be unobtrusive and will not require the patient to actively do anything.

Management of the "push" of information from the patient to the clinician will be critical to the success of the inCASA pilot. It will require systems that will enable the data to be collected, processed, sorted, prioritised and displayed to the clinician in a way that supports the patient's management plan, the clinicians need & delivery of the service. In addition, the introduction of habits monitoring will be a new level of monitoring that the clinicians will not have experience with. The management system will need to analyse the data being sent via the habits monitoring devices, analyse and display this data in a meaningful way to the clinician. The hope is that this information can then be correlated with the clinical information to find any patterns or relationships.

One of the main challenges of the introduction to telehealth programs is the increased workload that "alert" management can create. Many systems use simple high / low parameters to create alerts around a patient's data. These have been found to be highly susceptible to "false alerts" and often lead to clinicians having to call patients unnecessarily. We propose that responses to deviation from pre-determined parameters will be analysed using automated algorithms that will take into consideration factors such as change in medication etc. This will help keep "false alerts" to a minimum.

4.4.2 Basic clinical use cases of inCASA services

Use case 1: Blood Pressure
Overview: This service will provide a reminder to the patient about measuring his/hers blood pressure, check that the patient has done so, and send the measured value to a backend system where it is evaluated and stored.

Clinical purpose: To provide the clinical teams with a standardised measurement.

Procedure: Patient will take one resting blood pressure measurement per day – preferably by 11am. Where necessary we may request the patient to repeat the measurement in a day or they may choose to send a second reading at another point during the day.

Analysis: The clinical teams will look to ensure a patients' Blood Pressure is within pre-defined limits e.g. 140/85. The data will then be analysed using automated algorithms to track trend

changes in the patient's blood pressure measure in order to determine when intervention is required.

Alerts: The clinician will be alerted when there is a variance away from the desired or expected and allow for the efficacy of current medications, treatment plan and where necessary help manage any changes to medications or lifestyle.

Feedback to patients and relatives: Patients should be provided feedback by way of the monitoring hub, this should include displaying the current measurement that they have just taken and when data has been sent successfully.

Personalisation: The system should allow for clinicians to enter personalised optimum values for each patient and enable to patient to enter up to 4 readings per day.

Devices: Blood Pressure monitor that will record systolic, diastolic (mmHG) and pulse.

Use case 2: Body Weight
Overview: Patients who have a diagnosis of CHF and or those whose co-morbidities may suggest weight is an important factor will be provided with a weight scale

Clinical purpose: For those patients with CHF, the clinical teams will look to ensure there is no significant change in their weight which may suggest that they are retaining fluid (a sign of deterioration in their condition).

Procedure: Patient to take one measurement per day – preferably by 11am. This will provide the clinical teams with a standardised measurement. Where necessary we may request the patient to repeat the measurement in a day or they may choose to send a second reading at another point during the day.

Analysis: The data will then be analysed using automated algorithms to track trend changes in the patient's blood pressure measure in order to determine when intervention is required.

Alerts: The clinician will be alert when there is a variance away from the desired or expected and allow for the efficacy of medications and help manage any changes to medications.

Feedback to patients and relatives: Patients should be provided feedback by way of the monitoring hub, this should include displaying the current measurement that they have just taken and when data has been sent successfully.

Personalisation: The system should allow for clinicians to enter personalised optimum target values for each patient as well as be able to enter levels of change in weight over a defined time scale e.g. >1.4kg over 3 days. The system should also enable to patient to enter up to 4 readings per day.

Devices: A weight scale (should record the measurements in KG).

Use case 3: SpO2 (blood oxygen saturation level)
Overview: Patients who have a diagnosis of COPD and if deemed necessary CHF will be provided with a pulse oximeter.

Clinical purpose: The clinical teams will be looking at the patient's oxygen saturation levels which can be an indicator of deterioration in a patient's condition.

Procedure: We will ask each patient to take one measurement per day – preferably by 11am. This will provide the clinical teams with a standardised measurement. Where necessary we may request the patient to repeat the measurement in a day or they may choose to send a second reading at another point during the day.

Analysis: The data will then be analysed using automated algorithms to track trend changes in the patient's Spo2 in order to determine when intervention is required.

Alerts: The clinician will be alerted when there is a variance away from the desired or expected and allow for the efficacy of medications and help manage any changes to medications.

Feedback to patients and relatives: Patients should be provided feedback by way of the monitoring hub, this should include displaying the current measurement that they have just taken and when data has been sent successfully.

Personalisation: The system should allow for clinicians to enter personalised optimum target values for each patient as well as be able to enter levels of change in Spo2 over a defined time scale. The system should enable to patient to enter up to 4 readings per day.

Devices: A pulse oximeter.

Use case 4: Habits Monitoring – Chair Sensor, Bed Sensor, PIR motion detector

Overview: All of the patients within the monitoring program will be provided with a set of habits monitoring sensors. We will then be able to track changes to the average trend e.g. time spent sitting, whether someone has gone to bed etc.

Clinical purpose: A change / reduction in a person's movements can be indicative of deterioration and the clinicians would like to understand how and if this change can be seen prior to any changes to physiological measurements.

Procedure: The devices will be battery operated pressure pads and will record each time a person sits / lies down and when a person stands / gets out of bed. In addition the time and duration of each event will be recorded. A PIR motion detector will also be placed in a location e.g. hall where foot traffic is the greatest. As with the chair and bed sensors this will record the activation (motion) as well as the time and date of that activation.

Analysis: The management system will need to capture, analyse and present this information in a meaningful way to the clinicians. It is hoped that further development will enable the correlation of habits monitoring data and clinical data so that they can be compared.

Alerts: Within this pilot it is not anticipated that CHC will be using immediate alerts for the habits monitoring devices. Instead the focus will be on monitoring for trend. The clinician will be alerted when there is a deviation away from the trend.

Feedback to patients and relatives: Feedback would be useful for the carer or relative on the patients movements, They too could use the system to keep a track on the patient. This could be accessed via a carer web portal.

Personalisation: It is expected that we will be able to build up a model of "average" activity within a person's home. This model of a person's activity may take up to one or two weeks to create.

Devices: A chair and a bed sensor and a PIR motion detector.

Use case 5: Monitoring Hub - Contextual Monitoring / Feedback
Overview: Each patient will be provided with a monitoring hub that will link all the devices and act as a communication gateway for the transmission of data from the patient's home to the inCASA server.

Clinical purpose: Its primary purpose would be to provide a means to allow clinical data to be communicated. In addition, physiological data can be supported by asking patients contextual questions about their condition during the monitoring session.

Procedure: The monitoring gateway will act as a data collection source direct from the patient. For example the hub should prompt and instruct the patient in the use of the devices, provide visual / audio feedback of the measurement, display disease specific questions and allow the patient to input the answer to those questions.

Analysis: Data from the contextual questions will be analysed based on NICE clinical guidance.

Alerts: An alert would be generated in the event that a patient answers a question in such a way that falls outside of the guidelines. This data would be used to compare against and support the analysis of the clinical and habits monitoring data.

Feedback to patients and relatives: There would be no immediate feedback to the patient or carer.

Personalisation: The Hub should be capable of enabling different clinical devices to be attached dependent on patients need. Questions should be disease specific and be personalised for each patient.

Devices: The device should be able to display data in an accessible way for the patient to read. The device should be easy to use.

4.4.3 Expanded use cases

Expanded use case 1
At a pre-defined time each day the home monitoring hub will prompt the patient to take a reading. The patient will come to the hub and take their measurements using the devices e.g. put on the blood pressure cuff, stand on the weight scales and / or use the Spo2. At the end of taking each of the measurements the hub will display back the reading to the patient.

When all physiological measurements have displayed a series of questions to the patient, the patient entered their reply by touching buttons displayed on the screen, these buttons may be a combination of yes, no, like/don't like scale. One of these questions asked the patient if they were feeling dizzy. The patient responded yes.

The clinician accessed the clinical user interface and was alerted that the participant's blood pressure was higher than expected and that they had answered yes to one of the questions. The clinician reviewed the patients monitoring history and contacted the patient to ask them to come in for a review with a GP. The clinician made a note in the patients monitoring record and the patients EPR. The patient attended an appointment with the GP who conducted further investigations. These indicated that patient had high sodium levels. The participant was advised to reduce their fluid intake and was prescribed a change to their medication. This change in medication was recorded in the monitoring system and the patients EPR. The patient continued to take measurements and after a period of a few days their blood pressure began to reduce.

Expanded use case 2
On enrolment in the study the patient's base line blood pressure measurements were found to be above the study target. After 9 days of monitoring the data received via the monitoring system indicated an abnormal pulse rate and high blood pressure.

The patient's information was referred to a case conference where the patients EPR were reviewed. It was decided to contact the patient and ask them to come in to see a GP. Following further investigations carried out by the nurse and GP, the participant was diagnosed with suspected Bradycardia and referred to a cardiologist. The cardiologist was provided information obtained from the monitoring system. Shortly afterwards the participant was admitted to hospital and had a pace maker implanted. During this time the patient was "suspended" on the monitoring system.

Once discharged from hospital, the patient monitoring resumed. Data indicated that the pulse rate had returned to normal but that the Blood Pressure remained high. The patient was put on a close watch to see if the BP would normalise following the operation. After 2 weeks, it was decided that the patient would benefit from a change in medication. The patient continued to be monitored until the Blood Pressure fell within defined limits.

4.5 User profiles

End-user/patient
Patients will be selected from the chronic disease register at Chorleywood Health Centre (CHC). A total of 35 patients will be selected to participate as per inclusion / exclusion criteria outlined previously. They will be defined as frail and live alone in their own or rented property within the Chorleywood area.

The patient (end-user) is the person who:
- Consented to taking part in the study
- Have the monitoring equipment in their home
- Take daily measurements e.g. Blood Pressure, weight Spo2
- Answer questions via the monitoring data
- Receive feedback from the monitoring device about their measurements
- Receive health review from the clinicians

Carer/family member
The person nominated by the user such as a relative, friend responsible carer who may:
- Be present during the installation process
- View / access user data on a possible patient web portal.
- Assist the user in taking measurements e.g. putting on a blood pressure cuff.
- May sign the consent form

Clinician (nurse)
First line clinician responsible for patient. They will be responsible for:
- Enrolling the patients onto the study
- Taking part in the induction process
- Entering and viewing patient information on the clinical web user interface
- Monitoring and interpretation of the patients data on a daily basis
- Responding to data, alerts, direct requests from the patients and updating the web user interface
- Speaking with the patient
- Change the patient clinical management in response to data
- Set and edit patient alert parameters

- Escalate to appropriate General Practitioner

Clinician (GP)
Second line clinician responsible for patient - will liaise with Clinician – Nurse.

- Will consult with the first line clinician in the event patient data is outside of defined parameters
- Entering and View patient information during consultations with patients
- Set and edit patient alert parameters
- Escalate to other health care provider

Installer
The person (s) responsible for the:

- Liaise with the clinicians and admin team
- Liaise with the patients
- Installation of equipment into a patient's home including taking consent and patient training.
- de-installation of equipment
- Cleaning of equipment
- Stock management
- Fault liaison

Admin Support
The responsible for helping with

- Enrolling the patients onto the study
- Taking part in the induction process
- Providing 1st line support in the event as patient has a problem with the monitoring equipment
- Be a point of contact for project queries

Community Team
A person responsible for providing community support to the patient - Community Matron who as part of a wider service provision run by the Primary Care Trust may visit the patient in their own home concerning a particular illnesses / needs.

Other Health Provider
Hospital / A&E[15] / Social Services / Specialist

4.6 Infrastructure and service provisioning

4.6.1 The inCASA architecture

The following describes the inCASA architecture that we would want to use within the CHC pilot

- Medical Devices - Blood Pressure, Pulse Oximeter, Weight Scale
- Habits Monitoring Devices – Bed Sensor, Chair Sensor, PIR Motion Detector
- Network and communications infrastructure and architecture:
  - Hydra middleware
  - Zigbee solutions Brunel
  - Client - Server solution
    - CHC server
    - Gateway at home
  - Broadband line for client - server interconnection

[15] Accident & Emergency

    - Use ADSL , if an ADSL line already exists at patient's home
    - Else, a 3G wireless card will be chosen.
- Vertical services/applications: They will be built on top of Hydra middleware and they will be provided by NTUA / Brunel.

4.6.2 inCASA pilot service installation

The main inCASA server will be installed at CHC.

CHC will recruit patient through a defined recruitment process (please see 1.3.3) and medical staff will determine the specific parameters, procedures and alerts for each patient.

CHC and Brunel will organise the purchase of the required devices.

A CHC research team will be established and this team is responsible for ensuring that the patient understand the service offered by the inCASA pilot and its purpose. This includes training the patient on how to use to devices.

The research team is also responsible for installing the necessary devices in the patient's home and will make a follow up call to each patients within 24 hours of installation to confirm that the patient does not require any further support or training and to answer any question that have arisen since the installation of the equipment. If required a further site visit will be made. Informed consent will be obtained from all patients.

5 Institut National de la Sante et de la Recherche Medicale (INSERM), France

Institut National de la Sante et de la Recherche Medicale (INSERM) has long standing experience in the regulation of tolerability and efficacy of cancer treatments based on circadian rhythm, with research ranging from rodents to patients. It has conceived and implemented chrono-modulated treatment delivery to take advantage of the control mechanisms through which the circadian body clock modulates normal tissue physiology and tumour growth.

The present research work focuses on the control of normal and malignant cellular proliferation by the circadian rhythm as a determinant of cancer treatment success. The interaction between circadian physiology, molecular clocks and cell cycle and apoptosis processes have emerged as crucial in the further improvement in the treatment of human diseases.

5.1 Medical and social background for the pilot

In France, in 2004, 20% of the 62 million inhabitants were 60 years old and over. The mean life expectancy at birth is continuously increasing and is nearly 77 years for men and nearly 84 years for women. France has one of the highest life expectancies but, the lowest rate of activity after 60 years of age: 7% only of men and 4% of women are still in the economically productive, compared to 27% in the USA, 21% in the UK, 23% in Sweden, and 51% in Japan. This low rate of activity after 60 has no explanation from the health status. Indeed, only 6% of the population over 65 years of age, and 2% of the population between 60 and 69 years of age suffer from a dependency due to invalidating diseases.

In France, 18% of persons in their sixties live alone at home. This number increases to 30% of people in their seventies and to over 40% for people in their eighties. Improvements of health, the financial independence and the development of home care partly explain why a majority of seniors live in their own home.

In France, it is estimated that in average only 4% of people over 60 years are living in institutions. However, this proportion increases significantly from age 64: for people between the ages of 60 and 64 years fewer than 1% live in institutionalized homes whereas for people aged 65+ the number is 7%.

The challenge of the French policy on aging is to simultaneously promote health and activity as a long term perspective. Indeed, the majority of the population will age in a good condition of health, personal autonomy and productivity in the sectors where activity is allowed. But in spite of the progress in prevention, a minority of people is and/or may be victims of age-related diseases leading to dependency. As well, the significantly old, (90 years old and over) will remain a frail population whose autonomy is generally assisted.

In France, the Caisse Nationale de Solidarité pour l'Autonomie (National Solidarity Fund for Autonomy) has a dedicated strategy to provide assistance to older citizens who wish to remain in their home. There, they can have minimal out-hospital social care. In general, French National Solidarity Fund for Autonomy for the Elderly offers the following services: meal distribution, home help services (cleaning, food shopping, social help), and financial help (for seniors who need assistance to complete the essential activities of daily living, or whose condition requires regular monitoring).

The concept of Domomedicine has recently been developed by the French Academy of Technology, after five years of research and interviews with different actors (patients, doctors, nurses, health authorities, lawyers, industries, etc.) Domomedicine is based on a close relationship

between the patient and the doctor and involves a variety of services, information technology infrastructures as well as dedicated and patient-adjusted technologies, pending on the personalized treatment plan or the need to maintain autonomy. In such sense, Domomedicine contemplates the development of a new health sector, where hospital is a major player, yet it is not the core of the system.

5.2 Objectives of the pilot

The overall objective is to set up a tele-healthcare solution which provides continuous information on the conditions of the elderly cancer patients at home, so as to detect early signs of alterations related to cancer or adverse events of cancer treatments, and to make rapid decisions to improve safety of home delivery of cancer chemotherapy in elderly patients. Thus, the objective is also to demonstrate substantial prolongation of the time elderly ambulatory cancer patients can continue to be at home, as well as the resulting efficiency of the social and health care systems.

To reach these goals, we implement home care, monitor the patient's health status, implement and achieve a better approach to symptoms and side effects management in relation to patients who are receiving treatment at home, thus improving the patients' quality of life. More specifically, this includes monitoring the circadian rhythm of the patient and recording his activity and self-assessed symptoms, as well as body weight without hospitalising the patient. Pending upon the patient's condition, the following variables will also be self-assessed by the patient: blood pressure, blood glucose, INR (coagulation parameter). Also, the pilot aims to implement time series analysis and alarm generation.

The INSERM pilot will specifically:

- Measure rest-activity rhythm with wrist actigraphy monitoring (Actigraph, Ambulatory Monitoring),
- Rate daily self-assessed symptoms using the MD Anderson Symptom Inventory core items (MDASI scale) through a pad interface
- Measure body weight using a balance directly connected to the inCASA platform.

The following expected benefits for the patients involve early detection of adverse events such as:

- Disruption of circadian activity patterns, reflecting severe fatigue, or other behavioural abnormalities related to treatment toxicities or cancer disease.
- Rapid weight loss resulting from gastrointestinal symptoms related to treatment toxicities or cancer disease.
- Deterioration of other symptoms related to cancer disease or treatments, such as pain, loss of appetite, etc.

This early detection/intervention can thus improve safety of complex medical treatments at home and minimize disruptions of familial and social environment of the patient. The incorporation of the inCASA platform will improve the speed and the quality of healthcare services.

5.3 Pilot setup and challenges

5.3.1 Target Group

Within the InCASA project, the pilot will involve 30-50 patients as end-users who have been diagnosed with cancer, but who are at a stage in the course of their disease where they are not too ill (defined as being ambulatory at least 50% of the daily time). Patients will be 65+ years old, be self sufficient and living at home (either alone or with spouse).

Inclusion criteria:

- Cancer patients at the age of 65+
- Cancer patients living at home and receiving chronomodulated chemotherapy treatment at home
- Cancer patients who are self-sufficient

Exclusion criteria:

- Cancer patients whose disease has progressed to the extent that they spend more than 50% of their time in ambulatory care.

Patients will be selected based on the criteria above. 5-6 patients per month will be selected to participate in the pilot. Selected patients will be approached by their doctor who will explain fully the extent of the pilot and what patients may expect from participating. If deemed necessary, of if the patient wish so, the patient's relatives will also be fully informed.

Patients will be able to freely choose whether they want to participate or (and may withdraw at any time), and it will be made clear that should they refuse to participate then this will have no impact on their existent care plan. Patients will sign the informed consent form provided by the project before they actively participate in the pilot.

Patients will have repeat opportunities to ask questions and raise any concerns with the health care staff involved in the pilot.

Proper education for both healthcare professionals and patients on how to use the system will be critical for to be successful work.

5.3.2 Pilot setup and resources

Recording the rest-activity rhythm by actigraphy with a real-time transmission and data treatment thanks to the inCASA platform is a totally new service. Currently, in our team we already study the rest-activity rhythm of cancer patients to adapt their chemotherapy in a chronotherapeutic way. This is not done in real time conditions yet: the data of the patients are analysed after several days of collection of the data.

The inCASA solution will provide a completely new service through the early detection of rest-activity pattern abnormalities for ameliorating cancer treatment and quality of life. In addition to this rest-activity recording, the daily follow up of body weight (before, during, after chemotherapy) and the daily self-assessment of symptoms scoring in real time conditions will provide complementary accurate data that will improve the early detection of abnormalities in the patient health conditions, and rapid well adjusted intervention.

The pilot will involve several users in addition to the end-user (the patient). These are:

- Family member or carer
- Medical oncologist
- Clinical assistant (PhD student)
- Nurses
- Other medical specialists
- Home care organisations

5.3.3 Pilot execution

The INSERM pilot will involve cancer patients of any age beyond 65 years, living at his/her own home and thus not hospitalized. The patients will be recruited in the outpatient chronotherapy unit in the department of Medical Oncology (Dr Francis Levi) at Paul Brousse hospital and will be followed as outpatients. This may include temporary hospitalizations of short duration (≤ 7 days).

Cancer patients will receive chronomodulated chemotherapy, eventually associated with other treatments (supportive or for associated diseases). Chronomodulated chemotherapy will involve programmable drug delivery systems for intravenous or intra-arterial administration and/or timed oral therapies.

The administration of complex chemotherapy protocols is well-accepted by the patients, yet it is not widely available. The chemotherapy unit of INSERM has a large experience of such treatment delivery at home involving more than 2500 patients treated with chronomodulated protocols based on circadian clocks.

The inCASA solution will fill a gap regarding the safety of such home care therapies through continuous collection of qualitative and quantitative information on complementary aspects of the patient health.

5.3.4 Challenges

One particular challenge is to define a proper method for educating all the users in how to use the inCASA system so that they feel confident in using it.

It may also be a challenge to ensure that patients fully understand the extent, consequences and purpose of the pilot (as required for informed consent). They will therefore be given plenty opportunity to ask questions and raise any concerns with the health care staff involved in the pilot.

5.3.5 Ethical requirements in France

In France, Act n°78-17 of 6 January 1978 on Data Processing, Data Files and Individual Liberties was amended by the Act of 6 August 2004 relating to the protection of individuals with regard to the processing of personal data. The Act brought French law into compliance with the EU Directive 95/46/EC.

The Act allows for the processing of personal data when: “necessary for the purposes of preventive medicine, medical diagnosis, provision of healthcare or treatment, or for the management of healthcare services and carried out by a member of a medical profession, or by any other person who, due to his functions, is bound by a duty of confidentiality as stipulated in Article 226-13 of the Criminal Code”.

The pilot is currently investigating whether a formal approval from the local ethical committee is necessary to obtain before the pilot can start. Should an approval be necessary, the pilot will see to it that this is done in timely order.

5.4 Scenarios and use cases

In this section we will describe the clinical and medical scenarios that are typical for the patient groups. Frome here, we have derived the clinical services, i.e. what exactly is to be measured (parameters, when and how often) and the use cases and workflows that will be used to execute the services.

In the expanded use cases, we will also look at what combination of services the pilots should offer and how these will compliment or replace existent services. In the 2nd phases of the pilot, we are thus planning to include some telecare services, e.g. by monitoring behavioural parameters.

5.4.1 Clinical scenarios

Cancer patient receiving chronomodulated chemotherapy and living at his/her own home:

- Starting point: rest-activity rhythm measurement through the inCASA platform shows a value of the I<O index below the alarm threshold (<93 %?).
- The system confirmed a consistent decrease of I<O below the alarm threshold during an additional 24 hours span; which will produce a specific alert on INSERM screen.
- The nurse calls the patient by telephone to check 1) the technical aspects (according to checklist), 2) the patient's condition and symptoms (according to MDASI scale), and 3) to provide immediate advices to improve I<O if relevant for the patient condition.
- If I<O deterioration persists over 24h, a contact between the patient and his/her physician is arranged on the same day by the nurse.
- These alarms are transferred to the patient chart to be studied by the medical oncologist for possible treatment adaptation at next consultation.

Cancer patient receiving chronomodulated chemotherapy and living at his/her own home:

- Starting point: a decrease of the body weight below the alarm threshold reported by the inCASA after chemotherapy administration.
- In parallel, the values of the self-assessed symptoms of anorexia, nausea, vomiting, are degraded below respective alarms thresholds during the same time duration.
- The nurse calls the patient by telephone to check about 1) the technical aspects (according to checklist), 2) the patient's condition and symptoms (according to MDASI scale), and 3) to provide immediate advices to improve I<O if relevant for the patient condition.
- If severe condition is confirmed, the nurses will arrange telephone consultation with medical oncologist or arrange patient transfer to the hospital.
- These alarms are transferred to the patient chart to be studied by the medical oncologist for possible treatment adaptation at next consultation.

5.4.2 Basic clinical use cases of inCASA services

The first phase of the pilot (12 months) will focus on monitoring various parameters while the patient is receiving cancer treatment at home. More specifically, the rest-activity circadian rhythm of the patient and self-assessed symptoms, as well as body weight, will be monitored and recorded.

The use case presented below represents the requirements for the first phase of the pilot as seen from a medical and clinical point of view. In the consolidation phase, the use cases will be made more specific and generalised, so that the same inCASA infrastructure and services can be used in different pilots with the appropriate personalisation.

Use case 1: Actigraphy

Overview: This service will allow for the real-time transmission and analysis of rest-activity rhythm while patients receive chemotherapy thus enabling rapid intervention if necessary. Despite INSERM already uses wrist actigraph, we do not have Bluetooth actigraph with a direct transmission of the data from the actigraph to a web platform. Thus, in association with the company Ambulatory Monitoring, a Bluetooth actigraph is being developed to be used in the inCASA project. This will be a totally new service.

Clinical purpose: Measure rest-activity rhythm using wrist actigraphy monitoring with a real time transmission of the data (Actigraph, Ambulatory Monitoring).

Procedure: Patients will receive the actigraph at the chronotherapy consultation, and will wear it at least for 3 consecutive weeks. Data will be recorded continuously at the frequency of 1 per minute. The actigraph will transmit the recorded data by transmission to the inCASA platform twice a day (early morning and late evening).

Analysis: The rest-activity rhythm data are analysed daily through the I<O index. The daily changes in this parameter are assessed along the recording process over 3 weeks or more. A filter generates an alarm to be sent to INSERM screen if I<O decreases below 0.93. After the system has evaluated the evolution of the I<O and r24 index during a sufficient time period, it will determine if this level is risky or not.

Data fusion: All actigraphic data will be stored in a dedicated computer with permanent internet connection to the inCASA server.

Alerts: The system confirmed a consistent decrease of I<O below the alarm threshold (0.93) during a 24 hours span; which will produce a specific alert on INSERM screen. The nurse calls the patient by telephone to check 1) the technical aspects (according to checklist), 2) the patient's condition and symptoms (according to MDASI scale), and 3) to provide immediate advices to improve I<O if relevant for the patient condition.

Feedback to patients and relatives: The nurse calls the patient by telephone to check 1) the technical aspects (according to checklist), 2) the patient's condition and symptoms (according to MDASI scale), and 3) to provide immediate advices to improve I<O if relevant for the patient condition. If deterioration persists over 24h, a contact between the patient and his/her physician is arranged on the same day by the nurse.

Personalisation: Use of other inCASA medical devices pending upon associated disease, for instance, blood pressure monitoring if hypertension is associated to cancer or cancer treatment.

Devices: 10 BlueTooth wrist actigraph, 10 hubs connected between the BlueTooth actigraph and the inCASA platform for the transmission of the actigraphic data.

Use case 2: Symptoms self-assessment

Overview: Rate daily self-assessed symptoms using the MD Anderson Symptom Inventory core items (MDASI scale) through a pad interface.

Clinical purpose: To collect complementary accurate data that will improve the early detection of abnormalities in the patient's health condition thus enabling rapid intervention if necessary.

Procedure: Patients will self-assess their symptoms on a pad interface connected to the inCASA platform once a day (in the evening). Symptoms will include pain, fatigue, nausea, disturbed sleep, distress, drowsiness, nausea, anorexia, and vomiting.

Analysis: The symptoms chosen are significantly altered with chemotherapy and/or cancer disease: fatigue, disturbed sleep, drowsiness, anorexia, nausea, vomiting, pain, distress. All of them are self-rated by the patient daily using the validated MDASI scale (Guirimand et al., 2010; Kirkova et al., 2006).

Data fusion: All data should be store in a dedicated computer with permanent internet connection to the inCASA server.

Alerts: if the self-assessed symptoms scores are worsening, an alarm will be generated if: symptoms are degraded to grade 3 or 4 during 24 h, or grade 2 during more than 3 days. Then, the nurse is alerted and calls the patient by telephone to check 1) the technical aspects (according to checklist), 2) patient condition and symptoms (according to MDASI scale), and 3) to provide immediate advices to improve I<O if relevant for the patient condition.

Feedback to patients and relatives: The nurse calls the patient by telephone to check 1) the technical aspects (according to checklist), 2) patient condition and symptoms (according to MDASI scale), and 3) to provide immediate advices to improve I<O if relevant for the patient condition. If deterioration persists over 24h, a contact between the patient and his/her physician is arranged on the same day by the nurse.

Personalisation: Use of other inCASA medical devices pending upon associated disease. For instance, blood pressure monitoring if hypertension is associated to cancer or cancer treatment.

Devices: 10 pad interfaces directly connected to the inCASA platform.

Use case 3: Body weight
Overview: To measure body weight using a balance directly connected to the inCASA platform.

Clinical purpose: To collect complementary accurate data that will improve the early detection of abnormalities in the patient's health condition.

Procedure: Patients body weight will be recorded once a day (early morning) using a balance weight transmitting data directly to the inCASA platform.

Analysis: Weight measurements are compared over several days.

Data fusion: As the balance is directly connected to the inCASA platform, all the data should be store in a dedicated computer with permanent internet connection to the inCASA server.

Alerts: If there is a consistent decrease in body weight between several data points, the nurse is alerted and calls the patient by telephone to check 1 the technical aspects (according to checklist), 2) the patient's condition and symptoms (according to MDASI scale), and 3) to provide immediate advices to improve I<O if relevant for the patient condition.

Feedback to patients and relatives: The nurse calls the patient by telephone to check 1) the technical aspects (according to checklist), 2) the patient's condition and symptoms (according to MDASI scale), and 3) to provide immediate advices to improve I<O if relevant for the patient condition. If deterioration persists over 24h, a contact between the patient and his/her physician is arranged on the same day by the nurse.

Personalisation: Use of other inCASA medical devices pending upon associated disease. For instance, blood pressure monitoring if hypertension is associated to cancer or cancer treatment.

Devices: 10 balances directly connected to the inCASA platform.

5.4.3 Expanded use cases

The second phase of the pilot will expand into long term multi-parametric monitoring of physical and behavioural parameters, thus including more telecare (social care) services. It will build on the results of the first pilot phase and will define a new group of older patients. The expanded use cases for this second phase will be described at the end of the first phase of the pilot.

However we can already foresee some elements that are relevant to be integrate in the second phase of the pilot. Indeed, the duration of the home recording of the same variables will be prolonged (> 12 weeks for example). Other relevant physiological or behavioural variables can be integrated pending upon patient conditions (blood pressure, oxymetry,. and correlation between all the variables). Enrolment of patients older than 75 years, and also complement the existing variables measured.

5.5 User Profiles

End-user/patient

The pilot will include male and female patients with advanced or metastatic cancer, with a performance status of 0, 1 or 2 according to the NCIC criteria (Oken et al., 1982), and a life expectancy superior to 6 months, so that they will benefit from the inCASA solution. Co-morbidities will not be an exclusion criterion.

The patients will have adequate cognitive functions ensuring good cooperation for protocol management. This will be assessed with oncogeriatric evaluation performed at specialized consultation, with for example the mini-mental state test (MMSE, score>24) (Folstein et al., 1975). All patients will sign a detailed consent form after oral and written explanations of the inCASA protocol by the doctor, according to ethical procedures.

Motivations of the patients are in accordance with the main aim of the inCASA solution. Indeed, the recording of their rest-activity rhythm with a real-time transmission will allow to adapt quickly their chemotherapy to their circadian profile and habits. Thus, they can expect improvements of their medical follow up, quality of healthcare and quality of life, thanks to the inCASA solution and better treatment adaptation to their health condition.

Carer/family member

Each patient will identify his or her carer or chosen family member who will have the role of assist him or her in taking measurements if necessary. The identification of this person will be done in an initial nurse consultation. This designed person will be the closest person involved to assist the patient in taking measurements in the everyday life. Thus, the carer/family member needs to have a sufficient cognitive level to understand the importance of his/her role in the good use of the inCASA solution. He or she will also need to have sufficient technical knowledge to assist the patient in the first line, for potential problems when taking measurement.

Medical oncologist (doctor)

In our INSERM pilot part, the doctor will be the person recruiting the patient and thus the first contact with the patient involved in the first stage of the inCASA protocol. The responsible doctor of the patient will explain the inCASA protocol to the patient (the advantages and constraints of the study, conducts of the protocol, etc.), thus the patient will have a thorough knowledge of the protocol and will have sufficient information to sign the consent.

The doctor following the recruited patient will have access to all the inCASA platform and services. There will be a need for technical training so that the doctor can explain the relevant technical aspects to the patients. This is required for the patient to display a good comprehension of the study, a prerequisite for an informed consent.

The main expectation of the inCASA solution for the doctor is a better knowledge of the impact of health condition on real life of his/her patients, including circadian aspects. This will enable the doctor to quickly adapt chronomodulated chemotherapy of his/her patient in order to best personalize treatment delivery.

Clinical assistant (PhD)

The clinical assistant will be implied at the second stage of the inCASA protocol and daily he or she will be the person most involved in the protocol. Indeed, the clinical assistant will be the reference person for the patient who will assist the patient in the beginning (installation), during (technical and administrative support), and in the end (de installation) of the inCASA study. Thus the clinical assistant will need to handle all the technical, medical and administrative aspects of the project.

The clinical assistant will also receive the data collected from the inCASA platform and will analyse them. This first analysis by an expert person of the patients' data will allow then to begin a discussion with the designed doctor (oncologist) in order to quickly adapt the patient treatments if there are abnormalities in the patients parameters collected. Will work with nurses to provide administrative support.

Nurses
The nurses will be the primary responsible for health care of the patient. They can receive information from all the partners involved in the inCASA protocol (patients, clinical assistant, medical oncologist, geriatric, other health provider). They can receive data from the clinical assistant, and also manage the possible critical data (i.e. alerts). So, they have to check data, alerts for transmitting the information to the relevant physicians (GP, oncologist, geriatric, and surgeon). Will work with the clinical assistant to provide administrative support.

Other Health Providers
The INSERM users described above will work in close cooperation with several medical specialists (i.e. oncologist, onco-geriatric, surgeon, GP). This collaboration with hospital partners will also be expanded to home care companies (public or private companies) for home hospitalisation, etc. Both organisations may be involved in the delivery of health care in the patient home. Indeed, they have large expertise and collaborations with Dr Lévi's chronotherapy unit.

5.6 Infrastructure and service provisioning

5.6.1 The inCASA architecture

In order to assess the rest-activity rhythm, BlueTooth wrist actigraph will be installed; hubs connected between the bluetooth actigraph and the inCASA platform for the transmission of the actigraphic data. Although INSERM already uses wrist actigraph, we do not have Bluetooth actigraph with a direct transmission of the data from the actigraph to a web platform. Thus, in association with the company Ambulatory Monitoring, a Bluetooth actigraph is being developed to be used in the inCASA project.

In order to implement the self-assessment of symptoms, pad interfaces will be directly connected to the inCASA platform. This will allow for the treatment of symptoms scoring in real-time conditions. These symptoms are currently rated every 2-3 weeks by the oncologist at the patient consultation, which precedes chronotherapy delivery.

Finally, the home monitoring of body weight will be carried out using weight scales connected to the inCASA platform. This service will provide critical objective and quantitative information on the gastro-intestinal effects of cancer treatment and/or cancer progression.

For the parameters studied by INSERM in the inCASA project, the different questions concerning the form of communication, data filter, data structures and technical management of the alarm systems are currently being discussed both at our INSERM site and with the other inCASA partners prior to final approval.

From a system point of view, the inCASA network model of the INSERM pilot is consisted of the following high-level entities:

- Sensor devices to measure rest-activity rhythm, body weight, and symptoms.
- Hub/ home gateway.
- The Hydra solution to establish communication between the home gateway and each device, as well as to the backup system and the inCASA back-end.

- Backup system located at the INSERM department.

5.6.2 inCASA pilot service installation

The services will be organised in association with the different persons involved in the INSERM pilot, and will be installed by the clinical assistant in close cooperation with nurses which need to be formed inside our team. This designed person will also be responsible for server maintenance, data collection, problem management, etc. The organisation of the services will be articulated for our pilot around the INSERM team, the Paul Brousse Hospital, the nurses, and medical specialists (geriatrics, oncologists).

6 Konstantopouleio General Hospital of Nea Ionia (KGHNI), Greece

Konstantopouleio General Hospital of Nea Ionia (KGHNI) is a University Hospital with more than 500 employees (doctors, nurses, physicians and administrative personnel). It offers almost all medical specialties. Surgery department is fully equipped, and participated in national and European medical research project.

During the last years Konstantopouleio General Hospital of Nea Ionia hospital has been carrying out extensive research in elderly people, exploiting the technological advances. Using novel methods and owning great experience, KGHNI's personnel will strongly impact in the test of the inCASA's use cases.

This inCASA infrastructure will give the doctors of the Department of Cardiology of KGHNI the opportunity to have a real close follow-up of the patients, estimate the efficiency and safety of the medical treatment, make the appropriate regulations of the medication dose, detect acute changes of patient situation and early treatment of acute problems.

6.1 Medical and social background for the pilot

Several epidemiological studies conducted in the USA and Europe concludes that both incidence and prevalence of cardiovascular diseases (CVDs) in elderly are increasing. The same prevalence patterns have been reported in Greece for this specific age group. Nearly two thirds of all deaths in women and men aged ≥ 65 years are associated to cardiovascular diseases. There is a significant geographic variation in morbidity and mortality due to cardiovascular diseases between different countries and within the same countries. Cardiovascular diseases are a major cause of disability in the elderly. Atherosclerosis, hypertension, diabetes, smoking, obesity, and sedentary lifestyle are the main responsible factors for cardiovascular diseases, which cause 70% of all deaths of people over the age of 75. There are also differences associated to the sex, the race, the nationality, the geographic distribution and also the economic costs. The increasing burden of cardiovascular diseases in the ageing population poses a substantial economic burden on societies and their health care systems. Early diagnosis, prevention, detection, therapy and prognosis of cardiovascular diseases in the elderly can enhance both the quality and the quantity of their lives.

Elderly people in Greece live mostly with their families or near their families. The majority of elderly people are taken care of by their family environment. Social and healthcare services are used for the cure (treatment) of ill people and not for primary prevention. In Greece there are some social institutions called "Open Care Centres for Elderly" (one in each neighbourhood) where elderly people can meet each other, participate in excursions, etc. About 300 of these centres are presently functioning all over Greece. Most of them are situated in big cities, and it seems that they are very successful as they fit the needs of the Greek population. The Open Care Centres for the Elderly in Greece has contributed to the maintenance and the improvement of the social contacts and the social relations between the elderly. The elderly within the Open Care Centres for the Elderly in Greece have many opportunities to meet with other persons of their age, and develop various activities and interests. The Open Care Centres also provides minimal out-hospital medical care. In general, Open Care Centres for the Elderly in Greece offers the following services to the elderly:

- Health education
- Social and recreational facilities
- Meal distribution
- Physiotherapy
- Occupational therapy

- Social work services
- Nursing services
- Home help services
- Voluntary services.

For seriously ill people who stay at home there are some social services by numerous organizations (municipality, hospital, social insurance). For example, the program “Help at Home” for the elderly in Greece was designed by the Ministry of Health and Welfare, with the aim to encourage the active involvement of the elderly in self health care within their family and social environment and the prevention of social exclusion. Thus the elderly can avoid admission to an institution that is traumatic for the physical and psychological health.

The program "Help at Home" for the Elderly in Greece offers:

- Nursing care provided at home by nurses
- Social care provided by social workers
- Home help provided by home aids
- Voluntary help provided by volunteers from the local communities.

But generally most of the care for elderly people is given by their families and this is considered the highest guarantee of high quality of elderly people life. Concerning the home environment most elderly people live in private houses with a minimum level of automation.

6.2 Objectives of the pilot

The Greek pilot has been designed with a view to achieve the following main objective: To demonstrate substantial prolongation of the time elderly people can continue to be at home, as well as the resulting increased efficiency of the social and health care systems.

The inCASA infrastructure will give the healthcare professionals at the Department of Cardiology of KGHNI the opportunity to have a close follow-up of the patients; estimate the efficacy and safety of the medical treatment; make the appropriate regulation of the medication dose; detect acute changes in the patient’s situation; and instigate early treatment of acute problems with either clinical or social means.

In parallel, our target through the project is to demonstrate substantial prolongation of the time elderly people can continue to be at home, as well as the resulting increased efficiency of the social and health care systems. Through this monitoring, we will ensure best medical compliance for patients after discharge while staying at home. The lack of compliance of the patients to the medical therapy is generally the main factor for therapy failure. So it is very important to monitor and improve this parameter. One step beyond stands the improvement of medical therapy if needed, the decrease of re-hospitalization need, the improvement of the quality of life for the patients and finally the improvement of quality and cost effectiveness of delivered health care services.

The pilot will also demonstrate that the incorporation of the inCASA platform will improve the speed of delivery and quality of healthcare services while at the same time reducing costs. Further, the social involvement of relatives will demonstrate a further increase in the patients’ quality of life.

The main objective is thus to be achieved through the following five specific objectives:

1. Ensure best medical compliance for patients after discharge while staying at home:
    a. Coagulation time objectives:
    b. Avoid fatal conditions of patients

   c. Detect acute conditions requiring hospitalisation
   d. Compliance with therapy
2. Improve medical therapy, if needed
   a. Patients are compliant
   b. Improve condition based on improved therapy
3. Increase quality of life for patients
4. Reduce the need for re-hospitalisation (cost view)
5. Improve quality and cost effectiveness of delivered healthcare services

The objectives are listed in no particular order. The objectives will be prioritised in the following prioritisation phase according to clinical significance, cost of pilot, complexity of the inCASA platform and need for consolidation with other pilots.

6.3 Pilot setup and challenges

6.3.1 Target group

The Greek Pilot will address its services to elderly people that live alone and who mainly suffer from Chronic Heart Failure (CHF). The reason of selecting a specific target group is to have a well formed strategy and to better monitor and analyze the pilot results. The KGHNI Cardiology Department has an extended experience concerning heart failure cases.

Elderly people often feel insecure because they have health problems related to their age such as hypertension, arrhythmias (palpitations), chronic obstructive pulmonary disease, heart failure and often diabetes. For the majority of them it is not easy to communicate with the doctor each time they feel that their situation is worsened. For example, many elderly people get very anxious with slight fluctuations of blood pressure of trivial medical importance. The inCASA infrastructure will alleviate the anxiety and provide more closely follow-up by healthcare professionals.

Patients in our target group often have concomitant problems, such as hypertension, diabetes mellitus, atrial fibrillation and other arrhythmias, need for anticoagulant therapy, that influence on their disease and should be monitored as well. By monitoring simple parameters, such as blood pressure, heart rate, partial prothrombin time (INR), blood glucose, and/or blood oxygen saturation level (O_2 saturation), the inCASA services can make them feel safer and their disease better managed without forcing them to physically come to the hospital. It can also prevent the deterioration of severe health problems by increasing the dosage of some medications at the appropriate time. It is our intension to follow up the most important parameters that could play a role in the clinical status of these patients.

The patients, who will participate in the pilot, will be selected from a special outpatient clinic of KGHNI created with the specific goal to support the inCASA project. KGHNI will choose the patients that will gain the most from participation in the pilot by considering the social and family profile of the elderly people.

End-user inclusion criteria:

- Elderly people with Chronic Heart Failure who live alone
- Suffer from concomitant problems

End-user exclusion criteria:

- Patients who are already managing their condition well.

All patients will be informed in detail about the project, the use of their data and their rights. They will then be asked to sign a consent statement.

6.3.2 Pilot setup and resources

In connection with the inCASA project we intend to create a new outpatient clinic in our hospital dedicated only to this project. In this clinic, there will be appropriate staff for daily collected data overview. Furthermore, this clinic will be the place where we will have consultation with our patients. Since it is an experimental project, we plan to organize a meeting with each patient once per week in order to accomplish the following:

- Examine the patients and compare our diagnosis with what inCASA system has produced. This will be crucial during the first time and until the system becomes stable and reliable
- Interview with patients where they will express their thoughts concerning the new platform that they use
- Give to the patients Questionnaires in order to better analyze Pilot results
- Inquire about quality of life improvement
- Patient may refer to a psychologist or psychiatrist if necessary.

During this visit, we may also compare the conclusions of inCASA platform with our own estimation of patient's condition and "system" data" will be cross-checked and validated by our team. In this way, we can answer the question if the inCASA system is reliable and propose amendments to its functionality where needed.

We believe that the pilot users will feel much more secure and confident about the new platform if they see in our hospital that there is a specific clinic dedicated to this purpose. That's why our hospital will proceed on the establishment of a new inCASA outpatient clinic.

6.3.3 Pilot execution

We schedule to include 25 patients in total. The pilot will be formed of 5 groups of 5 patients (and their relatives) in each group. No control group will be formed. Each group will be followed for about 1-2 months.

The groups will be subject to 5 parallel inCASA services and all patients and relatives will be provided with the necessary equipment and infrastructure as well as installation support and training. The use case will run for at least one month per group. The use cases and the equipment will be rotated every 1-2 months (in accordance with the group rotation noted above). This will help us use the same equipment more than once and allow us to analyse more parameters per patient. Last but not least, this equipment rotation will significantly decrease the project's costs.

The healthcare professionals and other staff members will initially be given a thorough overview of the inCASA platform and the services that are provided for the pilot. The users will be trained in the use of the services, including how to personalise the services to each patient and how to set up alert schemes

The healthcare professionals (doctors) will review the collected data on a daily basis. A weekly consultation with the patient will be set up. The consultations will involve the making of an echocardiogram, interview with the patient based on a questionnaire, inquiry about quality of life and referral to psychologist or psychiatrist, if necessary.

The target group consists of patients that live alone and/or have limited help from their family. It is obvious that these people need more social care and since inCASA aims to combine health and

social care, they are an appropriate target group. The social workers of our centre will play an important role in this effort.

6.3.4 Challenges

The following challenges have been identified and should be addressed as part of the pilot execution:

Proper use of monitoring devices / infrastructure by the participants: We will try to overcome this problem by appropriate education of the patients and relatives.

Establishment of confidence between the doctor, the participant and the monitoring system: This achievement will guide us to accomplish the main objective which is the improvement of patient quality of life.

6.3.5 Ethical requirements in Greece

In Greece, The Protection of Individuals with regard to the Processing of Personal Data Law 2472/1997 (as amended by Laws 2819/2000 and 2915/2001) states that: “The object of this law is to establish the terms and conditions under which the processing of personal data is to be carried out so as to protect the fundamental rights and freedoms of natural persons and in particular their right to privacy.”

The collection and processing of sensitive data is prohibited, unless the processing relates to health matters and is carried out by a health professional, who is subject to the obligation of professional secrecy or relevant codes of conduct. Furthermore, processing is allowed when necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of healthcare services.

All the medical trials or studies in Greece should be approved by the local Ethical Committee of the hospital in which the study is running. After this, the final approval should be given by the Regional Health Authority of Attica Greece.

In addition, the Greek pilot will prepare an information form and an informed consent form that will be presented to the selected patients during the inclusion visit.

6.4 Scenarios and use cases

In this section we will describe the clinical and medical scenarios that are typical for the patient groups. Frome here, we have derived the clinical services, i.e. what exactly is to be measured (parameters, when and how often) and the use cases and workflows that will be used to execute the services.

In the expanded use cases, we will also look at what combination of services the pilots should offer and how these will compliment or replace existent services.

6.4.1 Clinical scenarios

To better present our goals and workflows we state below two use-case scenarios:

CHF patient with atrial fibrillation and anti-coagulant therapy.

Starting point: INR measurement through the inCASA platform shows a value of 5.3.

- After the system has evaluated this INR value as risky and after producing the relevant alert in our screen, the patient is informed to cease anti-coagulant pills and asked to inform us if

there is any minor or major sign of bleeding. He is asked to repeat the measurement after 2 or 3 hours.
- In our scenario, the same value is observed.
- A nurse or a medical resident visits him at home confirming that there is no bleeding.
- The next day's measurement shows a value of INR 9. The social worker is informed and arranges transfer of the patient to the hospital since such INR value requires immediate hospitalization.

CHF patient who lives alone with optimal medical therapy

- An increase in body weight (2 KGs) is observed through the inCASA system over one day period. Such scenario indicates also the already expressed need for historical data of the patient. Profiling a user is a core element in inCASA architecture as it will allow us to automatically detect cases of divergence.
- In parallel, the values from oximetry show a worsening of O2 saturation from a value of 95% to 89% (again historical data are crucial).
- Heart rate at this day shows an average value of 90-95 beats/minute with the value of the previous days being no more than 75 beats/minute.
- Blood pressure is also increased to a value of 180/90 mmHg while previous days measurements did not exceed the value of 120/80 mmHg.
- As an outcome of the above measurements, a resident doctor is informed for all these data by our nurse dedicated to this purpose.
- The doctor makes the conclusion that there is a worsening of the heart failure and asks the specialist cardiologist for extended help.
- The cardiologist decides that there is need for more diuretics and vasodilators and so alters the medical treatment respectively.
- The patient is informed for these changes and confirms us that he/she can follow our instructions.
- Our social worker informs the patient's relatives and makes sure that he/she could have some help from them.
- Upon refusal, he is ready to visit the patient at home by himself.

After all these actions, in the next day the patient's parameters are improved and the patient feels much better. Through this workflow combining automated measurements, social help and medical expertise a re-hospitalisation has been avoided.

6.4.2 Basic clinical use cases of inCASA services

The first phase of the pilot (12 months) will focus on monitoring physiological and behavioural parameters and providing tools for healthcare professionals that allow them to more closely follow medical compliance and improve medical therapy in the first period after discharge from the hospital.

The use case presented below represents the requirements for the first phase of the pilot as seen from a medical and clinical point of view. In the consolidation phase, the use cases will be made more specific and generalised, so that the same inCASA infrastructure and services can be used in different pilots with the appropriate personalisation.

Use case 1: Body weight
Overview: This service will provide a reminder to the patient about measuring his/hers body weight, check that the patient has done so, and send the measured value to a backend system where it is evaluated and stored.

Clinical purpose: An increase weight i.e. 1 kilo per day over maximum 2 days is an indication of body fluid retention i.e. worsening of condition, which needs proper intervention of a doctor.

Procedure: Measure every morning after visit to the toilet. It could be considered to have a reminder send to the patient after the toilet flushes between 7 and 10am in the morning.

Analysis: Weight measurements are compared over two consecutive days. If there are several measurements per day, the data from approximately the same time in the morning are compared.

Alerts: If the is a consistent increase in body weight of more than 1 kg between three data points, the responsible doctor is alerted.

Feedback to patients and relatives: None.
Personalisation: It is a requirement that the service can be personalised to each individual patient in terms of time of day and increment of the weight measurements.

Devices: For example A&D UC-321-PBT Electronic Scale. Bluetooth interface to gateway. One device for each of the 5 patients in a group.

Use case 2: Blood pressure
Overview: This service will provide a reminder to the patient about measuring his/hers blood pressure, check that the patient has done so, and send the measured value to a backend system where it is evaluated and stored.

Clinical purpose: The patient shall measure his/her blood pressure with a suitable device that can measure systolic, diastolic and average the blood pressure. It should also be able to measure the heart rate (pulse). With these measurements doctors can estimate the efficacy of the medications and the appropriate dosage. They can also see if patients have arrhythmias, combine them with reported palpitations and call the patient for further evaluation.

Procedure: Measurements shall be performed e.g. 3 times a day and the average should be calculated. However, for patients with fibrillations, this procedure is not useful. These patients should make the average over more measurements or discard the first measurement before averages are calculated. The patient may be notified of the need to perform the measurement.

Analysis: Data should be analysed for correctness (should be within certain limits) before being send on to the backend system where a clinical evaluation shall be performed. This evaluation will be based on filtering the measured value or comparing it to a reference value.

Data fusion: All data should be store in a suitable Electronic Healthcare Record.

Alerts: If values are outside certain bands, the responsible doctor should be alerted.

Feedback to patients and relatives: None.

Personalisation: It is a fundamental requirement that the service can be personalised and adapted to each individual patient and each doctor's preferences.

Devices: For example A&D UA767-PBT Blood Pressure Monitor with two sizes of inflatable arm cuffs. Bluetooth interface to gateway. One device for each of the 5 patients in a group.

Use case 3: Pulse oximetry
Overview: This service will monitor the patient's oxygen saturation level and follow its trend. If the patient's condition is deteriorating, the doctor and the patient are alerted.

Clinical purpose: Pulse oximetry is a non-invasive method allowing the monitoring of the oxygenation of a patient's haemoglobin. Oxygen saturation (S_{O2}) measures the percentage of haemoglobin binding sites in the bloodstream occupied by oxygen. S_{O2} is important to follow in patients with COPD or heart failure. Trends of the values of S_{O2} can predict if the patient is deteriorating. Doctors can then increase the medication or ask the patient to come to the hospital before the situation becomes critical.

Procedure: Measure the S_{O2} 3 times daily e.g. in connection with blood pressure measurements.

Analysis: Values are pre-conditioned at the point of measurement. Trends of the values of S_{O2} are derived from stored data.

Data fusion: All data should be store in a suitable Electronic Healthcare Record.

Alerts: Doctors are alerted of deteriorating condition and can take action (change in medication) via phone or by sending feedback to the patient. In serious cases, the patient can be called into the outpatient clinic.

Feedback to patients and relatives: Confirmation of changes of medication shown on display and send via SMS to relatives. Call for visits to the outpatient clinic can be confirmed by SMS to the patient and relatives.

Personalisation: None.

Devices: Several pulse oximetry devices exist in the Continua alliance list.

Use case 4: Heart rate

Overview: This service will measure the patient's heart rate when the patient is measuring blood pressure.

Clinical purpose: When a divergence in heart rate is observed, it may mean alteration of the clinical status of the patient.

Procedure: Collect the pulse data from the blood pressure monitor in connection with blood pressure data transmission. Data should be measured at least 3 times a day.

Analysis: Normal values are inside the range of 50 beats per minute and 100 beats per minute.

Data fusion: All data should be store in a suitable Electronic Healthcare Record.

Alerts: In serious cases, the patient can be called into the outpatient clinic.

Feedback to patients and relatives: A reminder could be sent to the patient if there are less than 3 measurements per day.

Personalisation: The analysis of the results should take into consideration if the patient has atrial fibrillation and/or other arrhythmias in order not to generate false alarms because it is quite common in such kind of patients to have heart rate abnormalities.

Devices: Heart rate can be measured with the BP monitor or oximetry meter.

Use case 5: Heart rhythm

Overview: The service will continuously measure the patient's heart rhythm, even when the patient is outside the home.

Clinical purpose: Arrhymia must convert to sinus rhythm within 24 hours to avoid heart attack. The monitoring must be able to detect arrhythmia and sinus rhythm.

Procedure: The patient wears a three or five point recording of ECG signals. Recordings can be either continuously or in regular time slots of at least 30 seconds each.

Analysis: ECG signals are analysed for arrhythmia and sinus rhythm. This is best done in an existing telemetry system.

Data fusion: All ECG data should be registered in the existing telemetry system at the Cardiology Department of the KHGNI

Alerts: If heart rhythm has not returned to sinus rhythm within a set time, the resident doctor is alerted.

Feedback to patients and relatives: None

Personalisation: The analysis of the results should take into consideration if the patient has atrial fibrillation and/or other arrhythmias in order not to generate false alarms because it is quite common in such kind of patients to have heart rhythm abnormalities.

Devices: ECGLink is a smartphone application developed by Care2wear (Denmark) which has a 5-point mobile solution. The ECG signals are sent to a central telemetry system via a GSM telephone.

Use case 6: Blood glucose

Overview: The service will collect and record measured data for blood glucose levels and provide feedback to the patient if adjustments are necessary.

Clinical purpose: Blood Glucose measurements are important in order to monitor blood glucose levels of diabetic patients with heart failure and adjust the dosage of their medication (pills of insulin) according to their needs.

Procedure: Diabetic patients measure their blood glucose levels 1 or 2 times per day. Non-diabetic patients do it once per week. Blood glucose levels are measured in a blood sample using traditional stick methods.

Analysis: Normal value is less than 120 mg/dl

Data fusion: All data should be stored in a suitable Electronic Healthcare Record.

Alerts: In case of patients that suffer from diabetes mellitus an alert should be generated when blood glucose exceeds 200 mg/dl while in other patients an alert should be generated when blood glucose exceeds 120 mg/dl. In serious cases, the resident doctor should be informed and if needed the patient can be called into the outpatient clinic.

Feedback to patients and relatives: None.

Personalisation: As described above, there should exist a discrimination between patients who suffer from diabetes mellitus or not.

Devices: Roche AccuCheck BG devices can be used.

Use case 7: INR (partial prothrombin time)
Overview: The service will collect and record measured INR data and will provide alerts to healthcare professionals and feedback to the patient if adjustments are necessary.

Clinical purpose: Arterial fibrillation can cause strokes and patients need to take anticoagulant medication. The regulation of the dosage is very difficult and depends on multiple INR (partial prothrombin time) measurements. The use of home INR measurements and the monitoring by a doctor is a very reassuring and very convenient service for the patients. It can also avoid cases of severe bleeding or ineffective dosage.

Procedure: INR measurements are performed once per week.

Analysis: The normal range is 1 - 2, but for CHF patients it is better to aim for 2 – 2.5. If the value is greater than 5 the patient is in a risky situation and if it is greater than 9 requires immediate intervention.

Data fusion: All INR data should be stored in a suitable Electronic Healthcare Record.

Alerts: Healthcare professionals are alerted if the values exceed 5.

Feedback to patients and relatives: None.

Personalisation: INR measurements should be examined with priority in CHF patients with anti-coagulant therapy.

Devices: Home INR devices exist but are quite expensive. So there are sticks to be used.

Use case 8: Movement
Overview: The service will monitor the movement of the patient in the home and alert healthcare professionals of abnormal conditions.

Clinical purpose: CHF patients have in general reduced mobility. A reduction in the average daily mobility (i.e. staying more hours in the bed) is a strong indicator of clinical status worsening. Another explanation for this reduced mobility could be the onset of depression something very common in these patients. The movement sensors will play a key role in the "social part" of the project as they can help us produce conclusions of the patient's psychological status much easier than any other clinical monitoring device.

Analysis: In order to determine the best course of therapy, physicians often assess the stage of heart failure according to the New York Heart Association (NYHA) functional classification system. The NYHA system relates symptoms to everyday activities and the patient's quality of life:

Class	Patient Symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is

	undertaken, discomfort is increased.

An advanced algorithm needs to be developed that allows the service to distinguish between class II and class III/IV. This algorithm should take into account the movements, the number of people in the home as well as subjective input from the patient.

Procedure: Movements are continuously measured in different sections of the home. Subjective input is provided via keyboard and video conferencing.

Data fusion: All data should be stored in a suitable Electronic Healthcare Record.

Alerts: Healthcare professionals are alerted if the algorithm detects class III or higher. Or if there is a change from one class to a higher class.

Feedback to patients and relatives: When there is a change from one class to a higher class, our social workers should call and encourage the patient. In parallel, relatives should be informed for such deterioration.

Personalisation: There should be a discrimination between patients that already had kinetic problems and the others that did not have. The system should not generate false alarms for the patients of the first category.

Devices: Wireless movement sensors are inexpensive and easy to install. Steinbeis can provide bed sensors that measure the time the patient spends in bed.

Use case 9: Instantaneous video conferencing

Overview: The service will allow the doctors or the patient to initiate a video conferencing session over the inCASA infrastructure.

Clinical purpose: In most cases of deteriorating conditions of the patient, the visual impression of the patient provides extremely valuable information to the doctor. In some cases it is absolutely necessary in order to make the right decision and many calls for admission to the acute department or to the outpatient clinic can be avoided if there is video conferencing capability in the inCASA system. Further, it provides security and a sense of well being to the patient.

Procedure: The video conferencing can be initiated either by the patient, in case of need, or by the doctor or nurse, in case of an alerted situation.

Analysis: Not applicable.

Data fusion: Time and length of the video consultation is stored in a suitable Electronic Healthcare Record.

Alerts: Not applicable.

Feedback to patients and relatives: Not applicable.

Personalisation: Not applicable.

Devices: The company CareView (Denmark) has a video consulting service that runs over ADSL or 3G lines. Special buffering technology provides Quality of Service management.

6.4.3 Expanded use cases

The second phase of the pilot will expand into longer term, multi-parametric monitoring of physiological and behavioural parameters. It will build on the results of the first pilot phase and will define a new group of older patients, who are living alone and do not have relatives in close vicinity.

The expanded use cases for the second phase of the pilot will be described at the end of phase one. However, some elements are already foreseen at present.

Local evaluation and data fusion
It will be desirable to relate one measurement to another, e.g. movement and oximetry. The purpose is to see if there is a correlation between the two.

It will also be interesting to combine more parameters such as lower mobility, decreased blood pressure, etc. which could points to a worsening condition, and involve home nurses or social care workers to visit the patient and provide advice and local care.

Social and healthcare integration - Influence of other parameters
Depression monitoring, need for medication and rehabilitation also leads to more involvement of home nurses or social care workers.

Compliance to medical therapy
The compliance with prescribed medicine intake is extremely important and one of the most common source of poor medical therapy. An electronic medication dispenser is available which can be used to monitor medicine compliance and alert patients, relatives and healthcare professionals of actual compliance.

Services involving home nurses and/or social workers
Several examinations, such as blood and urine tests, can in most cases only be performed in the home by involving home nurses and/or social workers. The inCASA platform can provide accessibility enhancing services (electronic keys, identity management, etc) and involving workflow optimisation for alert responses.

6.5 User profiles

End-user/patient
The patient (end-user) is the person who will have the monitoring equipment in their home, take measurements, input data into monitoring system and receive data, e.g. reminder to take pills, visit the hospital, or visit an Open Care Centre.

- Receive guidelines from healthcare professionals (possibly by phone, SMS or text display)
- Receive instructions from doctors (e.g. to visit the hospital, outpatient clinic or Open Care Centre).
- Receive reminders (e.g. to take pills, perform measurements).

Carer/family member
The person nominated by the user who may also view user data / assist user in taking measurements / assist patient in taking measurements or receive alerts from the condition of the elderly.

- Receive alerts about the condition of the elderly person and possible guidelines to alleviate the problems (e.g. by SMS or by phone in case of emergencies).

Clinician (Interns)

Interns are the first line clinician responsible for the patient. Will review the data on the web user interface, set alerts and liaise with the Chief medical responsible.

- Continuous monitoring of patients' parameters via a system (possible web system) accessible from the hospital. The system must ensure security and integrity of the delivered data.
- Ability to generate alerts to appropriate specialized doctors.
- Ability to send messages and communicate with the patients (e.g. send informative sms or phone).

Chief medical responsible
The clinician having overall responsibility for the patient and the procedures of the department will have the following roles and reasonability:

- Receive alerts (sms, mms, phone, etc.).
- Define emergencies/alerts based on parameter values.
- Define procedures that will be followed in case of emergencies.
- Define emergencies/alerts based on parameter values.
- Define procedures that will be followed in case of emergencies.

Psychologist – Psychiatrist
These users will interfere when there are signs of depression in our patients. As already mentioned, CHF patients may often develop depression during their disease.

Nurses
Nurses will be the first level support for our patients.

- Be the first to receive incoming patients' data on a 24/7 basis.
- Could apply any needed changes concerning patient's treatment and medication at home if the patient is unable to do it (lonely elderly people case).

Social workers
The social workers from our hospital will help the patients with daily task:

- Train them in the use of the new equipment given to them.
- Ensure their compliance to the medical treatment.
- Arrange their transportation from and to the hospital if needed.

inCASA installer
Will be responsible for the installation, de-installation of equipment and of patient training.

Admin Support
Will be responsible for providing support / answering calls from patients and support clinician.

6.6 Infrastructure and service provisioning

6.6.1 The inCASA architecture

Seen from a system point of view, the inCASA network model of the Greek pilot is consisted of the following high-level entities:

- Sensor devices to measure clinical or mobility data (to be further defined).
- Hydra proxies to establish communication between the home gateway and each device

- Home Gateway / Hub
- Backend system (EPR) located at our hospital.

The service will be installed and configured in the patients' homes with the appropriate devices and infrastructure.

The inCASA services will be based on a single gateway in the patient's home which connects the devices to a central server at KGHNI. The gateway will be OSGi compliant and delivered by Steinbeis. Hydra proxies will be used for medical and home monitoring devices. Sensors will be acquired from the relevant manufacturers.

The inCASA server will in turn connect to a dedicated EPR to be delivered by REPLY which will include patient registration and administration, data repositories for measured patient data and the necessary tools for securing privacy and data protection. An external inCASA database will be set up for extracting data for later transferral to a permanent service installed after the pilot.

The communication will be over ADSL lines, if such lines are already present in the patient's home. If not, a 3G data communication will be established. For simplicity, 3G communication may be established regardless of the availability of ADSL.

6.6.2 inCASA pilot service installation

The main inCASA server will be installed at the well equipped KGHNI Cardiac Care Unit and will make use of the existing infrastructure. There will be a need to enhance this server with the inCASA services platform.

The responsibility for the service installation will be as follows:

- KGHNI: Medical staff of the Department of Cardiology of KGHNI will choose the patients, follow up the parameters, define alarms and alerts, etc. Setting up of server and infrastructure in cooperation with NTUA and other partners.
- NTUA: Developers will design and implement the vertical services and applications. Technical staff will install, configure the equipments and provide maintenance.
- CNET: Provider of Hydra middleware and support for the development of the services.
- KGHNI will source the medical devices.
- NTUA will setup and arrange for network and communications infrastructure.

7 Policy, Regulatory and Standards Requirements

It is crucial to be aware of the policy and regulatory requirements that may affect the implementation of (new) e-Health services, such as those proposed by the inCASA project, as this is a prerequisite for entering the market.

This chapter will give an overview of the main EU policies, directives and standards that are relevant to inCASA and that need to be taken into account in designing the inCASA applications in each pilot. The deliverable D2.3 European country policies and ethical package will take a closer look at the national policies in the five pilot countries: England, France, Greece, Italy, and Spain.

7.1 EU policy programmes and action plans

EU policy programmes and action plans contain a number of policy statements and aims, which will have the potential to enter into direct regulations or stimuli at the medium to longer term. Policy programmes and action plans as such, normally does not lead to specific requirements for the pilot application, but may give useful hints and ideas for the development of sustainable services.

This section provides an overview of the policy programmes that may have an impact on the requirements for inCASA pilot applications.

7.1.1 The European Convention for the Protection of Human Rights and Fundamental Freedoms

The right to privacy is a human right and is protected by legislation. The European Convention for the protection of Human Rights and Fundamental Freedoms (ECHR) of 1950 which formed the European Court of Human Rights provides a very high protection of the individual [11]. The ECHR provides the legal background for the development of specific legislation to protect the interest of the citizen when ICT is used in healthcare. Article 8 of the ECHR, on privacy, is very relevant for healthcare ICT, e.g. regarding protection of personal data.

Article 8 states that:

1) Everyone has the right to respect for his private and family life, his home and his correspondence.
2) There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

Relevance to inCASA
inCASA technologies and application will have the necessary security measurements in order to protect privacy and personal data. Informed consent forms will be obtained from all end-users.

7.1.2 EU Charter of Fundamental Rights

The EU Charter of Fundamental Rights was signed in December 2000 and it defines the whole range of civil, political, economic and social rights of European citizens and all persons resident in the EU [12]. Article 7 and 8 of the Charter are especially important regarding privacy and data protection:

Article 7: Respect for private and family life:
1) Everyone has the right to respect for his or her private and family life, home and communications

Article 8 Protection of personal data:

1) Everyone has the right to the protection of personal data concerning him or her.
2) Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3) Compliance with these rules shall be subject to control by an independent authority.

The Charter is also important to consider when discussing ethical issues in relation to healthcare and assistive ICT (cf. deliverable D2.3 European country policies and ethical package).

Relevance to inCASA
inCASA technologies and applications will have the necessary security measurements in order to protect privacy and personal data. Informed consent forms will be obtained from all end-users.

7.1.3 Europe 2020: A strategy for smart, sustainable and inclusive growth

This particular communication from the Commission responds to the current economic crisis that has swept through Europe [13]. It wants to look beyond the short time goal of getting through the crisis, and looks at the lessons learnt and how to secure more jobs and better lives for the future. Active and healthy ageing is considered an important part of the strategy for inclusive growth, and represents a particular challenge for meeting the goals. The deployment of accessible online health and smart home is defined as an aim on national level. On EU level the aim is to create a single market for online content and services, to increase support in the field of ICT, and to promote internet access and take-up through actions in support of digital literacy and accessibility.

Relevance to inCASA
inCASA enabled services tested by the pilot sites may demonstrate how ICT can promote healthy ageing and prolong the time elderly can stay at home. This will potentially mean economic and resource savings on health and social care services for the elderly and people with chronic conditions.

7.1.4 A Digital Agenda for Europe

This is a follow-up *to i2010 – A European Information Society for growth and employment* that highlights the potential and importance of health care ICT for improving the quality of care; reduce medical costs and further independent living [14]. Its focus on e-Health fit in with the aims and objectives of inCASA. Notably, the monitoring of people with chronic diseases is stressed, and the fact that this type of service will allow patients a newfound freedom of movement, is conceived as a particular benefit which also enables independent living. Ambient Assisted Living (AAL) is also highlighted, particularly monitoring of chronic patients including services to support fall prevention and support for people with dementia. These types of e-Health systems and services are considered as key to promote independent living among the elderly. Two key action points for e-Health are mentioned:

- Undertake pilot actions to equip Europeans with secure online access to their medical health data by 2015 and to achieve by 2020 widespread deployment of telemedicine services;
- Propose a recommendation defining a minimum common set of patient data for interoperability of patient records to be accessed or exchanged electronically across Member States by 2012.

Two additional action points are mentioned:

- Foster EU-wide standards, interoperability testing and certification of e-Health systems by 2015 through stakeholder dialogue;
- Reinforce the Ambient Assisted Living (AAL) Joint Programme to allow older people and persons with disabilities to live independently and be active in society.

Relevance to inCASA
The issue of interoperability is a crucial prerequisite for successful e-Health services and products and in the inCASA platform this is precisely designed to allow interoperability of diverse devices.

7.1.5 Ageing well in the information society

In realising the potential of ICT for ageing, but also recognising the so far failure to take full advantage of this potential, the EU has put forward an action plan in 2007 on ageing well in the information society: *Ageing well in the Information Society: An i2010 Initiative. Action Plan on Information and Communication Technologies and Ageing* [2].

The objectives of the action plans is to enable a better quality of life for older people with significant cost-savings in health and social care, as well as to help creating a strong industrial basis in Europe for ICT and ageing. The action plan focuses on three areas of ageing well:

- Ageing well at work: staying active and productive for longer, better quality of work and work-life balance with the help of easy-to-access ICT, innovative practices for adaptable, flexible workplaces, ICT skills and competencies and ICT enhanced learning (resp. e-skills and e-learning)
- Ageing well at home: enjoying a healthier and higher quality of daily life for longer, assisted by technology, while maintaining a high degree of independence, autonomy and dignity
- Ageing well in the community: Staying socially active and creative, through ICT solutions for social networking, as well as access to public and commercial services, thus improving quality of life and reducing social isolation (one of the main problems of older people in rural, scarcely populated areas, as well as urban areas with limited family support).

The action plan's recommendations will benefit citizens, companies, and authorities in Europe in the following ways:

- Citizens: a better quality of life and better health through prolonged independent living, active ageing at work ensuring that older workers can regularly update their competencies, and increased social participation
- Companies: increased market size and market opportunities in the internal market for ICT and ageing in Europe, better skilled and productive workforce and a stronger position in the growing markets worldwide
- Authorities: cost-reductions, increased efficiencies and better overall quality in health and social care systems.

Relevance to inCASA
The objective identified here fit in with the objectives and aims of the inCASA project. Ageing well at home and Ageing well in the community are particularly relevant to the inCASA pilots that combine health and social issues. One of the main objectives of inCASA is precisely to support the end-user (i.e. the elderly person) independence, autonomy and dignity, and prolonging the time they can stay at home.

7.1.6 Together for Health: A Strategic Approach for the EU 2008-2013

On 23 October 2007 the European Commission adopted a new Health Strategy, "Together for Health: A Strategic Approach for the EU 2008-2013" [15]. The strategy aims to provide an overarching strategic framework spanning core issues in health as well as health in all policies and global health issues. The strategy aims to set clear objectives to guide future work on health at the European level, and to put in place an implementation mechanism – The Second Programme of Community Action in the field of Health 2008-2013 [16] – to achieve those objectives, working in partnership with Member States.

Three main challenges which spurred the development of this new health strategy are mentioned: 1) the ageing population, 2) new potential threats to health, and 3) the development of new technologies (including information and communication technologies). The first and third challenge is of particular relevance to the inCASA project:

- **The ageing population: Supporting healthy ageing and increasing healthy life years**
  The population ageing is likely to raise demand for healthcare while also decreasing the working population. This could push up healthcare spending by 1 to 2% of GDP in Member States by 2050. On average this would amount to about a 25% increase in healthcare spending as a share of GDP. However, Commission projections show that if people can remain healthy as they live longer, the rise in healthcare spending due to ageing would be halved.

  Healthy ageing must be supported by actions to promote health and prevent disease throughout the lifespan. Healthy ageing is supported by taking action to promote healthy lifestyles and reduce harmful behaviours. The action point on behalf of the Commission is to undertake measures to promote the health of older people and the workforce and actions on children's and young people's health.

  It is important that sophisticated and intelligent medical devices are developed according to the needs and demands of both patients and healthcare professionals. Intelligent devices must be interoperable allowing them to interact with other devices and services. The implementation of e-Health services faces a challenge in ensuring interoperability of heterogeneous systems and devices.

- **Development of new technologies: e-Health can improve care**
  New technologies have the potential to revolutionise healthcare and health systems and to contribute to their future sustainability. e-Health, genomics and biotechnologies can improve prevention of illness, delivery of treatment, and support a shift from hospital care to prevention and primary care. e-Health can help to provide better citizen-centred care as well as lowering costs and supporting interoperability across national boundaries, facilitating patient mobility and safety.

  The Health Strategy states that nevertheless "new technologies must be evaluated properly, including for cost-effectiveness and equity, and health professionals' training and capacity implications must be considered. New and unfamiliar technologies can generate ethical concerns, and issues of citizen's trust and confidence must be addressed".

  To boost investment in health systems, the Commission has already instated a number of instruments aimed at enhancing EU growth, employment and innovation including the Lisbon strategy. The instruments include the 7th Framework Programme for Research, the Joint Technology Initiative on Innovative Medicines, the Competitiveness and Innovation Programme and Regional Policy. However, further action is needed, e.g. in relation to the capacities of regions, which are key actors in delivering healthcare.

A clear Community framework will also help to support dynamic and sustainable health systems by providing clarity regarding application of EC law to health services and support Member States in areas where coordinated action can bring added value to health systems. Specific actions foreseen in this area includes a community framework for safe, high quality and efficient health services, support for Member States and Regions in managing innovation in health systems and support implementation and interoperability of e-Health solutions in health systems.

Relevance to inCASA
Challenge 1 "the ageing population and Challenge 3 "the development of new technologies (including information and communication technologies)" are particularly relevant to inCASA's aims and objectives. The inCASA pilots may thus provide useful knowledge and experiences in how to meet these challenges.

7.1.7 On telemedicine for the benefit of patients, healthcare systems and society

In 2008 a communication from the Commission on telemedicine for the benefit of patients, healthcare systems and society once again stressed the importance of ensuring interoperability and standardisation in relation to telemedicine [17]. The following action points are defined:

- By the end of 2010, the Commission invites industry and international standardisation bodies to issue a proposal on the interoperability of telemonitoring systems, including both existing and new standards
- By the end of 2011, the Commission, in cooperation with Member States, will issue a policy strategy paper on how to ensure interoperability, quality and security of telemonitoring systems based on existing or emerging standards at European level.

Some Member States already have legal frameworks considering telemedicine. In other Member States existing privacy regulations in the medical domain may actually hinder the use of telemedicine, e.g. the physical presence of the patient and the health professional in the same place is required for it (the medical act) to be legally recognised as a medical act. Limitations in law or administrative practice on reimbursement of telemedicine may also act as a hinder of the deployment of ICT-enabled healthcare services and provisions.

Relevance to inCASA
Future policy developments in these areas are relevant to inCASA as the legal environment may limit the possibility of implementing e-Health services in some Member States.

7.1.8 Cross-border interoperability of electronic health record systems

In this recommendation from the Commission, the importance cross-border interoperability of electronic health record systems is explained further [18]. The recommendation highlights that the current lack of interoperability of electronic health record systems not only jeopardises the quality and safety of care, it also restrICT the free movement of patients and healthcare professionals. Interoperability must be achieved and it must be safe and secure, thus protecting the privacy and data of the individual. The following directives and regulation to safeguard the individuals' rights are therefore highlighted:

- Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms
- Article 8 of the EU Charter of Fundamental Rights
- Directive 95/46/EC

- Directive 2002/58/EC

Relevance to inCASA
This recommendation is highly relevant for inCASA as interoperability is exactly what the inCASA solution is based upon. As inCASA is at the same time dedicated to maintain strict rules of privacy adherence to the directives mentioned here will be given.

7.2 EU Regulatory requirements

EU directives provide both indirect and direct legal requirements which the inCASA services and applications will have to observe and apply with. The following section brings an overview of the relevant directives from which the requirements for each pilot application can be derived.

7.2.1 Directive 95/46/EC on processing personal data

With the development of e-Health in Europe, it is important to consider the issue of personal data protection. The Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data applies “to the processing of personal data wholly or partly by automatic means, and to the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system” [19].

In relation to national laws, the Directive states that: “Each Member State shall apply the national provisions it adopts pursuant to this Directive to the processing of personal data where: (a) the processing is carried out in the context of the activities of an establishment of the controller on the territory of the Member State; when the same controller is established on the territory of several Member States, he must take the necessary measures to ensure that each of these establishments complies with the obligations laid down by the national law applicable; (b) the controller is not established on the Member State's territory, but in a place where its national law applies by virtue of international public law; (c) the controller is not established on Community territory and, for purposes of processing personal data makes use of equipment, automated or otherwise, situated on the territory of the said Member State, unless such equipment is used only for purposes of transit through the territory of the Community.”

Relevance to inCASA
inCASA technologies and applications will have the necessary security measurements in order to protect personal data. Informed consent forms will be obtained from all end-users.

7.2.2 Directive 2002/58/EC on data protection

The development of ICT raises some specific requirement issues to ensure the users’ right to privacy and protection of data. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector identifies various requirements that must be met for user to trust electronic communication services [20]. Of particular relevance to inCASA, the Directive states that the provider of an electronic communications service must protect the security of its services by: 1) ensuring that personal data is accessed by authorised persons only; 2) protecting personal data from being destroyed, lost or accidentally altered; and 3) ensuring the implementation of a security policy on the processing of personal data.

Relevance to inCASA
inCASA services will have the necessary security measurements in order to protect privacy and personal data. Informed consent forms will be obtained from all end-users.

7.2.3 Directive 2006/24/EC on data protection

Directive 2006/24/EC [21] on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC. This directive amends Directive 2002/58/EC for harmonising public security and personal privacy. It establishes the category of data to be stored and the security requirements for retained data. The scope of the directive is thus applied to the "*traffic and location data on both legal entities and natural persons and to the related data necessary to identify the subscriber or registered user. It shall not apply to the content of electronic communications; including information consulted using an electronic communications network".*

Relevance to inCASA
inCASA technologies and applications will have the necessary security measurements in order to protect privacy and personal data. Informed consent forms will be obtained from all end-users.

7.2.4 Directive on the application of patients' rights in cross-border healthcare

Spurred from an investigation instigated in 2003 on the rights of patients in the field cross-border healthcare, this proposed directive is a result of years of research and analysis [22]. It has a special section on e-Health as this raises unique questions related to safety, standards and interoperability. Although the benefits of e-Health services and systems are emphasised, particularly for chronic patients, the directive cautions that shared formats and standards and interoperability are perquisites for effectively reap these benefits, particularly in the context of cross-border healthcare. The directive thus seeks to promote interoperability once e-Health systems are in place.

Relevance to inCASA
The inCASA platform supports interoperability.

7.2.5 2007/47/EEC Medical Device Directives

The objective of the EU medical device directives is to ensure safety and proper running of medical devices and at the same time facilitate trade and international commercialization in the European Economic Area. Until recently, Medical Device Directive 93/42/EEC [23] was the key directive on regulation of medical devices.

As of March 2010 the key directive is 2007/47/EEC [24], which amends directive 93/42/EEC, and its compliance is mandatory from 21 March 2010. It provides alignment of directive 90/385/EEC with directive 93/42/EEC. Additionally the directive provides regulation of medical software, which is considered a medical device only if it is intended for diagnosis or therapy.

Relevance to inCASA
The medical devices that are going to be used as part of inCASA service will be in compliance with this directive.

7.3 European and International Standards Requirements

EU and international standards provide agreed technical standardisation which the inCASA services and applications may have to observe. Standards do not have direct legal application but can be referenced in directives and laws. Further, standards may be dictated by users for interoperability and sustainability of commercial services.

The standards and regulations mentioned here are indeed relevant to inCASA as personal health data and behavioural data will be collected, transmitted and stored. The following sections provide

an overview of relevant European, international and industrial standards from which requirements for each pilot application can be derived

7.3.1 Standards and Regulations for Data Protection and Privacy

The exchange of health information is subject to privacy and legal issues. Information related to the patients' medical condition, billing information, and medical advice is considered highly sensitive. It is mandatory that these data will only be accessible to authorized personnel. It is also important to keep data integrative avoiding any kind of manipulation or data corruption.

EN 14485:2003
This health informatics standard provides guidelines for the security of personal identifiable health information in the case of international distribution of this information.

EN 12251:2004
This health informatics standard provides guidelines for authentication of individual users working with healthcare IT systems, by improving the software procedures linked to the management of user identifiers and passwords. It does this without using additional hardware facilities. This standard applies to electronic patient records and patient administrative systems.

CEN 15299:2006
This standard discusses the procedures for identifying patients and related objects.

OECD Guidelines Governing the Protection of Privacy and Trans-Border Flows of Personal Data

The OECD defines the following recommendations for protection of personal data:

1) Notice: data subjects should be given notice when their data is being collected
2) Purpose: data should only be used for the purpose stated and not for any other purposes
3) Consent: data should not be disclosed without the data subject's consent
4) Security: collected data should be kept secure from any potential abuses
5) Disclosure: data subjects should be informed as to who is collecting their data
6) Access: data subjects should be allowed to access their data and make corrections to any inaccurate data
7) Accountability: data subjects should have a method available to them to hold data collectors accountable for following the above principles.

The spirit of these principles is at the core of European directives related to data protection.

ISO 27002
ISO 27002 code of practice describes best practices for information security.

AES
AES stands for Advanced Encryption Standard. It is an standard for secure data transmission.

TDEA
TDEA stands for Triple Data Encryption Algorithm (Triple Data Encryption Standard (3DES)). It is a standard for secure data transmission .

SHA
Secure Hash Function it is part of a family of algorithms published by the National Institute of Standards for computing message digests.

MD5

MD5 stands for Message-Digest Algorithm 5. It is a standard for secure data transmission.

OASIS v2.0
OASIS v2.0 of XACML (eXtensible Access Control Markup Language) is a standard for secure data transmission.

EPAL
Enterprise Privacy Authorization Language. It is a standard for secure data transmission.

7.3.2 Standards and Regulations for Patient Safety, Risk Management and Quality Assurance

EU Council Recommendation on General Patient Safety Issues
This document provides recommendations for improving patients' safety in all EU Member States, through sharing information, best practice and expertise.

CEN/TS 15260:2006
CEN/TS 15260:2006 Health informatics: Classification of safety risks from health informatics products.

EN 1041:2007
Standard for specifying the minimum information supplied by the manufacturer of medical devices.

EN-ISO 14155
Standards for clinical investigation of medical devices for human subjects.

ISO 14971
ISO standard published in 2007 representing the requirements for a risk management system for medical devices.

ISO 13485:2003
This is a standard for quality management system requirements for regulatory purposes.

ISO TR 14969:2004 Medical Devices
Guidance for quality management systems on the application of the above ISO 13485:2003.

IEC 62366 Medical Devices
Application of usability engineering to medical devices.

IEC 80001 1
Standard for risk management for IT networks incorporating a medical device.

IEC TR 80002 1
Standard for software risk management.

IEC 60601-1:2005
Standard for general requirements for basic safety and essential performance for medical electrical equipment.

IEC 61508-3:1998
This Standard provides specifications for ensuring functional safety of electrical/electronic/programmable systems. It also provides software requirements and methods for the determination of safety integrity levels.

IEC 80001
Developed by the ISO /CEN joint group, this standard establishes the risk management procedures for IT-networks incorporating medical devices.

Proposal IEC TR 80002
This is a guidance proposal for applying ISO 14971 to medical devices software.

Good Clinical Practice (GCP)
Good Clinical Practice is an international quality standard provided by the International Conference on Harmonisation (ICH). Good Clinical Practice guidelines include protection of human rights.

7.3.3 Standards and Regulations for Medical Data Interoperability

HL7
Standards developed by ANSI for medical information exchange.

CDA (Clinical Document Architecture) of HL7
The CDA Release 2.0 provides an exchange model for clinical documents (such as discharge summaries and progress notes) - and brings the healthcare industry closer to the realization of an electronic medical record.

SNOMED
SNOMED is a systematically organised clinical terminology allowing indexation, storage and aggregation of unambiguous clinical data.

DICOM
DICOM stands for Digital Imaging and Communications in Medicine. It is a standard for managing digital medical images defining the protocols for exchanging them. European CEN has contributed to DICOM through EN 12052.

OpenEHR
OpenEHR (open source) provides descriptions for managing, storing, retrieving and exchanging health data.

CEN 13606
This standard proposes a scheme for designing Electronic Health Record (EHR) for data exchange among different systems.

ISO/IEEE 11073 Personal Health Data (PHD)
ISO/IEEE 11073-20101:2004 provides the upper layer [i.e., open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications.

ISO/TR 18307
This standard describes the key characteristics for interoperability and compatibility in exchanging medical information.

ISO/IEEE 11073
Specifically ISO/IEEE 11073-20601a and -104xx for specific medical devices. This describes the standards for data interoperability at device level. It also creates data models that are used to drive other communications such as HL7, 13606 and OpenEHR.

7.3.4 Standards and Regulations for Healthcare Software Systems

CEN/TR 15640
CEN/TR 15640 CEN Health informatics: Measures for ensuring the patient safety of health software.

CEN/TS 15260
CEN/TS 15260 CEN Health informatics: Classification of safety risks from health informatics products.

CEN/TR 27809
CEN/TR 27809 CEN Health informatics: Measures for ensuring the patient safety of health software.

CEN/TS 25238
CEN/TS 25238 CEN Health informatics: Classification of safety risks from health informatics products.

IEC 62304
This standard defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes.

ISO/CEN 27799:2008
ISO 27799:2008 CEN Health informatics: Information security management in health using ISO/IEC 27002 (ISO 27799:2008).

ISO/IEC 27000-Series
ISO/IEC 27000-series: LIS Information security management systems.

ISO/IEC 27799
ISO/IEC 27799, Health informatics: Information security management in health using ISO/IEC 27002 (ISO 27799:2008).

ISO/IEC 90003:2004
ISO/IEC 90003:2004 Software engineering: Guidelines for the application of ISO 9001:2000 to computer software.

IEC TR 800021:2009 Medical Device Software
This standard provides guidance on the application of ISO 14971 to medical device software.

IEC 60601
This is a harmonised standard for electrical programmable systems.

IEC 62304
IEC 62304, Ed. 1: Medical device software. Software life cycle processes, computer software.

8 Summary

The table below summarizes which parameters the five inCASA pilots wish to monitor:

To be monitored	ATC	KGNHI	CHC	INSERM
Blood pressure		X	X	
Blood Oxygen Saturation Level (SpO2)		X	X	
Blood Glucose		X		
Heart Rate		X		
Heart Rhythm		X		
Partial prothrombin time/INR		X		
Body Weight		X	X	X
Symptoms Scoring (yes/no Q)/Feedback			X	X
Movement at home	X	X	X	
Contact (e.g.: Door/Bed/Chair permanence)	X		X	
Wrist movement (Actigraphy)			X	X
Instantaneous video conferencing		X		
Ambient Temperature	X			
Ambient Humidity	X			
Water Leak	X			
Gas Leak	X			

At the current stage, pilots have defined these parameters in a preliminary manner meaning that the precise functional and non-functional requirements for the inCASA system will be adjusted and modified if and as necessary as the pilots progress. This work is actually part of the consolidation and prioritisation iteration which will be documented in D2.2 Requirements Consolidation and Prioritisation Iteration 1, D2.4 Requirements Consolidation and Prioritisation Iteration 2, and D2.6 Requirements Consolidation and Prioritisation Iteration 3.

In sum, the pilots different aims and objectives, the different parameters, the end-user profiles, the international and nation policy, regulatory and standards requirements will create a weighted matrix of requirements that will help fulfilling the final integrated inCASA solution and services affect an integrated inCASA solution. inCASA technicians can refer to the user, regulatory and standard requirements defined here and in the other WP2 deliverablesin order to define the architecture and requirement specifications that need to be installed in the pilots. The results of WP2 thus fed into the tehcnical work planned for WP3 Architecture Design.

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[19] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML

[20] Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) http://eur-lex.europa.eu/pri/en/oj/dat/2002/l_201/l_20120020731en00370047.pdf

[21] Directive 2006/24/EC on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks and amending Directive 2002/58/EC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:105:0054:0063:EN:PDF

[22] Directive on the application of patients' rights in cross-border healthcare, COM(2008) 414 final, http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf

[23] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML

[24] Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biological products on the market, http://ec.europa.eu/consumers/sectors/medical-devices/files/revision_docs/2007-47-en_en.pdf

Appendix 1: Pilot Instruction Sheet

The Pilot Instruction Sheet was distributed to the pilots with the intention of gathering data for the current deliverable (as well as for D2.2 Requirements consolidation and prioritization iteration 1).

Introduction

Instructions:

This chapter will describe the local background of the pilot site and the environment surrounding the users.

The chapter could follow the proposed summary:

General Background – An introduction to the sample choosen to collect information
Demography – Demographic outlines from your Country (epidemiologic point of view)
Living conditions – Data and discussions about elderly people's living conditions in your country
Home environment – Outline of the common notion of "home" in your country: diffusion of home automation, issues, expectations
Social and healthcare services provision system – the services offered and delivered within your country
Home care services – Home care services provided by your country – private/public entities and their interaction
Informal social care – The involvement of caregivers (e.g. neighbours, parents, friends and others) and their level of interaction with elderly people quality of life.

Pilot background and infrastructure

Instructions:

This chapter will give a short description of the pilot site you would like to implement, including:

- Services you would like to offer
- Service providers you would like to involve (all actors involved)
- Service infrastructure you would like to re-use or introduce for inCASA pilot

End-user profile[16]

Instructions:

This chapter will describe the end-user of the pilot site's implementation of the inCASA solution.

In maximum 2 pages give a demographic description of the end-user and of the surrounding environment. This shouldn't be a description of the pilot, but only of the particular users.

Write down information about the number of end-users to be involved (max 35) and break down the sample in groups: the best would be one to three groups based on common issues.

[16] End-user here refers to the elderly person, patient and/or tenant.

For example:

Group	Issue
1	Loneliness
2	Dementia
3	Cancer

End-users should not be randomly selected among the population and not substantially chosen based only on chronological age (over 65): people aged 55 with problems/needs should be considered as much as people over 65.
As far as possible they should be well known and have confidence in the social and/or healthcare services.

It might be good to take pictures and videos of the environment on which pilot will take place.

Objectives of the pilot

Instructions:

This chapter will describe the objectives of the pilot within inCASA project, from two points of view: the end-user and the pilot.

objectives by end-user point of view:
Set the needs and concerns (e.g. end-users are not living a quality life - what is the reason). Set the causes in clusters, assigned to the 2-3 groups of the first breakdown of pilot sample (for example: one with medical problems, one with loneliness);

objectives by pilot point of view:
Set high level goals, like improving well-being; decreasing healthcare costs (to improve social care investments); building an integrated model of social and healthcare teams with integrated services;

Procedure and Challenges

Instructions:

This chapter will describe the procedures introduced on the pilot site in order to reach the goals, including defining end-users' problems and needs and what they will gain, as well as what professional users will gain from the pilot.

The work can be carried out using focus group interviews with the pilot owners (i.e. professional users).

The work to be performed is to:

Identify the main challenges for the end-users
Prioritise the challenges
Ask the pilot owners to agree on the pilot with the aim of helping the end-users' problems (meeting the challenges)

Define the monitoring scheme to alliviate the problem.

List only those challenges that are relevant.

Write a brief introduction to the challenges.

Provide a short description of each challenge and of how to overcome the challenge (expected outcomes).

Explain why it is important for the end-users to overcome challenges.

Once you have a description what could help to solve the problems - for each of the challenges try to describe the infrastructure to be implemented.

Starting from the list of variables provided with the first questionnaire, try to suggest the devices to be implemented, the level of interaction between them and inCASA platform.
For example:

Nature of the monitoring (continuous, once-a-day, twice-a-day, hourly, etc.);
Nature of data transmission to the service provider (daily transmission, continuour transmission, weekly transmission);
Alerts (sms, Interface Alert for Service provider Interface, Priority, etc.) and targets of the alerts (Service provider, neighbor, relative, etc.)

Insert a list of stakeholders involved in your pilot (for example: Relatives, Social works, neighbor, medicians, etc.)

Describe what kind of services a Service provider should offer to the listed stakeholders, giving also a short description of the interfaces: how would you like to access the information about inCASA - how data should be read - what are the sources of data (e.g. we want to have web system to access and data must be extracted from a trusted platform ...)

Say something about the organization of data: how they should be grouped and accessed (e.g. single user access or care-team acces). Describe how to use the results provided by the platform.

Regulatory and Ethical issues

Instructions:

This chapter will describe the regulatory and ethical issues related to the pilot site; these issues are important to consider to ensure that the pilot does not violate any regulations or cause any ethical problems that could stop the pilot from being realised.

List and describe the local (national) laws about protection of data, privacy and security, and other relevant laws and regulations that (may) affect the pilot site.

Some ethical considerations and/or concerns, e.g.:

Privacy and protection of data
Privacy can be defined as the state in which an individual's or a group's desired level of social

interaction is not exceeded. The concept of privacy also refers to the right to control other's access to one's personal world[17]. When dealing with information the principle of privacy is defined as the ability of individuals to reveal information about them selectively.

Constant and ubiquitous multimodal observation of the user and its daily context raise obvious data protection and privacy issues with regard to both the user himself, and his or her occasional or regular visitors (whose interactions with the users, movements within the users' home etc. will also, as a matter of fact, be observed and recorded).

Stigmatisation
The significance of appearance in our society should not be underestimated, and a device which signals "inability" loud and clear risks stigmatising the individual unnecessarily. Also, being constantly monitored can cause some people to feel stigmatised.

Dignity and integrity
Dignity can be defined as being respected, protected and valued. People who need some form of assistance in their daily lives whether they live at home or in assistive living residencies, should not as a consequence of their required assistance/care loose their right to dignity. The right to integrity is inherently part of the notion of human dignity.

Notion of "home" (invasion of home?)
Ubiquitous communication technologies in the home erode the traditional boundary between private and public space – even if the public access to private data, to the home sphere, is restricted. However, this erosion may be accepted if the perceived benefits in terms of increased security are deemed higher.

[17] G.R. Van den Bos, Ed., *American Psychological Association's Dictionary of Psychology*, 1st ed., 2007.

Appendix 2: Pilot Requirements Form

The following form was used to gather the initial pilot technical requirements.

inCASA Project

Doc. D2.1-001.1

Pilot Requirements **Step One: Pilot Specifications**

Completed by Date
Partner Code Partner Description

This Pilot Specifications Requirements form is a means of initiating a dialog with you, the Pilot Sites, about the inCASA project you are a part of. By working with your National Coordinator on the answers to these questions, inCASA team will better understand your needs and your constraints in applying inCASA solution to your environment. That will enable us to propose the best solution to meet your requirements with the best results at the lowest effort for the whole project.
Target users of inCASA project are European citizens, over 65 years old, living at home alone and with a sufficient level of autonomy and self-care ability. They may have a need to improve self-confidence and ability to cope with day-to-day life, in order to increase independence and prolong the time they stay in their own home.
Deployment is divided into two steps:
Step one: the service will be piloted with 5 users in two pilot countries. This will serve as validation for the model and fine tune the solution.
Step two: the tuned solution will be extended to 30-40 users for each country. Total number of users: 175 across pilot countries.
The inCASA Platform takes advantages of a series of existing products and integrates them to create an enhanced socio-medical platform, able to monitor both user behaviour and clinical conditions, and a user behaviour model. Alerts are generated in case of anomalous situations with respect to the user behaviour model.
In particular the new services created with this platform are:

- Combining user behaviour and clinical conditions into a unique behaviour model
- A user clinical profile ready for access from social care, hospital, emergency services and regional/national healthcare information systems
- A common working framework and a strong link between social-care, hospital and emergency services
- A scalable and open platform that allows easy integration of additional monitoring and related alert services

A Section One Pilot Specifications

Solutions will be piloted in different service scenarios having different mixes of social and health

care networks and local environments. The pilot sites will have different levels of existing experience but all will involve self-sufficient elderly people living in their own home or in social housing structures. Service providers will be established by local authorities within ad-hoc structures; in such structures operators will take the active role to develop the service model, and provide support while implementing the solution. The set of sensors installed in each elderly home will be connected to the Local Service Provider centre, via wired or wireless broadband communications, depending on network availability. The monitoring data coming from the motion sensors in the home will be stored in the base station and periodically (or real time where applicable) sent to the central point of contact. Given that the solution will collect personal data for social and clinical purposes and will involve medical devices, a clinical trial protocol will be included. Having a common clinical trial protocol will allow study data from each country to be combined. Emergency calls can be initiated directly by the user by pressing an emergency button on a call pendant or automatically by the inCASA platform.
Based on the system architecture and the expertise within in the consortium, the inCASA project will define a "pilot implementation methodology" that will be shared between all the pilot site stakeholders in order to define a common European framework.
The pilot in each phase will follow an approach taken from ergonomic studies, called Human Centred Approach. Ergonomics has the purpose of ensuring fit for purpose by the user, including the things they do, objects they use and the environment in which they live. Basic topics of Ergonomics are 'User-Centred Design' (UCD) and 'inclusive design'.
The system is designed for monitoring and support of the elderly and will reuse existing infrastructure and relationship with the users, or existing services. Moreover the inCASA solution will exploit existing wearable/non wearable monitoring system and obtain other hardware that will be adapted for the specific need of the local pilots, utilising where possible grants from regional-national level. These aspect will be considered as "Pilot Upgrades".

A.01	***Common***	
A.01a	How many users will pilot the inCASA solution?	No.
A.01b	Do your target users have specific diseases?	☐ NO ☐ YES .....
A.01c	Do your target users have specific issues (e.g.: daily/weekly treatment at home)?	☐ NO ☐ YES .....
A.01d	Do you already have a Contact Centre/Service Provider?	☐ YES ☐ NO
A.01e	If YES, does this structure provide social/Healthcare/Both support?	☐ SOCIAL ☐ HEALTHCARE ☐ BOTH ☐ Other .....
A.01f	Is a VOIP communication service available in the pilot's area?	☐ YES ☐ NO
A.01g	What kind of communication service is available in the pilot's area for DATA?	☐ PSTN/ISDN ☐ XDSL ☐ GPRS/EDGE ☐ HSDPA/WDCMA ☐ Other .....
A.01h	What kind of communication service is available in the pilot's area for VOICE?	☐ PHONE ☐ GSM ☐ 3G ☐ Other .....

A.01i	How many users will pilot the inCASA Basic SET[18] for habits monitoring? (at least 10 users)	No.
A.01j	Do you have "case management"[19] skills (merged social and healthcare) in your organization?	☐ YES we already have case management skills ☐ NO but we plan to introduce case managers during the Project's life ☐ NO ☐ Other ……
A.01k	How many "Case Managers" will follow the users participating in the social and healthcare integrated model? (At least one)	No.
A.01l	Does your organization need a public call for bids to buy devices for the inCASA project?	☐ YES ☐ NO ☐ ……

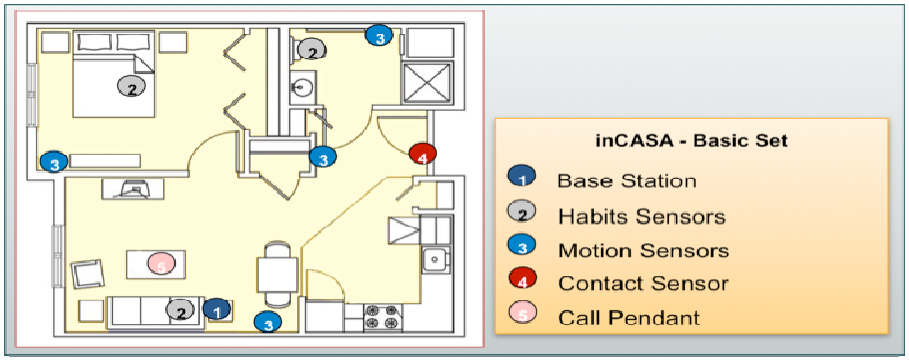
A.02 inCASA UPGRADES

A.02l UPGRADE 1

Provide a short description of the Upgrade.

A.02la		
A.02lb	What's the domain of Pilot Upgrade?	☐ VAS (SME/PA) ☐ Human Monitoring ☐ Environment Monitoring ☐ Home Automation ☐ Public Services Integration ☐ Other …… ……
A.02lc	What's the nature of the Upgrade you would like to introduce in your Pilot?	☐ A Service ☐ An EU Project ☐ A NON EU Project ☐ A Device (off-shelf) ☐ A Product/Solution (off-

18



19 A Case Manager takes care of a single person and their family, facilitating self-care which involves the person, care-giver and relatives. This could include educational activities, interactions with healthcare and social services, and professional consulting. Operating within the Service Provider, the Case Manager takes responsibility for a limited number of users, and is trained to manage all the social and healthcare needs.

		shelf) ☐ A prototype ☐ A Research/A Study ☐ Other …… ……
A.02Id	Is the Upgrade still running/available in your country?	☐ YES ☐ NO ☐ Available in other countries ……
A.02Ie	Is the Upgrade already funded by public/private funds?	☐ PUBLIC ☐ PRIVATE ☐ NO: it needs to be charged to inCASA Pilot's Budget ☐ Other ……
A.02If	Is there Public/Accessible documentation about the Upgrade?	☐ YES ☐ NO ☐ Other ……
A.02Ig	Does the Upgrade have a technological infrastructure?	☐ YES HARDWARE ☐ YES SOFTWARE ☐ YES HARDWARE/SOFTWARE ☐ NO ☐ Other ……
A.02Ih	If YES, will this infrastructure be available during the project's life?	☐ YES for FREE ☐ YES for BUY/RENT ☐ NO ☐ Other ……
A.02Ii	Will the Upgrade produce data to be collected into user's Personal Record?	☐ YES ☐ NO ☐ Other ……
A.02Ij	Will the Upgrade need Smart Personal Platform integration (data elaboration for alerts/Decision Support)?	☐ YES ☐ NO ☐ Other ……
A.02Ik	Will the Upgrade need integrations?	☐ YES BASE STATION (User's home) ☐ YES SERVICE PROVIDER ☐ YES BASE STATION /SERVICE PROVIDER ☐ NO ☐ Other ……
A.02Il	***UPGRADE 2*** Provide a short description of the Upgrade.	
A.02Ila		

A.02IIb	What's the domain of Pilot Upgrade?	☐ VAS (SME/PA) ☐ Human Monitoring ☐ Environment Monitoring ☐ Home Automation ☐ Public Services Integration ☐ Other ……
A.02IIc	What's the nature of the Upgrade you would like to introduce in your Pilot?	☐ A Service ☐ An EU Project ☐ A NON EU Project ☐ A Device (off-shelf) ☐ A Product/Solution (off-shelf) ☐ A prototype ☐ A Research/A Study ☐ Other ……
A.02IId	Is the Upgrade still running/available in your country?	☐ YES ☐ NO ☐ Available in other countries
A.02IIe	Is the Upgrade already funded by public/private funds?	☐ PUBLIC ☐ PRIVATE ☐ NO: it needs to be charged to inCASA Pilot's Budget ☐ Other
A.02IIf	Is there Public/Accessible documentation about the Upgrade?	☐ YES ☐ NO ☐ Other
A.02IIg	Does the Upgrade have a technological infrastructure?	☐ YES HARDWARE ☐ YES SOFTWARE ☐ YES HARDWARE/SOFTWARE ☐ NO ☐ Other
A.02IIh	If YES, will this infrastructure be available during the project's life?	☐ YES for FREE ☐ YES for BUY/RENT ☐ NO ☐ Other
A.02IIi	Will the Upgrade produce data to be collected into user's Personal Record?	☐ YES ☐ NO ☐ Other
A.02IIj	Will the Upgrade need Smart Personal Platform integration (data elaboration for alerts/Decision Support)?	☐ YES ☐ NO ☐ Other
A.02IIk	Will the Upgrade need integrations?	☐ YES BASE STATION (User's home) ☐ YES SERVICE PROVIDER ☐ YES BASE STATION /SERVICE PROVIDER ☐ NO

☐ Other
.....

A.03 inCASA VARIABLES

A large amount of variables can be monitored through the inCASA platform. They may be human related, environmental, socio economic, and so on. They can be monitored through devices, through SPP[20] elaboration or be taken into consideration during the project's evaluation phases.

A.03I VARIABLE 1

Provide a short description of the variable to be considered/monitored.

A.03Ia

A.03Ib	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....
A.03Ic	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03Id	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03Ie	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....
A.03If	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03Ig	Unit of Measure of the Variable?	.....
A.03Ih	Range of normality of the Variable?	.....

A.03II VARIABLE 2

[20] SPP – Smart Personal Platform – for further details see document "Description of Work"

Provide a short description of the variable to be considered/monitored.

A.03IIa

A.03IIb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....
A.03IIc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03IId	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03IIe	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....
A.03IIf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03IIg	Unit of Measure of the Variable?	.....
A.03IIh	Range of normality of the Variable?	.....

A.03III ***VARIABLE 3***

Provide a short description of the variable to be considered/monitored.

A.03IIIa

A.03IIIb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....

A.03IIIc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03IIId	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03IIIe	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....
A.03IIIf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03IIIg	Unit of Measure of the Variable?	.....
A.03IIIh	Range of normality of the Variable?	.....

A.03IV ***VARIABLE 4***

Provide a short description of the variable to be considered/monitored.

A.03IVa

A.03IVb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....
A.03IVc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03IVd	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03IVe	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....

A.03IVf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03IVg	Unit of Measure of the Variable?	.....
A.03IVh	Range of normality of the Variable?	.....

A.03V ***VARIABLE 5***

Provide a short description of the variable to be considered/monitored.

A.03Va

A.03Vb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....
A.03Vc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03Vd	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03Ve	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....
A.03Vf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03Vg	Unit of Measure of the Variable?	.....
A.03Vh	Range of normality of the Variable?	.....

A.03VI ***VARIABLE 6***

Provide a short description of the variable to be considered/monitored.

A.03VIa

A.03VIb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....
A.03VIc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03VId	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03VIe	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....
A.03VIf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03VIg	Unit of Measure of the Variable?	.....
A.03VIh	Range of normality of the Variable?	.....

A.03VII ***VARIABLE 7***

Provide a short description of the variable to be considered/monitored.

A.03VIIa

A.03VIIb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....

A.03VIIc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03VIId	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03VIIe	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....
A.03VIIf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03VIIg	Unit of Measure of the Variable?	.....
A.03VIIh	Range of normality of the Variable?	.....

A.03VIII ***VARIABLE 8***

Provide a short description of the variable to be considered/monitored.

A.03VIIIa

A.03VIIIb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....
A.03VIIIc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03VIIId	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03VIIIe	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....

A.03VIIIf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03VIIIg	Unit of Measure of the Variable?	.....
A.03VIIIh	Range of normality of the Variable?	.....
A.03IX	***VARIABLE 9***	
	Provide a short description of the variable to be considered/monitored.	
A.03IXa		
A.03IXb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....
A.03IXc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03IXd	Does the variable to be monitored needs a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03IXe	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....
A.03IXf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03IXg	Unit of Measure of the Variable?	.....
A.03IXh	Range of normality of the Variable?	.....
A.03X	***VARIABLE 10***	

	Provide a short description of the variable to be considered/monitored.	
A.03Xa		
A.03Xb	Type of Variable	☐ HUMAN ☐ ENVIRONMENTAL ☐ SOCIAL ☐ ECONOMICAL ☐ Other .....
A.03Xc	Nature of Variable	☐ Measure ☐ Calculation ☐ Qualitative indicator ☐ Other .....
A.03Xd	Does the variable to be monitored need a Device?	☐ YES ..... ☐ NO ☐ Other .....
A.03Xe	Does the variable to be monitored need a Formula?	☐ YES ..... ☐ NO ☐ Other .....
A.03Xf	Does the variable respect an international Standard?	☐ YES ..... ☐ NO ☐ Other .....
A.03Xg	Unit of Measure of the Variable?	.....
A.03Xh	Range of normality of the Variable?	.....

NOTE: IF YOU NEED MORE VARIABLES PLEASE CUT&PASTE THIS SECTION AND UPDATE THE CODES