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inCASA

Integrated Network for Completely Assisted Senior citizen's Autonomy

D2.6 Requirements Consolidation and Prioritisation Iteration 3

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Executive summary

This deliverable presents the third iteration of inCASA user requirements which corresponds to the Third Pilot Phase, also known as the Pilot Escalation Phase. The Pilot Escalation Phase focuses on implementing integrated Telehealth and Telecare services enabled by the inCASA platform. In order to provide the integrated services, pilots have defined new use cases to be implemented in this 3rd phase. Consequently, the technical requirements have been reviewed and updated as necessary; only minor changes have actually been made to the technical requirements.

The Italian pilot, ATC, will implement three new use cases in Phase Three with a focus on monitoring three different clinical parameters. The data will be combined with data from the already implemented behavioural/habits monitoring in order to provide integrated care. The figure below illustrates the three pilot phases for ATC:

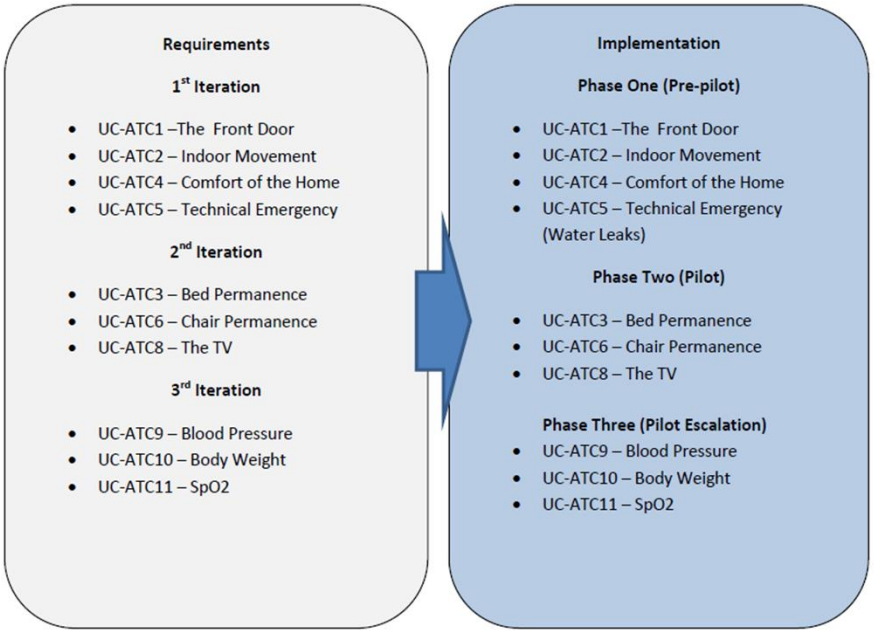

Figure 1: ATC Deployment Strategy

The UK pilot, CHC, implemented an integrated process by implementing Telecare and Yelehealth services in Phase Two and will continue with this service. In addition, a patient tablet will be introduced in Phase Three where it is suitable. This will enable patients to view the data that they are sending each day. Information can also be fed back to the patient. The figure below illustrates the three pilot phases for CHC:

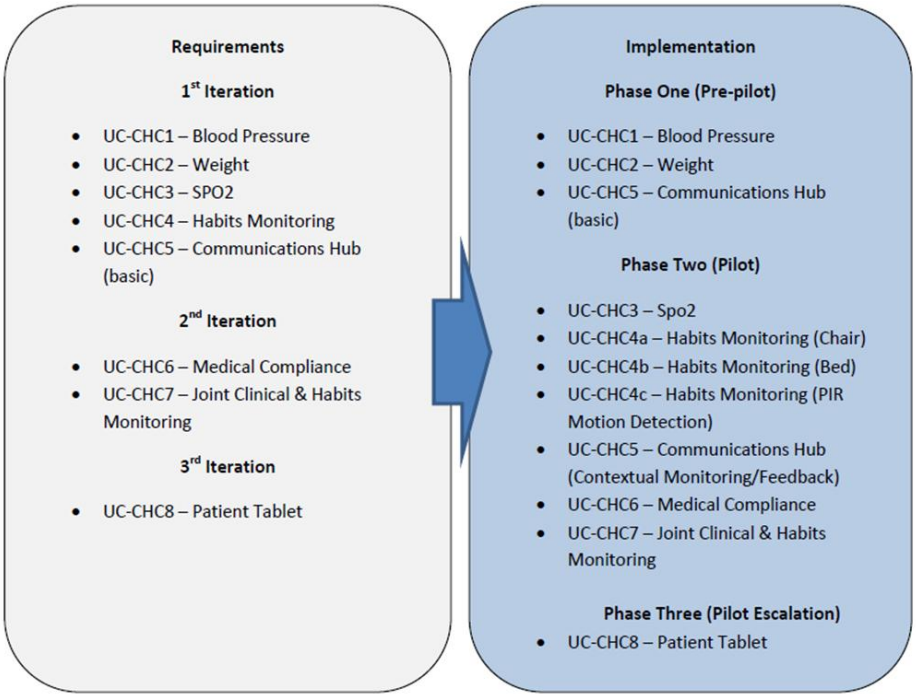

Figure 2: CHC Deployment Figure

The Spanish pilot, FHC, will introduce a new use case in Phase Three that will enable the integration of social service by allowing a method for assessing whether a patient's activity level corresponds to his/her health status, and in cases where discrepancies are found it may indicate that social issues are present. A social worker will thus intervene as necessary. The figure below illustrates the three pilot phases for FHC:

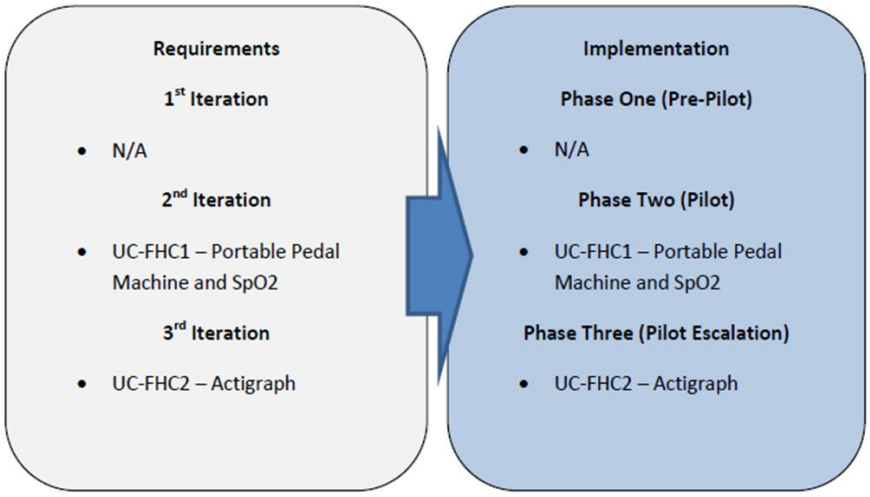

Figure 3: FHC Deployment Figure

The French pilot, INSERM, will implement one new use case which will enable the integration of Telehealth and Telecare services. The use case describes the new business process and organisation which aims to improve the coordination of healthcare and social care professionals involved with the patient. This involvement will be based on all the data collected in the patient's home using telecare and telehealth devices. The figure below illustrates the three pilot phases for INSERM:

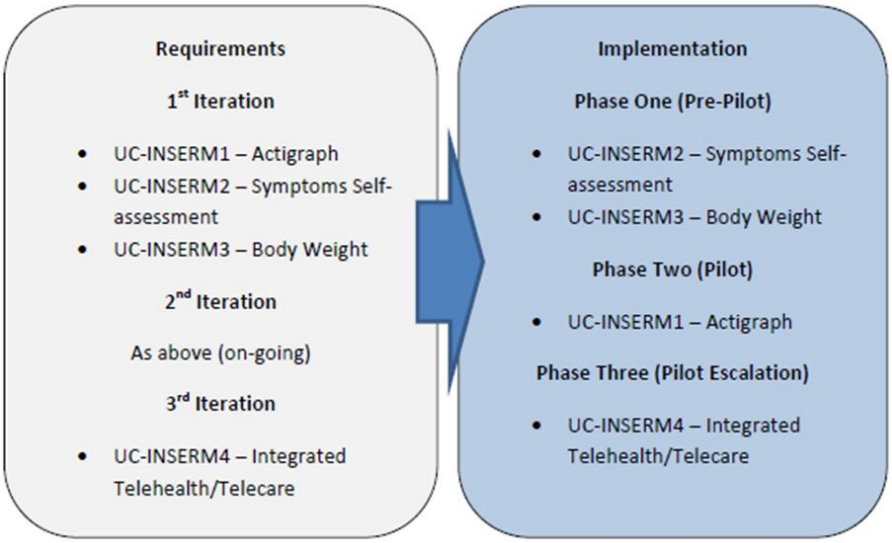

Figure 4: INSERM Deployment Figure

The Greek pilot, KGHNI, will introduce five new use cases focusing on behavioural/environmental monitoring. The aim of the integrated use cases introduced during the Pilot Escalation Phase is to allow the clinicians to concurrently view clinical and habits monitoring data[1] and observe any correlation between change in usual habits and any decline in physical health. Four originally planned use cases have been removed due to either integration risks, limited applicability or limited medical value. The figure below illustrates the three pilot phases for KGHNI:

[1] Both clinical and habits monitoring data visualized in tabular and graphical format; prioritization of patients' display according to their clinical needs and alerts severity.

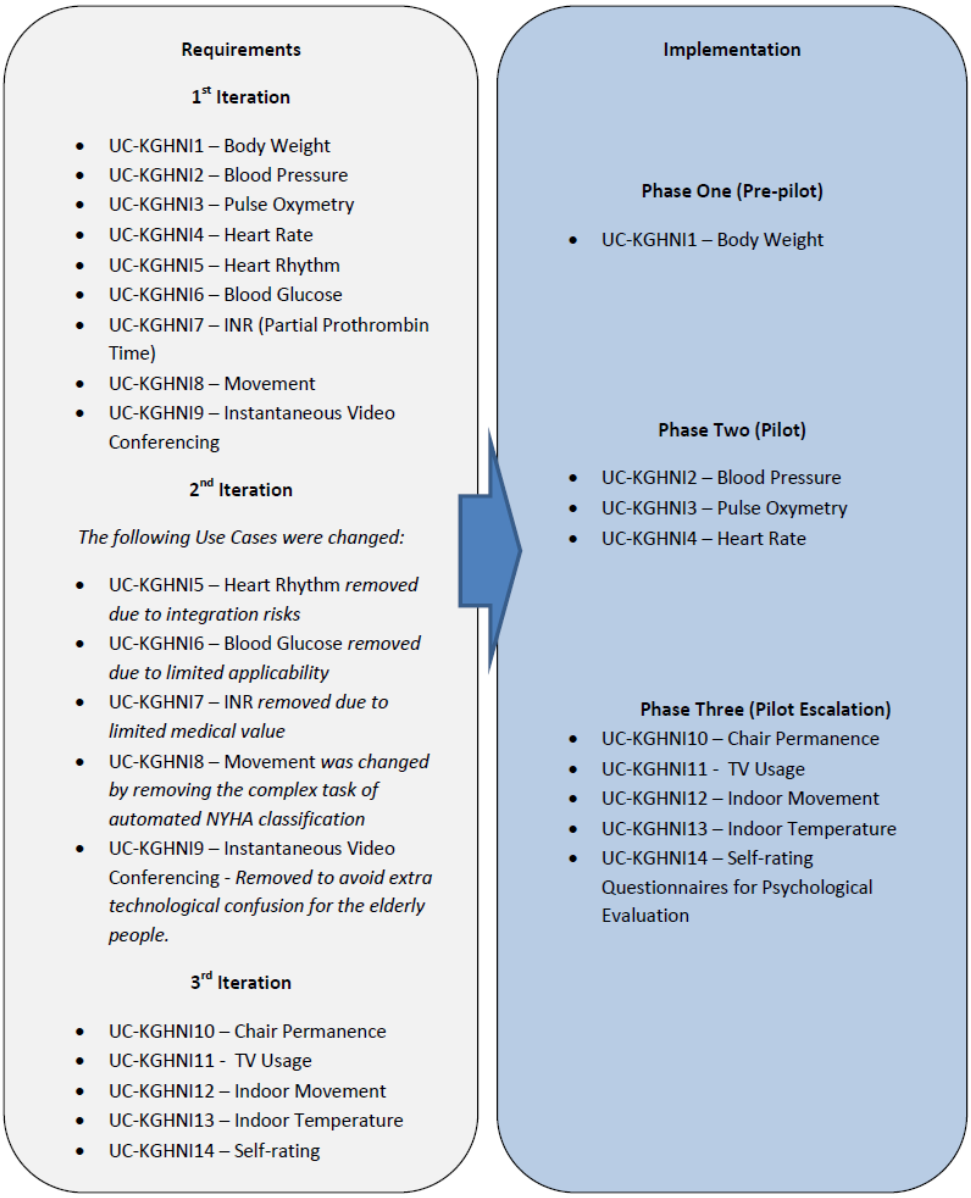

Figure 5: KGHNI Deployment Figure

The technical requirements have been updated as necessary. Only minor changes have been made for this 3rd iteration mainly reflecting the removal of the four KHGNI use cases and changes in prioritisation scoring as pilots have defined new use cases.

Finally, the business risk assessment and functional risk assessment have also been updated.

1 Introduction

The requirement engineering process adopted by inCASA is iterative, thus allowing for a continuous fine-tuning of the requirements. Three iterations have been conducted in inCASA and the present deliverable presents the results of the 3rd and final iteration. It has both an organisational perspective and a technical perspective. The results will feed into WP3 Architecture Design where the technical requirements will be more technically described and turned into system specifications.

1.1 Purpose and content of this deliverable

This deliverable presents the third iteration of inCASA user requirements which corresponds to the Third Pilot Phase, also known as the Pilot Escalation Phase. It builds on the 2nd iteration which was documented in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* and *Annex to D2.4 Requirements Consolidation and Prioritisation Iteration 2_v1.0*.

The Pilot Escalation Phase focuses on implementing integrated Telehealth and Telecare services enabled by the inCASA platform. The pilots will thus test and demonstrate how the inCASA solution can provide both types of services and promote an integration of healthcare and social care services to the targeted users, in the case of inCASA elderly people suffering from chronic conditions and often living alone and/or without a significant family network close by.

In order to provide integrated services, pilots have defined new use cases to be implemented in this 3rd phase. Here most pilots have been able to benefit from the other pilots in inCASA and have adopted some of the use cases and parameters (adapting them to fit their own specific aims and objective) that have already been implemented in other pilots in the previous phases. Some of the use cases that will be implemented have a particular organisational focus and thus do not entail monitoring of clinical or behavioural/habit parameters, but rather focus on establishing cooperation between health professionals and social care professionals. In most cases, this cooperation represents workflows and organisational structures that are completely different from those currently in place in the given site (country/region).

The technical requirements have also been reviewed and updated as necessary. Only minor changes have actually been made and mainly reflect the changes made in connection with use cases. The business risk assessment and technical risk assessment have also been updated.

1.2 Outline of this deliverable

The aims and objectives of each pilot site are presented in Chapters 2 through 6. The pilots report on organisational aspects, service delivery processes, and business processes relevant for this 3rd phase.

Chapter 7 presents the lists of technical requirements consolidation and prioritisation using the same method as in the previous two iterations. The requirement business and functional risk assessment is also presented in this chapter. The changes made for the 3rd iteration are marked in red.

Appendices A through E describe the already implemented use cases for each pilot; these use cases were described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* but are presented in the appendices to ease referencing.

2 ATC

This chapter presents the 3rd phase of the ATC pilot, the Pilot Escalation Phase. It focuses on the organisational aspects, service delivery processes, and business processes relevant for this 3rd phase.

Three new use cases focusing on health monitoring have been defined and will be implemented in this 3rd phase of the pilot. The technical requirements relevant for ATC have been updated accordingly. A complete report of all the updated requirements can be found in Chapter 7.

2.1 Aims and Objectives

The ATC pilot aims to develop an integrated service delivery model that will combine health and social care in response to the needs of frail older people with long term conditions. This service integration is driven by both health and social care. Information about the user and data from the remote monitoring will be shared and exchanged between the General Practitioner (GP) and social services.

The main part of this task has to be developed in cooperation with the Social Services Department offices of the Municipality of Torino, the main authority responsible of the Social Services District 1.

Secondly, ATC will integrate Telecare and Telehealth services in the 3rd phase of the pilot in cooperation with the General Practitioners of Federazione Italiana dei Medici di Medicina Generale (FIMMG), one the most important association of GPs in Italy.

The planned Telehealth services will focus on monitoring blood pressure, weight and blood oxygen saturation level (SpO2).

The overall aims and objective of the ATC pilot are to:

- Implement a new model of local welfare (integration of social services and social housing)
- improve quality of life (loneliness/safety)
- promote remote health monitoring of people living alone
- implement new services (home automation)
- improve relations with neighbours (social neighbourhood)
- integrate a free number of ATC (24 hour call service) with social services' network
- develop a local community among users.

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

- Self-sufficient citizens over 65 who require light support by professionals to increase their autonomy in addition to or in replacement of the family network (where absent)
- Citizens over 65 partially self-sufficient or not self-sufficient who require support by professionals to increase their autonomy in addition to or in replacement of the family network (where absent)
- Patients who have a diagnosis of COPD and/or CHF
- Different combinations of the above situations
- 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.

In the third phase of the pilot, ATC will recruit an additional 20 users in order to reach a total of 40 users.

2.1.1 Rationale

The third phase of the ATC pilot is dedicated to the integration of the new Telehealth services with the existing Telecare ones. This effort, which will involve more users than the previous phase, will run for 6 months in order to collect and monitor data for a sufficient time period in order to be able to analyse the data and impact of the services. This time frame will also allow a proper evaluation of the report which will be reported in *D6.6 Pilot Evaluation Report and inCASA platform validation and recommendation Report*.

2.2 Organisational aspects

ATC, FIMMG and the Social Services department all belong to the sector of Public Adminstration. However, there is no existing working relationship that coordinates their services and initiatives directed at frail and elderly people.

The ATC pilot's goal to integrate healthcare services and social service therefore represents a brand new initiative and a challenge in terms of organisational processes; it is a new role and task that ATC aims to fulfil. By implementing an integration of inCASA Telecare and Telehealth services the ATC pilot aims to meet this challenge and is committed to improving the care of the frail elderly people living in ATC housing.

The ATC pilot seeks to incorporate the concepts, values and standards of the inCASA solution into the organisational structure and culture of the local environment. The quality of life for frail elderly people and the quality of work of social and health professionals will be improved by enabling cooperation between the social and healthcare organisations. Moreover, it will provide local authorities with an opportunity to contribute to the public health agenda, incorporating health promotion as a daily work activity.

For the Italian environment these activities can be an essential part of improving social and healthcare service delivery in light of the increasing prevalence of lifestyle-related and chronic diseases. Profile driven therapeutic education (single case focused) and strategies enabling patients to take an active role in chronic disease-management or motivational counselling can support better healthcare outcomes. The involvement of social services will also contribute to the maintenance and improvement of elderly people's social relations as they will have many opportunities to meet with other elderly.

2.2.1 Pilot Structure

The ATC pilot structure is pictured below:

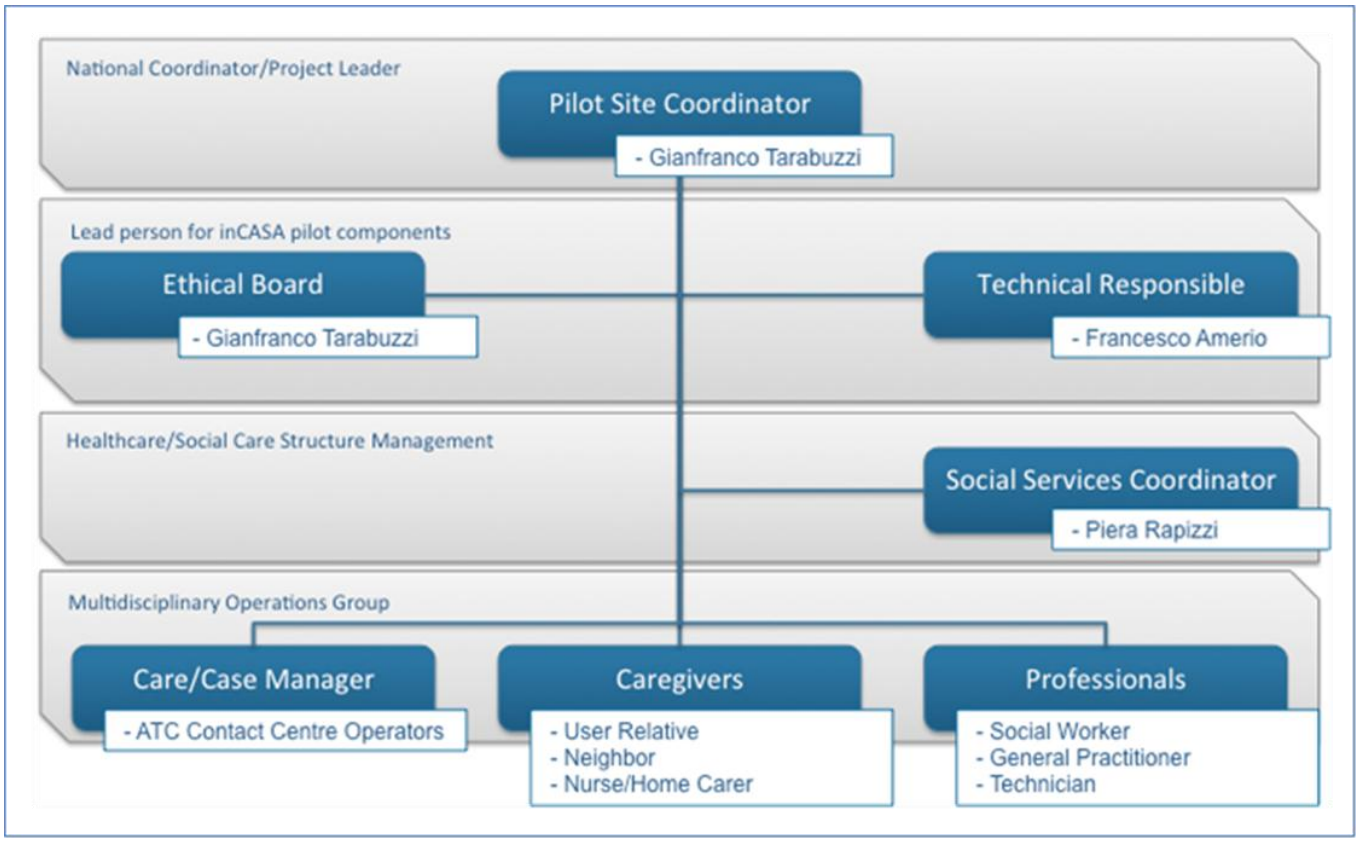

Figure 6: ATC Pilot Structure

The structure is unchanged compared to the 2nd phase (the Pilot Phase) that was described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2*.

2.3 Service Delivery Process

The service will be installed and configured in the users' homes with the appropriate devices and infrastructure. The ATC pilot will implement the following services/use cases:

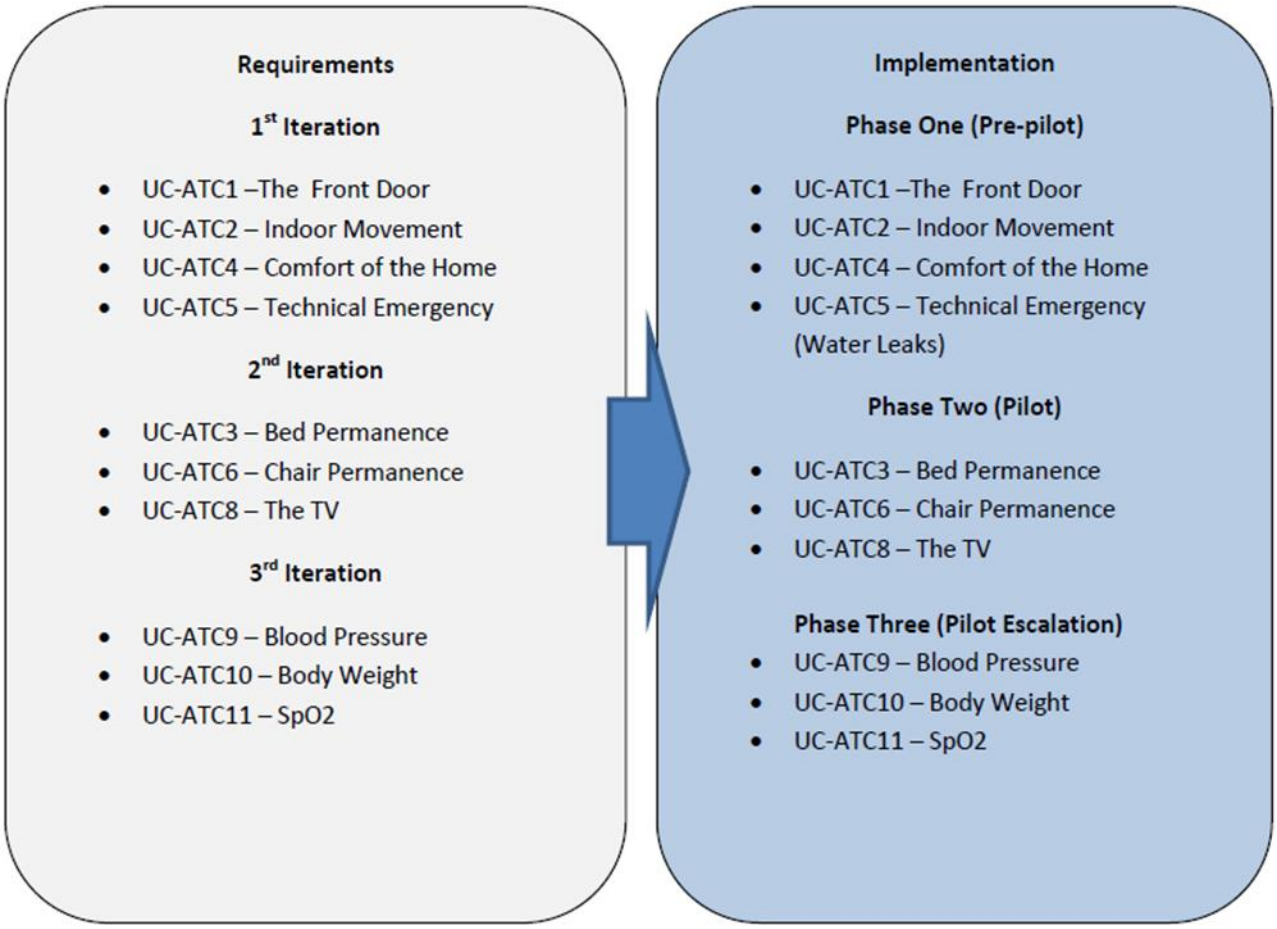

Figure 7: ATC Deployment Strategy

In the first two phases, ATC has focused on monitoring behavioural and habits parameters. Specific health parameters will be introduced in the third and final phase of the pilot. More specifically, the habit sensors will be combined with three health sensors for blood pressure, weight and SpO2. For this purpose, ATC elderly residents who suffer from COPD or CHF will be recruited for this 3rd phase of the pilot (see also inclusion criteria above).

The parameters that will be monitored are (accumulative[2]):

Parameter	Phase
Front door	Pre-pilot
Indoor movement	
Temperature and humidity	
Water leaks	
Bed permanence	Pilot
Chair permanence	
TV	
Weight	Pilot Escalation
Blood pressure	
SpO2 (blood oxygen saturation level)	

Table 1: ATC Parameters

[2] By "accumulative" we mean that the parameters in the pre-pilot will also be monitored in the pilot and so forth.

The aim of the social/health integration scenario in the ATC pilot will be to demonstrate how social care and healthcare organisation may work together to deliver a continuity of care. The scenario is enabled by the technological tools provided within the project: the contact centre (which will support the communication flow among different professionals) and the monitoring system (which will profile user habits according to monitored data).

The integration of habits and clinical monitoring introduced in the ATC pilot will aim to define extended profiles by correlating physiological parameters to daily life habits. Healthcare and social care professionals (or Case Managers with both roles) will thus be better able to make the right decisions and to plan interventions to prevent social and healthcare risks for the individual user.

Frail elderly users will be monitored by a combination of health and habits sensors in their own homes. Sensor data is transferred from the home to the health care team in the general practice and to a key social worker in social services. Data can be viewed on a combined health and social care interface. Changes in usual clinical measurements and levels of activity are measured and processed. The resulting patterns of behaviour and physiological data, including in-bed restlessness, habits and deviations from habits, rapid weight loss or gain, blood pressure, weight and SpO2 will be assessed to provide decision support for the health and social care professionals for cases such as loss of autonomy or early detection of clinical deterioration.

Responses to the data will be managed by joint case conferences between GPs and social workers from the Municipality of Turin. These will be held weekly or more frequently if deemed necessary. Appropriate social and/or medical interventions can then be determined by the joint team.

2.3.1 3rd Phase Use Cases

In the 3rd phase, the ATC pilot has added three Telehealth use cases which will measure and monitor health parameters.[3] These Telehealth use cases will be combined with the Telecare use cases already implemented in the 1st and 2nd pilot phase, thus providing integrated Telecare and Telehealth services.

The use cases already implemented focus on behavioural monitoring. A full description of these can be found in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* and may also be found in Appendix A.

Use case 9: Blood Pressure

Overview: This service will monitor a patient's blood pressure and collect 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 and requested by the clinician, the patient may be asked to repeat the measurement on the same day. The patients can also take a measurement at a time of their choosing.

Analysis: The service will ensure that patient's blood pressure is within pre-defined limits. The data will be analysed using automated algorithms to track trend changes in the patient's blood pressure in order to determine when intervention is required.

[3] These three new telehealth use cases are based on the use cases implemented by the CHC pilot. This allows ATC to benefit from CHC's experience.

Alerts: The clinician will be notified when there is a variance away from the desired or expected values and where necessary help manage any changes to medications, treatment plans or lifestyle.

Feedback to patients and relatives: The blood pressure provides immediate feedback to the patient on their current Blood Pressure and Pulse. If intervention is required, the GP will contact the patient by phone.

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

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

Use case 10: Body Weight

Overview: To measure body weight using a weight scale directly communicating with the inCASA system.

Clinical purpose: For those patients with CHF or where it seemed appropriate, the clinical teams will monitor for significant change in a patients weight. A change may suggest that the patient is retaining fluid (a sign of deterioration in their condition).

Procedure: Patient to take one measurement per day – preferably by 11am. This will provide the GP with a standardised measurement. Where necessary and requested by the GP, the patient may be asked to repeat the measurement on the same day. The patients can also take a measurement at a time of their choosing.

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

Alerts: The GP will be alerted when there is a variance away from the desired or expected values.

Feedback to patients and relatives: The weight scale provides immediate feedback to the patient on their current weight. If intervention is required, the GP will contact the patient by phone.

Personalisation: The system should allow for GPs to enter personalised optimum target values for each patient as well as limits for change in weight over a defined time period, e.g. >1.4kg over 3 days. The system should also allow the patient to enter up to 4 readings per day.

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

Use case 11: SpO2 (blood oxygen saturation level)

Overview: Patients who have a diagnosis of COPD will be provided with a Pulse Oximeter (SpO2)

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

Procedure: Patients will be asked to take one measurement per day – preferably by 11am. This will provide the GPs with a standardised measurement. Where necessary and requested by the clinician, the patient may be asked to repeat the measurement in the same day. The patient can also take a measurement at a time of their choosing.

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 GPs will be alerted when there is a variance away from the desired or expected values to help manage any changes to medications and/or treatment plans.

Feedback to patients and relatives: If intervention is required, the GP will contact the patient by phone.

Personalisation: The system should allow for GPs to enter personalised optimum target values for each patient as well as limits for change in SpO2 over a defined time period. The system should allow the patient to enter up to 4 readings per day.

Devices: A pulse oximeter.

2.3.2 Intervention Protocols

The following describes the steps that will be undertaken based on certain use cases. It is anticipated that more than one use case and maybe a combination of both clinical and habits may inform pathways.

2.3.2.1 Physiological Measurement Deteriorates – Use Cases 9-11

1. The patient takes daily physiological measurements using the devices provided and installed depending on the patients clinical needs, e.g. blood pressure, weight, SpO2.
2. Once the patient takes a measurement using the device it is automatically transmitted to a central server.
3. Data is automatically analysed using rules defined by the clinicians. If the data is outside of the thresholds, it will be highlighted on the inCASA portal to notify the clinician of the variance.
4. The GP reviews the data on the inCASA portal and performs a 1st line triage each day that determines if immediate intervention is required or if the patient should be referred to a case conference.
5. Immediate intervention occurs when the monitoring data indicates a significant risk to the patient.
6. If immediate intervention is required, the GP contacts the patient by telephone. The patient may either be asked to attend an appointment at the health centre or, if necessary, a home visit will be arranged. Any actions are recorded in the inCASA portal.
7. If the patient is to be referred to a case conference, a note is made in the inCASA portal.
8. At the case conference, the patients monitoring data is reviewed by a combination of GPs and Nurses. Outcome of the case conference is recorded in the inCASA portal. If intervention is required, the patient is contacted and asked to attend an appointment at the health centre.
9. The monitoring of the patients will continue as long as the service is deemed to be required.

2.3.2.2 Change in Habits Monitoring Data – Use Cases 1-6 and 8

These use cases are described in detail in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* but may also be found in Appendix A.

In this 3rd phase (Pilot Escalation) of the ATC pilot, habits monitoring and clinical monitoring is integrated to provide an integrated Telecare and Telehealth service. The following describes the intervention protocols related to the habits monitoring data enabled by the already implemented Telecare services:

1. The patient is provided with a series of sensors which passively monitor movement within the patient's home, and data is automatically transmitted to the server.

2. Data is automatically analysed using rules defined by the professional users. If the data is outside of the thresholds, it will be highlighted on the inCASA portal to notify the professionals of the variance.
3. Immediate intervention occurs when the monitoring data indicates a significant risk to the patient. Data is compared against information and any social information that is contained on the inCASA portal.
4. If immediate intervention is required, the social worker contacts the patient by telephone and may either ask them to attend an appointment at the health centre or refer them to social services. Any actions are recorded in the inCASA portal.
5. If the patient is to be referred to social services as an immediate case, an electronic referral form is completed on the inCASA Portal. A phone call is made to the social worker nominated.
6. Interventions made by the social worker are recorded in the inCASA portal
7. If the patient is to be referred to a case conference, a note is made in the inCASA portal, and a phone call is made to the social worker to schedule the conference.
8. At the case conference, the patients monitoring data is reviewed by a combination of GPs and social workers. The patients' health and social service history is reviewed in conjunction with the monitoring data. Outcome of the case conference is recorded in the inCASA portal.
9. If intervention is required, the patient will be contacted and asked to attend an appointment at the health centre, or will be contacted by social services
10. The monitoring of the patients will continue as long as the service is deemed to be required.

2.3.3 Telehealth and Telecare Integration Scenario

The following scenario describes how Telehealth services may be integrated with the current ATC Telecare services, and how the integration will be supported by the inCASA platform.

Living with Chronic Heart Failure

Mario Rossi, a 75 year old male with Chronic Heart Failure (CHF), goes to play cards with friends every Tuesday and Thursday afternoon in a Cultural Centre in Turin a few minutes' walk from his house. The inCASA Telecare motion and contact sensors detect that he goes out usually between 2:30 and 3:00 pm and returns at about 6:30 pm to have dinner. The inCASA Telehealth SpO2 monitor and weight scale provide information on Mario's clinical condition and overall health status.

In May, he doesn't go out of his home on Tuesday and Thursday for one week, but continues to move around his apartment as usual. Telecare motion and contact sensors relay this information to the activity hub and to the inCASA platform, from which SPP[4] detect a change in habits and an alert is forwarded to the inCASA Contact Centre Operator.

Minor changes in weight (750g weight loss) over two weeks and 1% decrease of average SpO2 are not enough to declare a significant worsening of clinical condition, even if they triggered some low level alerts from the inCASA platform notifying Dr Vittorio Verdi, Mario's primary care clinician, who is aware, but continues monitoring the trends through the inCASA interface, waiting for other changes.

Francesca Bianco, Mr Rossi's Case Manager, knowing his passion for playing cards and based on the analysis of the information, considers there might be some problems. Checking the socio-clinical database Francesca finds also from the notes that Mario has not called his home help for two weeks to buy food and other goods. Combining the information, Francesca gives a call to Mario, and finds him really tired and depressed. She promptly calls Dr Verdi to explain her worries. The combination of minor clinical changes and habits changes leads Francesca to schedule a visit to Mario for the next day. When she meets him, she notices clear symptoms of fatigue and

[4] The SPP, provided by Reply, is a server-side component that stands as the master inCASA repository of all collected data.

evidence of worsening of his clinical condition. This prompts a visit of Dr Verdi, who changes Mario's medication; his condition improves within a few days. He resumes his short walk to the Cultural Centre to play cards again, and avoids hospitalisation.

2.4 Integrated Telehealth/Telecare Business Process and Workflow

The figure below illustrates the overall business processes and workflows in ATC for both Telecare services and the integrated Telecare/Telehealth services enabled by the inCASA solution:

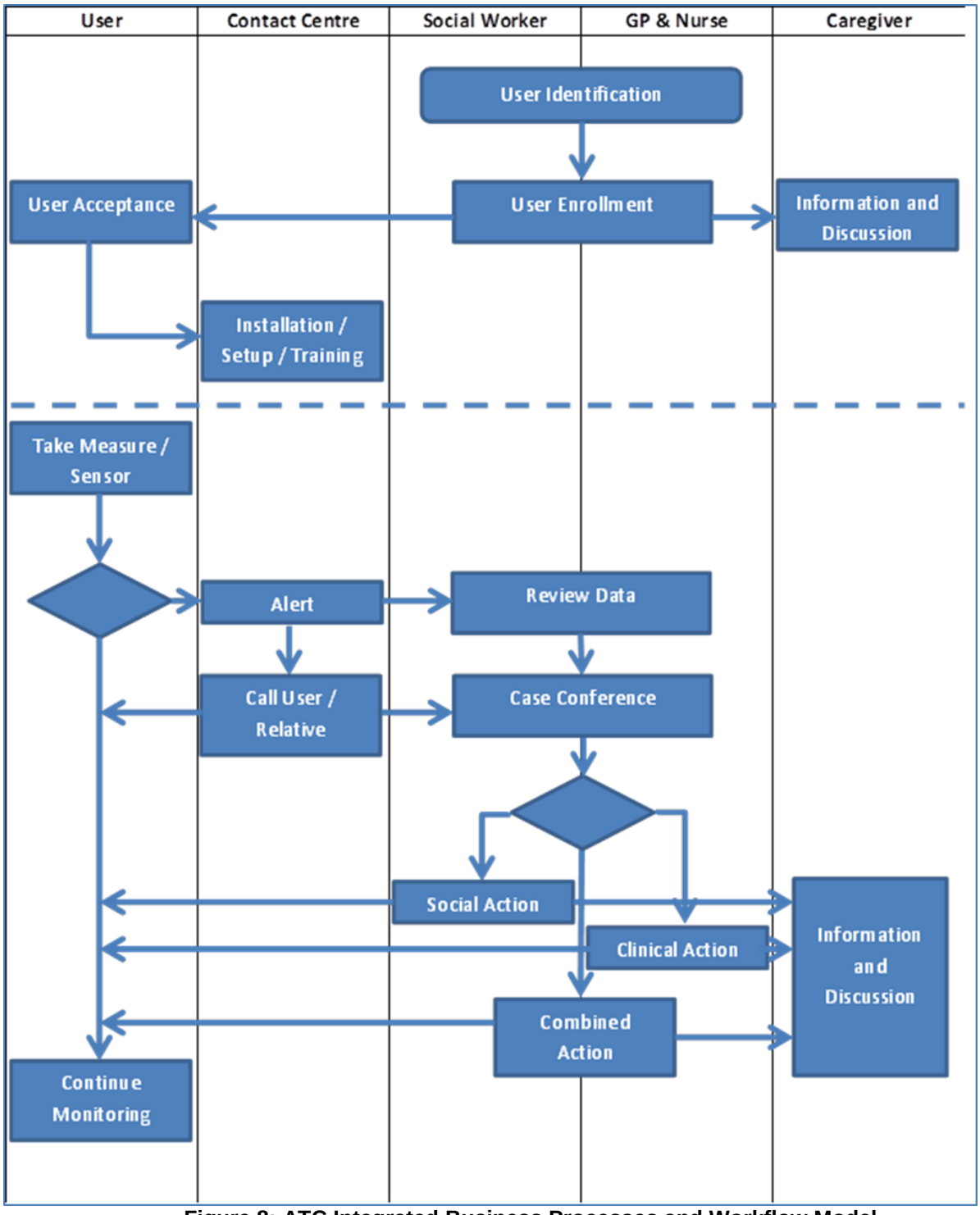

Figure 8: ATC Integrated Business Processes and Workflow Model

2.5 Schedule

Date	Action
March 2011	Pre-pilot Users' Home Inspection
July 2011	Follow-up pre-installation and Interviews with Users
July - September 2011	Pre-pilot Training of Multidisciplinary Operations Group
October 2011	Pre-pilot is running
27th October 2011	1st Pre-pilot Installation
3rd November 2011	2nd Pre-pilot Installation
6th December 2011	3rd Pre-pilot Installation
March 2012	Pilot is running
8th – 9th March 2012	5 Pilot installations
26th – 17th March 2012	5 Pilot installations
29th – 30th March 2012	3 Pilot installations
28th – 29th June 2012	4 Pilot installations
July/September 2012	Involvement of General Practitioners and local authorities to identify Healthcare/Social care integrated scenarios
October 2012	Iteration 3 is running
March 2013	Conclusion of Pilot monitoring and final evaluation beginning
April-June 2013	Conclusion of evaluation and of Pilot activities overall

Table 2: ATC Pilot Schedule

2.5.1 Updates since Iteration 2

Three new use cases focusing on health monitoring have been defined and will be implemented in this 3rd phase of the pilot. With these new uses cases, ATC will provide integrated Telecare and Telehealth services for its users. This has an impact on existing cooperation between health and social services organisations; new workflows will be tested during this 3rd phase of the pilot.

The technical requirements relevant for ATC have been updated accordingly. A complete report of all the updated requirements can be found in Chapter 7.

3 CHC

This chapter presents the 3rd phase of the CHC pilot, the Pilot Escalation Phase. It focuses on the organisational aspects, service delivery processes, and business processes relevant for this 3rd phase.

3.1 Aims and Objectives

The CHC pilot aims to develop an integrated service delivery model that will combine health and social care in responding to the needs of frail elderly people with long term conditions. This service integration is driven by both health and social care. Information about the patient and data from the remote monitoring will be shared and exchanged between the general practice and social services.

While the numbers within the project will not be large enough to provide an in-depth clinical study of statistical significance, it does hope to be able to provide some evidence through case studies some of the outcomes outlined below.

The overall objectives are to:

- Build the integrated health and social service to deal with the data from both remote patient monitoring and environmental monitoring.
- Evaluate the value of the integrated service to both the frail elderly person and the social and clinical services that care for that person.
- Understand and measure the impact of such a service to a patient's quality of life
- Prevent or delay the eligibility of frail patients for social services
- Prevent or reduce the numbers of unnecessary interventions and hospital admission
- Reduce length of stay and enable early discharge of the frail patient into their own home.

The CHC service model supports the identification and monitoring of those frail patients with chronic disease who are at risk of sudden deterioration so that they can be treated and supported in their own home. The integrated health and social team can monitor, review and respond to the patients' needs as they change by providing comprehensive support covering a range of services.

Costly hospital admissions can be avoided and the number of bed days can be reduced and early discharge can be enabled. Appropriate social support can be identified earlier in order to enable the frail elderly patients to remain safe and independent in their own home.

The project will monitor 40 frail elderly patients who are currently on the chronic disease register at Chorleywood Health Centre. Each patient will be provided with a monitor in their home that will capture and transmit a number of different physiological measurements (see Table 1 below) on a daily basis. In parallel to the clinical monitoring, the patients will also be provided with environmental sensors (see Table 1 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 patient's normal routine.

User Group	BP	Weight	Spo2	Chair Sensor	Bed Sensor	PIR	Medication Dispenser
CHF	X	X		X	X	X	X
COPD	X		X	X	X	X	X
Hypertension	X			X	X	X	X

Other condition*	X	X	X	X	X	X	X

Table 3: CHC Physiological and Behavioural Measurements per User Group.

*Other disease groups may be included in the pilot.

Patient inclusion criteria:

- Must be registered with CHC
- Must be determined to be Frail as defined by the Edmonton Frail Score (see table 3 in D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2)
- Must have more than one co-morbidity
- Must be living alone
- Must have had 1 unplanned hospital admission in the past 6 months or 2 in the past 12 months.

3.1.1 Rationale

Each patient will be monitored for a period of 6 months. This time frame was chosen as it would allow sufficient time for changes in patterns to be observed, reported and for appropriate clinical and/or social intervention to take place based on individual patient/end user needs.

3.2 Organisational Aspects

Currently health and social services are delivered separately. Adult services are organised by Hertfordshire County Council and Chorleywood Health Centre provides primary care to over 6000 residents within the area. While work elsewhere in the county is looking at integrating health and social care, it has not yet been accepted as a model by West Hertfordshire where Chorleywood Health Centre is located. Referral between health and social care is currently carried out by referral letter and by phone. Social workers are then assigned to the patient directly and no further communication between health and social care takes place.

Information about the patient is kept in separate health and social silos. Coordinating responses to patients' needs is complex. There are many competing interests between the two organisations in order to reduce costs. This separate working is recognised as possibly leading to inappropriate or missed interventions which ultimately can impact on the patient, their carers and the organisations charged with delivering the care whether it is health or social.

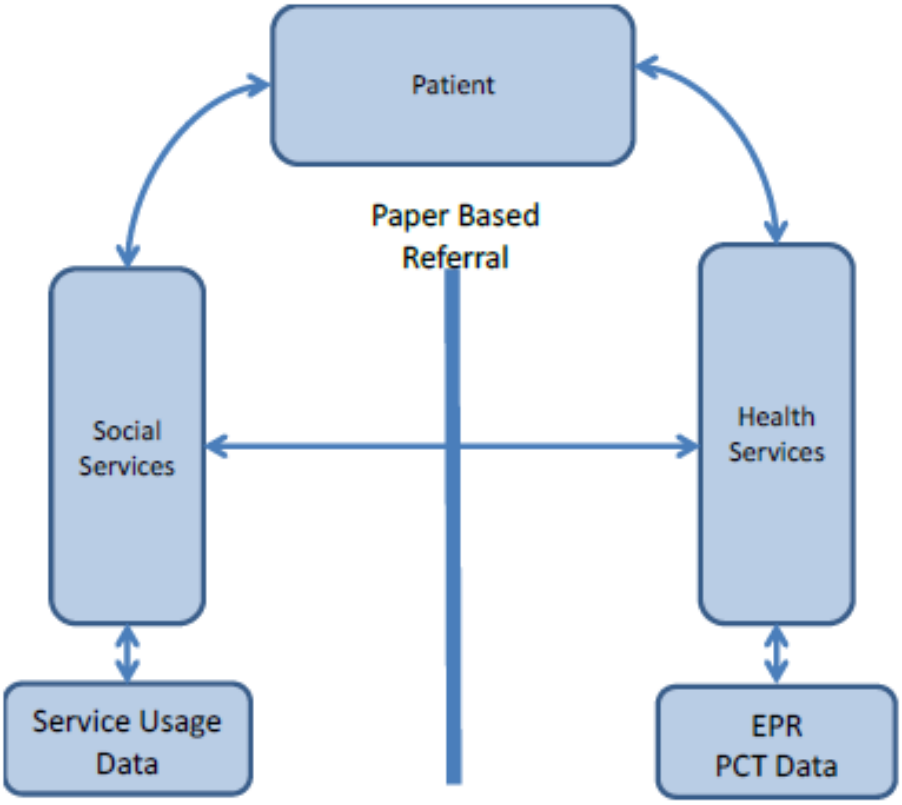

Figure 9: Current Health and Social Services Delivery Process in West Hertfordshire

There are two main challenges that impact on the elderly frail person and the use of social services. Firstly carer breakdown, which is when the informal carer (unpaid carer) can no longer cope with the needs of the person they are caring for. Secondly it is when hospitals choose to discharge elderly frail patients into residential care rather than enable the person to return to their own home.

For health providers the challenge is to identify those of its frail elderly patients who are at most risk from deteriorating and requiring costly and avoidable admissions to hospital. While there are measures in place such as the Quality Outcome Framework (QOF) which supports the tracking of chronic disease every six months, measures of frailty are not recorded within primary care. However, it is the older frail patients that are at most risk of sudden deterioration and which can go undetected until the condition deteriorates and hospital admission is unavoidable.

The CHC pilot will implement an integrated process by implementing Telecare and Telehealth services. A frail elderly patient will be monitored by a combination of health and habits sensors in their own home (blood pressure, weight, SpO2, etc., bed, chair PIR sensors). Sensor data is transferred from the home to the health care team in the general practice and to a key social worker in social services. Data can be viewed on a combined health and social care interface. Changes in usual clinical measurements and levels of activity are identified.

Incoming data will be monitored by the healthcare team at Chorleywood Health Centre. Patterns of behaviour and physiological data, including in-bed restlessness, habits and deviations from habits, toilet visits, eating patterns, rapid weight loss or gain, medication adherence, blood pressure, weight, SpO2 etc., will be assessed to provide decision support for the health and social care professionals for cases such as loss of autonomy or early detection of clinical deterioration. Responses to the information will be managed by joint case conference between health professionals at Chorleywood Health Centre and social workers from Hertfordshire Adult Social Services. These will be held weekly or sooner if deemed necessary and facilitated by means of

video conferencing or teleconferences. Appropriate social and/or medical interventions can then be determined by the joint team.

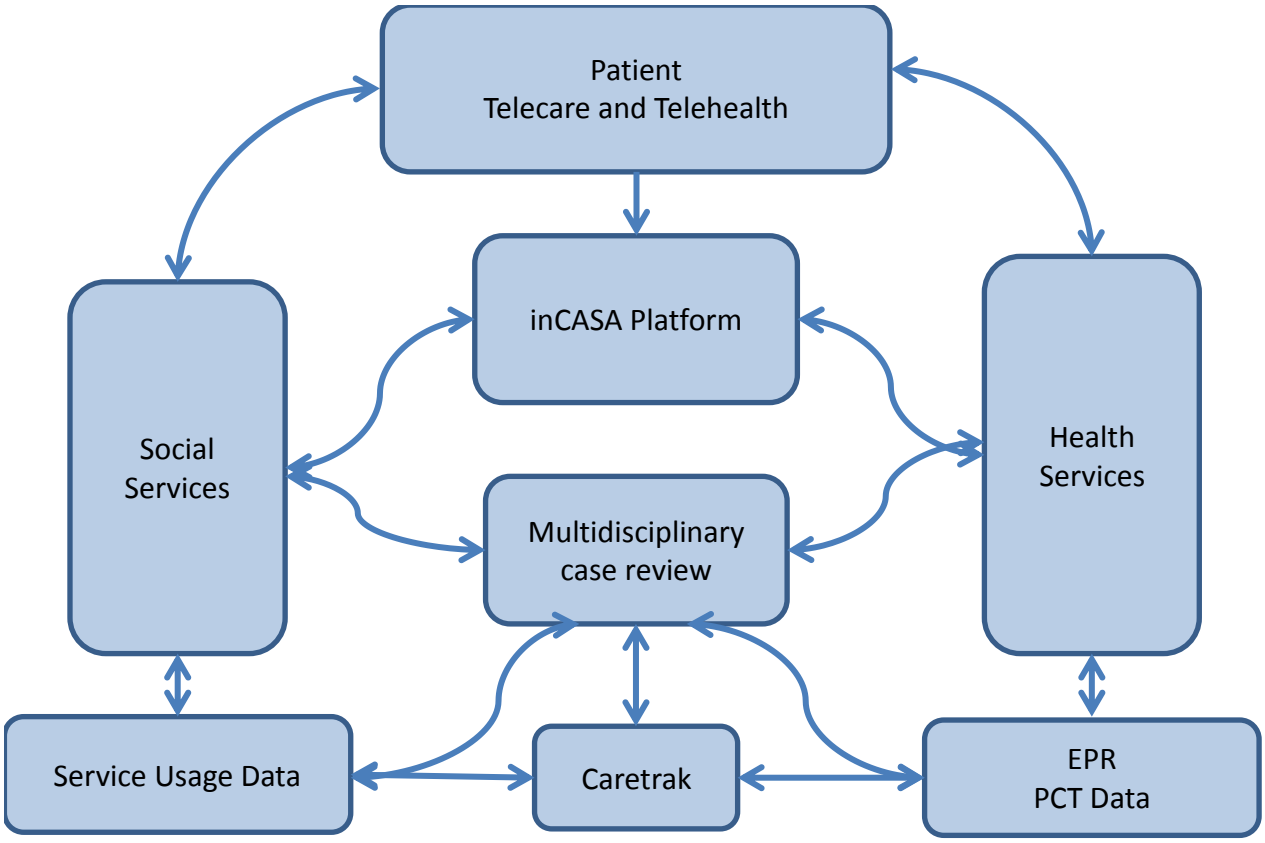

Figure 10: Integrated Process enabled by inCASA

Current paper-based referrals between health and social care will be supported by the new service model. This integrated service model will overcome the issue of separate silos of information. The teams will be able to share information and liaise directly with each other in order to identify targeted and appropriate support for those patients that require additional care.

3.2.1 Pilot Structure

The CHC pilot structure is pictured below:

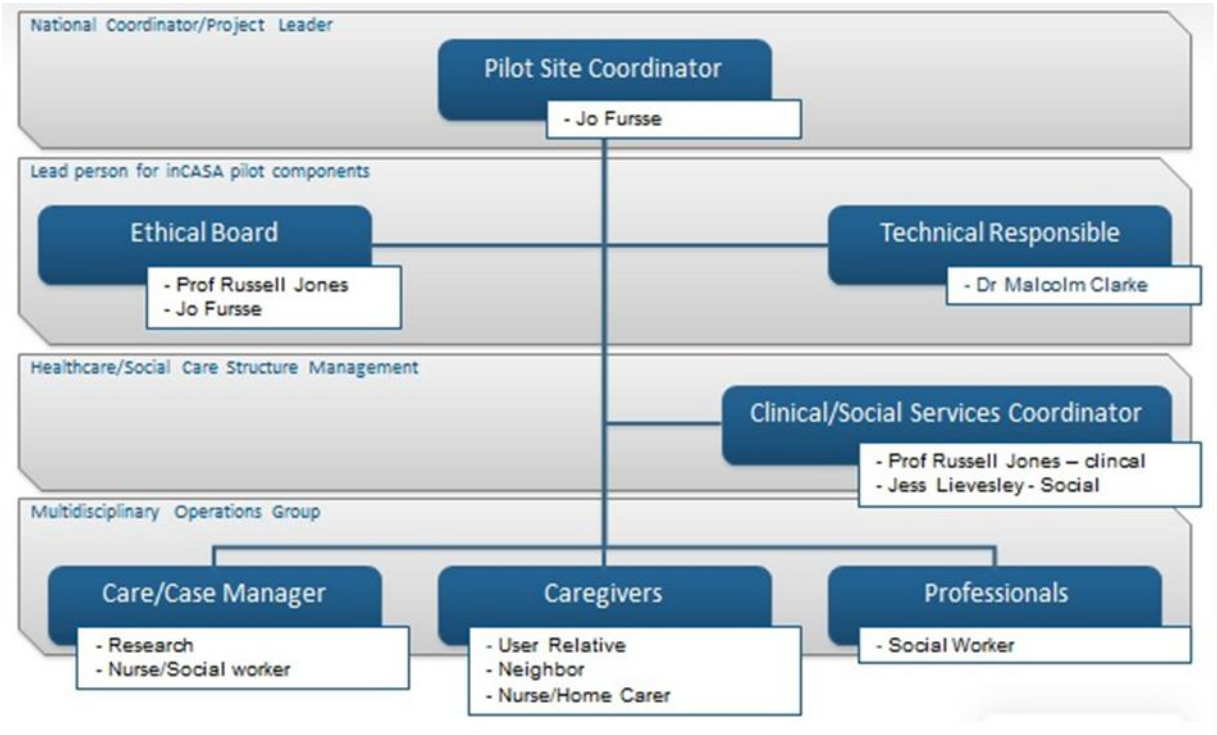

Figure 11: CHC Pilot Structure

The structure is unchanged compared to the 2nd phase (the pilot phase) that was described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2*.

3.3 Service Delivery Process

The main inCASA server will be installed at CHC. CHC will recruit patient through a defined recruitment process and medical staff will determine the specific parameters, procedures and alerts for each patient.[5] The CHC pilot will implement the following services/use cases:

[5] More detailed information on service installation, recruitment process, procedures etc. can be found in D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2.

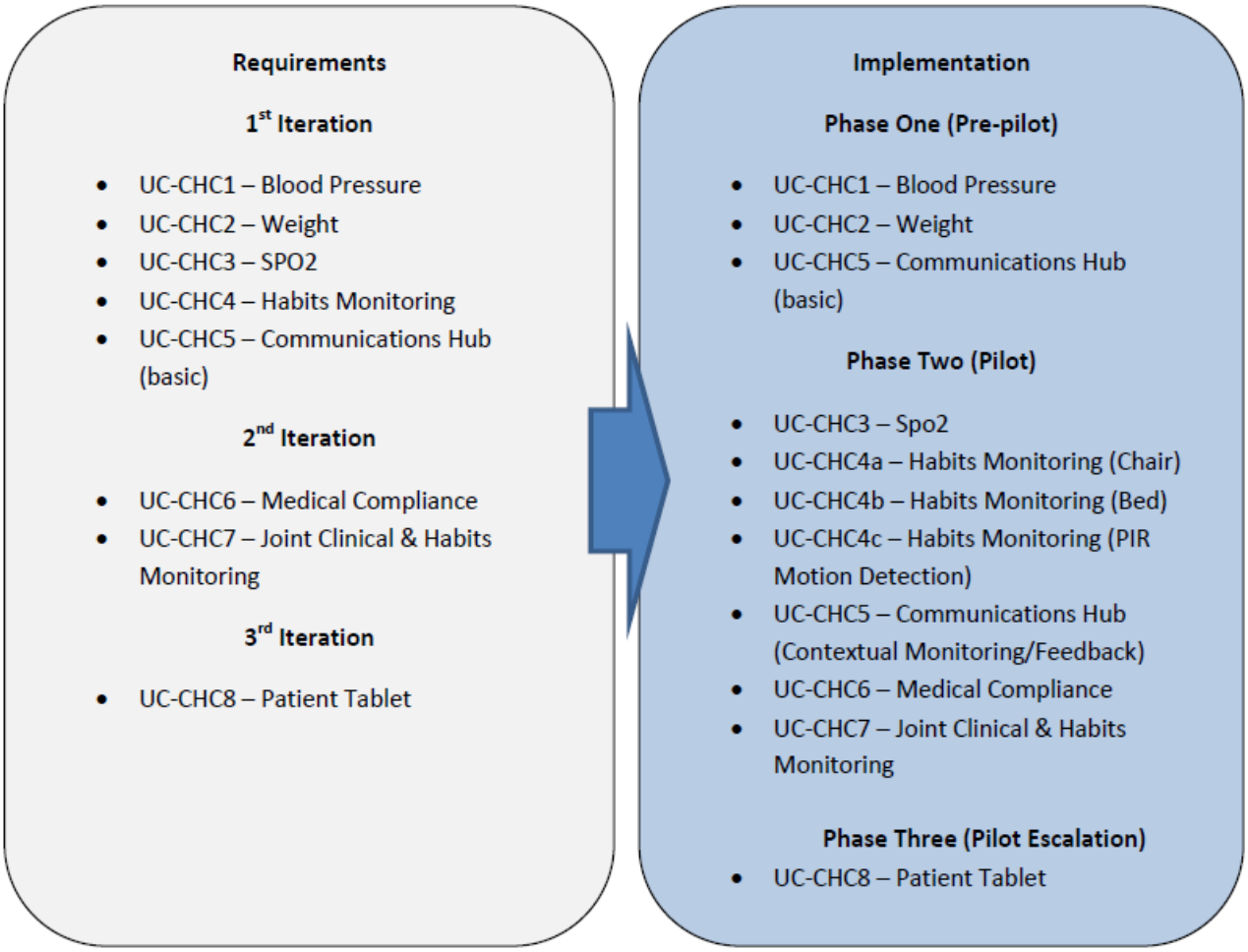

Figure 12: CHC Deployment Figure

The CHC pilot is being implemented in three phases. The Pre-pilot introduced a Telehealth monitoring device to the patients participating in the pre-pilot phase. This phase was mainly used to support the testing of the technology as it was made ready by our technical partner.

Phase two saw the introduction of habits monitoring to the platform as well as a combined clinical and habits monitoring interface. Phase two will also see the introduction of the integrated health and social working practices beginning in October 2012. Information generated from the devices will be shared amongst health and social professionals. Joint working practices and learning will be developed in order to react to the data in an appropriate way. The new integrated social and health service model was described and put into practice.

For phase three, a patient tablet will be introduced where it is suitable. This will enable patients to view the data that they are sending each day. Information can also be fed back to the patient. This may include educational and helpful resource information for both health and social care.

The parameters that will be monitored are (accumulative):

Parameter	Phase
Blood pressure	Pre-pilot
Weight	
SpO2 (blood oxygen saturation level)	Pilot
Bed permanence	
Indoor movement	
Chair permanence	
Medical compliance	
As above (on-going)	Pilot Escalation

Table 4: CHC Parameters

The following sections provide 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 more detailed Use Cases that describe some of the main scenarios.

Patients who benefit from the service will be those that are 65 or over and who have more than one co-morbidity such as COPD, CHF, Hypertension or Dementia. They will have had at least one unplanned hospital attendance within the last 6 months and be deemed frail as defined by the Edmonton Frail Scale. In addition, they may also be using services provided by Hertfordshire social services or currently being assessed for social needs.

A “normal” non-Telehealth pathway for a patient 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 individual’s 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, once a month or the patient may not be seen for many months. 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 may be 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 directly from the patient during the visit.

The main objective of introducing the inCASA platform to patient management is to enable the clinicians to have access to more complete and 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
- Reducing Hospital Admissions
- Increased independence
- Reducing inappropriate use of services
- Improved information sharing between organisations.

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.

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 clinician's 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.

3.3.1 3rd Phase Use Cases

As noted above, the CHC pilot implemented both clinical and behavioural use cases already in Phase Two in order to implement an integrated Telecare and Telehealth service model. Phase Three will continue with these use cases. Use cases 1 to 5 are described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* and can also be found in Appendix A. The following will describe use case 6 to 8. The following use cases describe a single parameter being measured. The reality of monitoring is that is often a combination of parameters that will determine intervention.

Use case 6: Medical Compliance

Overview: Dependent on the individual patient's health or social requirements a patient may be provided with a medication compliance dispenser.

Clinical purpose: The medication dispenser will provide social and health professionals information about a patients medication intake. A difference in expected medication usage will provide compliance information.

Procedure: The medication dispenser will be filled with one week's dose of medication by the pharmacist. The patient will be given the medication dispenser which will communicate medication dosage and usage information via the monitoring hub. Data will be viewable on the clinical and habits monitoring portal.

Analysis: The data will be analysed using the management system to track the patients' medication intake and compliance with the prescribed dosage.

Data fusion: All data transmitted via the hub will be stored on the inCASA server.

Alerts: The clinician / social worker will be alerted when there is a variance away from the desired or expected medication usage.

Feedback to patients and relatives: Patients will be notified via a phone call if the health or social professionals think that an intervention is required.

Personalisation: The system should allow for clinicians to enter personalised optimum target values for each patient.

Devices: A medication dispenser will be provided. The device should be easy to use.

Use case 7: Combined Clinical and Habits monitoring Clinical Portal

Overview: The clinical team should be able to access the clinical user interface and see both clinical and habits monitoring data visualized in tabular and graphical format. Patients should be prioritised in order of clinical need on the screen based on pre-defined rules. The data should be viewable for each individual patient.

Clinical purpose: The ability to view both clinical and habits monitoring data will help clinicians to view trends and possibly observe any correlation between change in usual habits and any decline in physical health.

Procedure: Patients will be given a set of Telehealth equipment and Telecare equipment. Data will be transmitted and received on a server. Patterns in clinical and habits data will be observed and the trend analysed. Significant change in patterns will be identified and the patients will be prioritised via the clinical user interface.

Analysis: Habits data will be analysed to determine a usual habits monitoring template. Rules will be created to determine degree of deviation from the "normal". These variances will be correlated with any changes in trend of the physiological data to determine any relationship.

Data fusion: All data will be stored on the inCASA server and a copy will be posted into the local EPR.

Alerts: If values are outside of those prescribed by the clinician, a notification will be viewable on the clinical user portal.

Feedback to patients and relatives: Feedback will be provided to the patient and their next of kin by means of contact from the clinician. This contact will normally only occur in the event of a clinical need.

Personalisation: Both the clinical and habits monitoring template will be personalised for the individual patient. It will take into consideration the patients other co-morbidities.

Devices: Blood Pressure, Weight, Sp02, TV Sensor, Chair Sensor, PIR Motion Sensor.

Use case 8: Patient Tablet

Overview: Patients who are being monitored may be provided with a patient tablet that will enable the display of monitoring data to the patient and collect contextual data from the patient.

Clinical purpose: The patients will be able to view their own trend measurements and other educational content that may help them with education and management of their condition. The health and social professionals may be able to obtain further contextual information from the patient via the tablet such as dietary intake.

Procedure: Patients will be given a tablet that will link to a patient portal via a URL. The patient will log on to the URL using their own username and password. The patient will be able to view their

trend monitoring data. The patient may also be asked to complete diet and activity questionnaires on the portal. The patient will be provided with personal feedback based on their answers to the questions. The clinicians will be able to view the patients' responses to the questionnaires on the clinical and habits portal.

Analysis: The data from the questionnaires will be analysed using the management system to track the patient's responses.

Data fusion: All data transmitted via the hub will be stored on the inCASA server.

Alerts: The clinician/social worker will be alerted when there is a variance away from expected responses to the questionnaires.

Feedback to patients and relatives: Patients will be notified via a phone call if the health or social professionals think that an intervention is required.

Personalisation: The system should allow for patients to be provided with Questionnaires and feedback that are based on the individual patients need.

Devices: The device should be a touch screen tablet or the patient can be provided with a secure URL link to a website which can be accessed via the internet.

3.3.2 Intervention Protocols

The following describes the steps that will be undertaken based on certain use cases. It is anticipated that more than once use case and maybe a combination of both clinical and habits may inform pathways.

3.3.2.1 Physiological Measurement Deteriorates – Use Cases 1-3

1. The patient takes daily physiological measurement's using the devices provided and installed by the clinical team and depending on the patient's clinical need e.g. blood pressure, weight, SpO2.
2. Once the patient takes a measurement using the device it is automatically transmitted to a central server.
3. Data is automatically analysed using rules defined by the clinicians. If the data is outside of the thresholds, it will be highlighted on the inCASA portal to notify the clinician of the variance.
4. The clinical team at CHC review the data on the inCASA portal and perform a 1st line triage each day that determines if immediate intervention is required or if the patient should be referred to a case conference.
5. Immediate intervention occurs when the monitoring data indicates a significant risk to the patient. Data is compared against information contained within the EPR.
6. If immediate intervention is required, the clinician contacts the patient by telephone and may either ask them to attend an appointment at the health centre or if necessary a home visit will be arranged. Any actions are recorded in the inCASA portal and the EPR.
7. If the patient is to be referred to a case conference, a note is made in the inCASA portal and the EPR.
8. At the case conference, the patients monitoring data is reviewed by a combination of GPs and Nurses. The patient's EPR is reviewed in conjunction with the monitoring data. Outcome of the case conference is recorded in the inCASA portal and EPR. If intervention is required, the patient is contacted and asked to attend an appointment at the health centre.
9. The monitoring of the patients will continue as long as the service is deemed to be required.

3.3.2.2 Change in Habits Monitoring Data – Use Cases 4a,b,c

1. The patient is provided with a series of sensors which passively monitor movement within the patient's home, and data is automatically transmitted to the server.
2. Data is automatically analysed using rules defined by the professional users. If the data is outside of the thresholds, it will be highlighted on the inCASA portal to notify the professionals of the variance.
3. The clinical team at CHC review the data on the inCASA portal and perform a 1st line triage each day that determines if immediate intervention is required or if the patient should be referred to a case conference or to social services.
4. Immediate intervention occurs when the monitoring data indicates a significant risk to the patient. Data is compared against information contained within the EPR and any social information that is contained on the inCASA portal.
5. If immediate intervention is required, the clinician contacts the patient by telephone and may either ask them to attend an appointment at the health centre or refer them to social services. Any actions are recorded in the inCASA portal and the EPR.
6. If the patient is to be referred to social services as an immediate case, an electronic referral form is completed on the inCASA Portal. A phone call is made to the social worker nominated.
7. Interventions taken by the social worker are recorded in the inCASA portal
8. If the patient is to be referred to a case conference, a note is made in the inCASA portal, an EPR and a phone call is made to the social worker to schedule the conference.
9. At the case conference, the patients monitoring data is reviewed by a combination of GPs Nurses and social workers. The patient's EPR and social service history is reviewed in conjunction with the monitoring data. Outcome of the case conference is recorded in the inCASA portal and EPR.
10. If intervention is required, the patient will be contacted and asked to attend an appointment at the health centre or will be contacted by social services
11. The monitoring of the patients will continue as long as the service is deemed to be required.

3.3.2.3 Change in medication compliance – Use Case 6

1. The medication dispenser is filled with one week's dose of oral medication by the pharmacist.
2. The patient is provided with the dispenser that contains his/her medication.
3. The patient takes medication from the dispenser as per the usual and prescribed schedule.
4. The medication dispenser sends an automatic message via the hub in the patient's home each time the medication dispenser is used.
5. Data is automatically analysed using rules defined by the professional users. If the data is outside of the expected values e.g. medication has not been taken or too much has been taken, it will be highlighted on the inCASA portal to notify the professionals of the variance.
6. The clinical team at CHC review the data on the inCASA portal and perform a 1st line triage each day that determines if immediate intervention is required or if the patient should be referred to the case conference or to social services.
7. Immediate intervention occurs when the monitoring data indicates a significant risk to the patient. Data is compared against information contained within the EPR and any social information that is contained on the inCASA portal.
8. If immediate intervention is required, the clinician contacts the patient by telephone and may either ask them to attend an appointment at the health centre or refer them to social services. Any actions are recorded in the inCASA portal and the EPR.
9. If the patient is to be referred to social services as an immediate case, an electronic referral form is completed on the inCASA Portal. A phone call is made to the social worker nominated.
10. Interventions taken by the social worker are recorded in the inCASA portal

11. If the patient is to be referred to a case conference, a note is made in the inCASA portal, an EPR and a phone call is made to the social worker to schedule the conference.
12. At the case conference, the patients monitoring data is reviewed by a combination of GPs, nurses and social workers. The patients EPR and social service history is reviewed in conjunction with the monitoring data. Outcome of the case conference is recorded in the inCASA portal and EPR.
13. If intervention is required, the patient will be contacted and asked to attend an appointment at the health centre or will be contacted by social services
14. The monitoring of the patients will continue as long as the service is deemed to be required.

3.3.2.4 Patient Tablet – Use Case 8

1. The patient is provided with either a touch screen tablet or a URL to a patient portal accessed via the internet using their own internet connected device.
2. The patient is provided with a secure username and password to access his/hers information contained on the portal.
3. At a time when the patients choose they are able to access the patient portal to view their individual and trend monitoring data in both tabular and graphical form.
4. The patient may have also been instructed by the professional to complete an activity or diet questionnaire. If this is the case the patient will at the prescribed interval and time, complete the questionnaire on the patient portal.
5. The results of the questionnaire will be viewable to both the patient and to the health professionals on the professional clinical and habits portal.
6. The clinical team at CHC review the data on the inCASA portal and perform a 1st line triage each day that determines if immediate intervention is required or if the patient should be referred to a case conference or to social services.
7. Immediate intervention occurs when the monitoring data indicates a significant risk to the patient. Data is compared against information contained within the EPR and any social information that is contained on the inCASA portal.
8. If immediate intervention is required, the clinician contacts the patients by telephone and may either ask them to attend an appointment at the health centre or refer them to social services. Any actions are recorded in the inCASA portal and the EPR.
9. If the patient is to be referred to social services as an immediate case, an electronic referral form is completed on the inCASA Portal. A phone call is made to the social worker nominated.
10. Interventions taken by the social worker are recorded in the inCASA portal
11. If the patient is to be referred to a case conference, a note is made in the inCASA portal, an EPR and a phone call is made to the social worker to schedule the conference.
12. At the case conference, the patients monitoring data is reviewed by a combination of GPs Nurses and social workers. The patients EPR and social service history is reviewed in conjunction with the monitoring data. Outcome of the case conference is recorded in the inCASA portal and EPR.
13. If intervention is required, the patient will be contacted and asked to attend an appointment at the health centre or be contacted by social services.
14. The monitoring of the patients will continue as long as the service is deemed to be required.

3.3.3 Telehealth and Telecare Integration Scenario

The following scenario envisions how the inCASA platform could provide integrated Telehealth and Telecare services for an elderly patient suffering from several chronic conditions.

Managing Chronic Conditions and Maintaining Independence

Mrs Osbourne is 79 years old. She lives alone in a ground floor flat in Chorleywood. She has chronic heart failure, diabetes and hypertension. She has a daughter who lives 200 miles away who visits regularly but otherwise she lives a quiet and independent life. Two months ago, Mrs Osbourne's health deteriorated quite rapidly and she was admitted to hospital due to renal failure.

After discharge, she was assessed using the frailty scale by the general practice team. The results indicated that she was becoming frailer but was very keen to maintain her independence. She was offered the opportunity to be monitored using the inCASA solution. She was provided with a weight scale to monitor her weight, a bed sensor and a PIR sensor which was positioned in the hallway near her kitchen.

Each day, data from the sensors was analysed by the system for degrees of change from normal pattern. After 5 weeks, the nurse who was looking at the data was notified by an alert from the system that activity levels in the home had reduced. The health care team continued to monitor closely over the next few days and noticed a slight reduction in weight and then a sudden increase. Mrs Osbourne was contacted by the nurse and said that she had not been feeling very well and had not been feeling well enough to cook and so had not been eating. A visit was made to the patient in her home by a GP who discovered that she was retaining fluid which was why she had been feeling poorly and had not wanted to eat. The patient was provided with diuretic medication to reduce the fluid levels.

Mrs Osbourne's was continued to be monitored and notes were reviewed at the next joint health and social case review. It was suggested that while Mrs Osbourne was determined to remain independent she may need some short term support in her home such as meals on wheels and home help during the week. The social care team contacted Mrs Osbourne and also her daughter to discuss the options available. A care package was agreed which provided additional social support.

3.4 Integrated Telehealth/Telecare Business Process and Workflow

The figure below illustrates the overall business processes and workflows in CHC for the integrated social and health pathway:

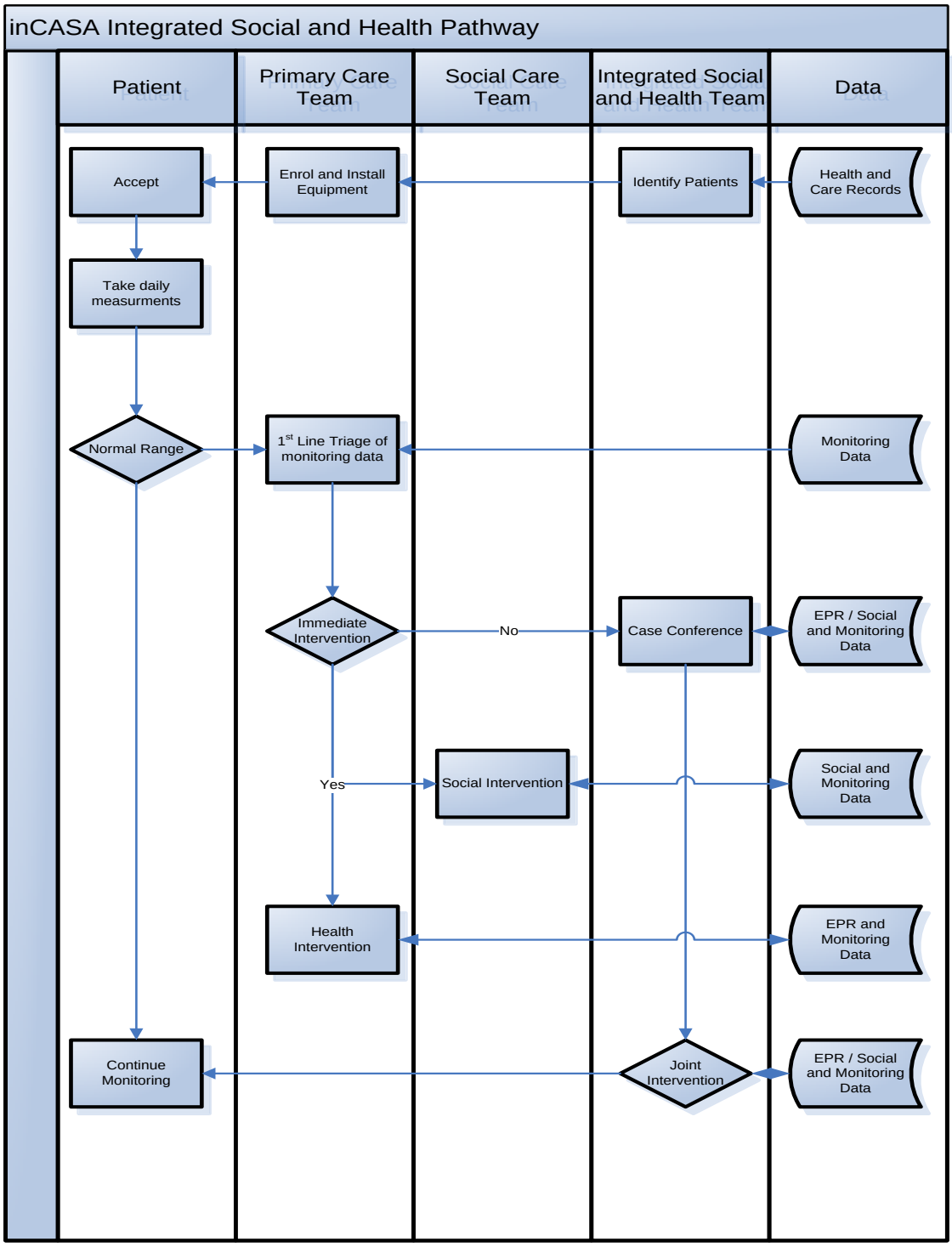

Figure 13: CHC Integrated Business Processes and Workflow Model

The following provides a more detailed overview of the integrated workflow process. It describes the interaction between health and social organisations and how the data generated from inCASA is processed and responded to.

1. The patient is provided with Telehealth and Telecare and asked to take measurements each day. Passive sensors will transmit data automatically.
2. Data is transmitted from the devices to the inCASA platform where it will be stored.
3. Data is analysed using pre-defined rules to identify change from trend and notifications for the social worker and clinicians are generated.

4. Both the clinicians and social workers are able to access the data via the inCASA portal. Additional information can be entered into the system by the clinicians and social workers.
5. The clinical team at CHC act as a 1st line triage for the monitoring data. They view the data daily and determine if intervention is required.
6. Clinicians use information from the patients EPR to help with their decision. If immediate intervention is required they will contact the patient directly. If necessary they will refer the patient directly to social services using an online referral form accessed via the inCASA portal. The social service team may contact the patient directly if required. The patient may also so be referred to an integrated case conference which is attended by both social and health teams.
7. The integrated case conference is attended by both health and social teams. Both monitoring data and data from the patients EPR and social records are viewed side by side. Decision to intervene is determined through joint discussion.
8. Outcome of the case conference is recorded in the inCASA portal, EPR and social record. The patient is contacted by either the health and or social team dependent on the patient need.

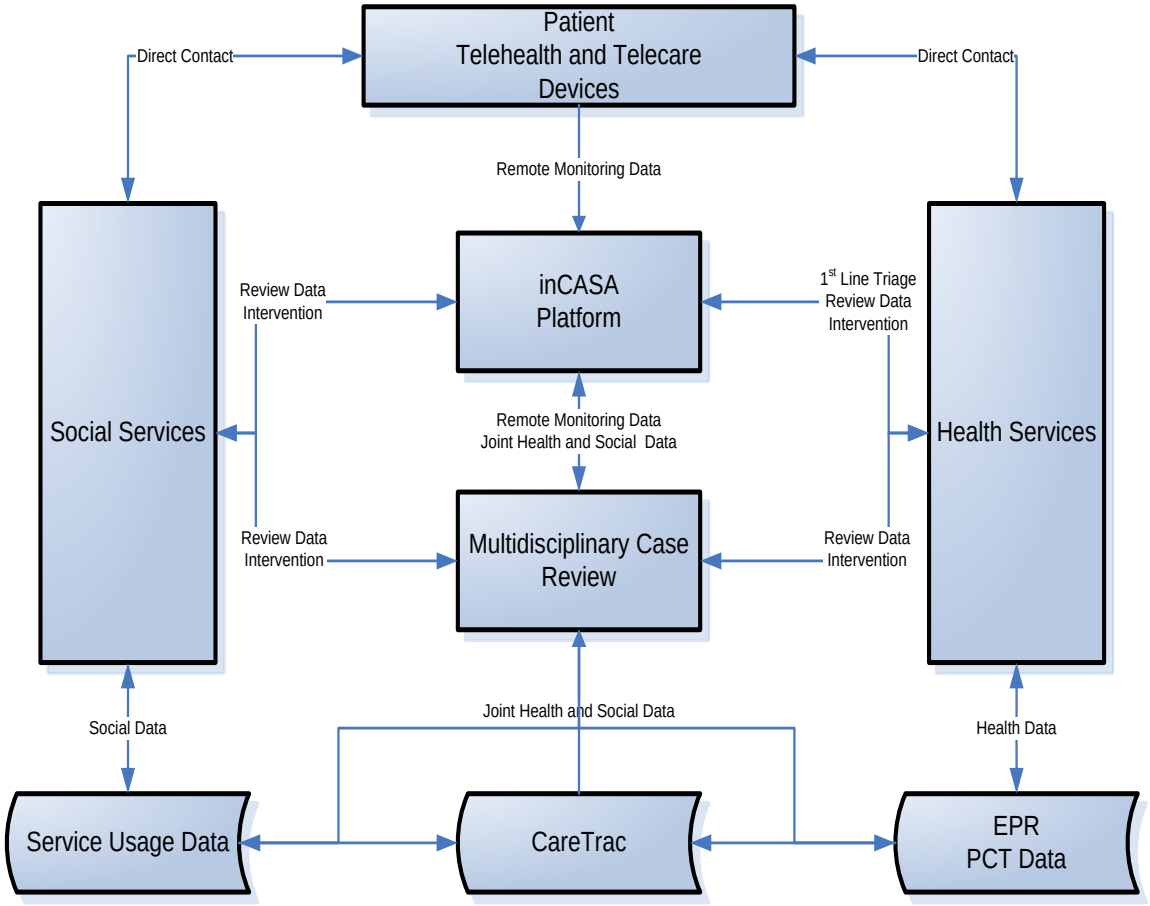

Figure 14: CHC Detailed Integrated Workflow Process

EPR (Electronic Patient Record) Data consists of the patient's data including demographics, medical history, medication and allergies, laboratory test results, some radiology images, physiological measurements and notes taken during clinician consultation.

PCT (Primary Care Trust) Data relates to data that is collected by the Primary Care Trusts. This data includes resource usage data collected from Secondary Care, Accident and Emergency, walk in centres and GP out of hours. This data is not always available on the Electronic Patient Record

CareTrac data is data that has been matched for each patient from Social services (Service Usage Data) and data collected by the PCT (PCT Data). This enables a complete picture of a patient's use of both health and social services.

Service Usage Data relates to social services data that describes what social services a patient is using.

3.5 Schedule

The following table provides an overview of the CHC pilot schedule:

Date	Action
October 2011	Pre-Pilot Commences
February 2012	D6.2 Pre-Pilot Report – Telehealth – Reported D6.2
March 2012	Pre-Pilot Extension – New Gateway, Telecare sensors, Combined Clinical Habits
September 2012	Installation Report – Report D6.3
October 2012	Integrated and Social Service Model Commences
January 2013	Interim Report D6.5
March2013	6 months of evaluation - Pilot Ends
June 2013	Evaluation Report D6.6

Table 5: CHC Pilot Schedule

3.5.1 Updates since Iteration 2

No major changes or updates have been made from Iteration 2 to the present iteration 3 in relation to the non-technical aspects. However, in terms of the deployment strategy that was reported in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* (Chapter 3.4), the following will provide a more detailed insight into the events and progress from the pre-pilot start to date.

The Pre-pilot phase was mainly used to support the testing of the technology as it was made ready by our technical partner.

The main objectives of the pre-pilot phase were thus to:

- Test functionality of the equipment
- Develop clinical interface with the users
- Provide feedback to the technical teams on additional requirements
- Develop basic habits monitoring protocol
- Train clinical users on equipment and clinical interface
- Refine monitoring and clinical protocols
- Use information gained to inform the ethical approval authority

- Gain a better understanding of how to effectively evaluate the service

The pre-pilot lasted from October 2011 to June 2012. The CHC delay has been predominantly due to availability of technology that would be suitable to use within the pilot phases.

Despite the delay in the initial user requirement collection, CHC had a clear understanding of the technology that would be required to deliver the integrated service however it became clear during the 1st year that we were not able to find a supplier of the required technology.

During the early planning of the pilot, talks were held with one of the technology partners to provide an integrated Telehealth and Telecare platform. The requirements were clear in that we needed a system that would integrate both Telecare and Telehealth so that users did not have multiple technologies in their home as well as data integration, processing and display for the professionals. Despite numerous attempts which involved face to face meetings and conference calls, including those with senior members of the organisation we were not able to secure agreement that the required integration based on the user requirements would be possible. A further meeting with a UK Telecare supplier was also unsuccessful in finding a solution that would support the pilot.

As a result it was decided to work with our technology partner, Brunel University who had been developing a standards based system in another project that would enable the integration of sensors which would ultimately support the system. The pre-pilot initially began in April 2011 but had to be cancelled due to a number of reliability problems with the technology. The pre-pilot phase started again in October 2011 with a subset of Telehealth devices and using an existing Smart Meter gateway to transmit data. This was reported in *D6.2 Pre-Pilot Installation Reports*. The pre-pilot phase was extended in order to include and test the final inCASA integrated health and care sensor solution.

Phase two saw the introduction of habits monitoring to the platform as well as a combined clinical and habits monitoring interface. The platform and sensors that are being used have been procured from Acute Technology. The devices are Continua and ZigBee Alliance certified. All devices work through a simple-to-use home gateway that accepts ZigBee ZHCP compliant devices and transmits data over GPRS using IHE-PCD01 standard messages. This will integrate directly to the Reply reasoning engine.

The integrated platform underwent robust and rigorous field tests in order to ensure reliability and usability by both professional and patient groups. In March 2012, the pre-pilot phase was extended and a further 9 additional patients were recruited in order to complete the pre-pilot phase.

Phase two will also see the introduction of the integrated health and social working practices beginning in October 2012. Information generated from the devices will be shared amongst health and social professionals. Joint working practices and learning will be developed in order to react to the data in an appropriate way. The new integrated social and health service model was described and put into practice. A total of 40 patients will be included in the pilot phase and will on the service for 6 months.

For phase three, a patient tablet will be introduced where it is suitable. This will enable patients to view the data that they are sending each day. Information can also be fed back to the patient. This may include educational and helpful resource information for both health and social care.

As an extension, family and carers could also be given access to the information being collected. The patient portal can be viewed via a URL which can be accessed via any device that has an internet connection. It is envisaged that relatives and/or carers would be able to monitor data if they are concerned or live far away.

The technical requirements relevant for CHC have been updated. A complete report of all the updated requirements can be found in Chapter 7.

4 FHC

This chapter presents the 3rd phase of the FHC pilot, the Pilot Escalation Phase. It focuses on the organisational aspects, service delivery processes, and business processes relevant for this 3rd phase.

A new use case that will enable the integration of social service by allowing a method for assessing whether a patient's activity level relates to his/her health status, and in cases where discrepancies are found it may indicate that social issues are present. A social worker will thus intervene as necessary.

The technical requirements relevant for FHC have been updated accordingly. A complete report of all the updated requirements can be found in Chapter 7.

4.1 Aims and Objectives

During the development of the FHC pilot and the recruitment process, several preselected patients chose not to participate in the pilot. A closer investigation into their reasons for opting out indicated that both health and socially related issues were influential. When looking at the social factors, it became clear that they play in important role in determining whether a patient would participate or not. In other words, social issues can have a significant effect on a patient's health status and how his/her health is managed.

In order to address this issue, the FHC pilot decided to include a social worker with the aim of addressing some of the social issues that may exclude patients from participating in the pilot. This way, the FHC pilot aims to improve the link between social and health units on regional and local levels in order to establish an integrated approach for addressing patient's needs.

Secondly, a use case involving Actigraph to measure the patient's activity level will be introduced and used to analyse how well patients' respond to the prescribed exercise (do they do the exercise or not). In case of a lower than expected activity level in relation to the patient's health status, a social worker may contact the patient to assess whether the low activity level is caused by social problems.[6]

The overall aims and objectives of FHC pilot are:

- To test the efficiency of FHC's Rehabilitation programme
  - Design of a prospective, legatorial and controlled study.
  - Statistical treatment of media comparison at the beginning and at the end of the programme.
  - In-home group (exercises at hospital for 4 to 5 weeks + 4 to 5 weeks at home) vs. 1 control-group (8 to 10 weeks of exercises at hospital gym).
- To design a programme based upon tele-rehabilitation / in home exercises to push forward adherence to treatment through use of new technologies:
  - Protocol of installation, data transmission from patients 'homes on-line at real time by using SARA solution (Salud y Atención Remota Avanzada) by Telefonica (TID).
- To improve the protocol used for the selection of the best candidates for participatione in the programme for tele-rehabilitation for COPD patients via Actigraph use (efficiency)
- To detect possible risk factors for social exclusion that complicate the COPD rehabilitation programme through social assessment of patients (effectiveness).

[6] The use case is described in more detail below.

The FHC pilot will involve at least 34 self-sufficient patients aged 65+ who have COPD, and who live far from the hospital. Patients will be sent from the respiratory medicine department of the hospital and must meet these criteria:

1) Age
   - 65 years old or older
2) COPD level and related health indicators for each patient (i.e. health issues)
   - COPD levels II or III
   - Clinically stable
   - With or without oxygen at home
   - No cognitive impairment
   - No motor deficit
   - No known coronary diseases
   - No other severe associated disease (e.g. neoplasm)
3) Relevant social issues
   - With caregiver at home
   - With telephone network (landline or mobile)
   - Non-smoker or about to start a smoking cessation programme
4) Patient's commitment to the programme
   - High motivation to participate in the pilot.

4.1.1 Rationale

The duration of the foreseen programme of tele-rehabilitation will run for a period of 6 to 12 weeks in accordance with scientific evidence (please refer to Appendix C). The programme of 6-12 weeks produces benefits that are maintained until 12-18 weeks from the beginning.

4.2 Organisational Aspects

FHC is a county hospital oriented to specialized assistance for acute patients, mainly consisting of an outpatient surgery. Therefore, FHC suffers from the lack of pre-existing integrated services that combine both social and health aspects.

At the beginning of the FHC pilot, the need for inclusion of specialised professionals (notable social workers) had not been foreseen because the impact social issues would have on whether patients would and could enrol in the pilot had been underestimated. However, as a consequence of the acquired experience as described above, it was decided to incorporate a new role (social worker)[7] in the form of a person who would be in charge of carrying out social assessments of the patients involved.

The management board at FHC has thus decided to establish cooperation guidelines with the units in charge of providing social services within the regional public organisation. Secondly, FHC has decided to redefine the roles for some of their staff whose tasks presently includes attending to patients and users (by managing complaints and claims) and who only occasionally carry out social tasks. They will be part of the project and will play an active role.

FHC's social worker will be the interlocutor between the health professionals of FHC and the social workers at primary care level. This will also create a better connection to social services and municipalities. The flow diagram of the design process was modified initially to adequately reflect the activities to be undertaken by the social worker.

After reviewing the necessities, it was decided that the FHC social worker will apply the GIJON assessment scale in personal character interviews with each of the patients. As of 15 October 2012, 9 of these evaluations have been completed.

[7] We will refer to this social worker as the "FHC social worker".

The GIJON assessment scale is a validated instrument for use in care management in a diverse array of areas including home care. It has a socio-familiar character and allows detection of the social risks of each patient, analysing 5 areas which are:

- Familial situation
- Economic situation
- Housing
- Social relations
- Social network support.

The result is expressed by assigning a value on a the points scale:

- From 5 to 9 indicates a good or an acceptable social situation
- From 10 to 14 indicates that a social risk exists
- Higher than 15 indicates that a social problem exists.

Employing this social assessment has been proposed both at the beginning and at the end of the rehabilitation treatment at home.

However, there are already patients who have finished the treatment (and participation in the pilot) and in these cases it will not be possible to carry out both evaluations; only the patients who are currently enrolled in the pilot will be assessed. In turn, the FHC social worker included in the pilot will form part of the work group that includes the social workers from other care levels in the public network. The FHC social worker will maintain regular contact with social workers from other municipalities where patients participating in the project reside.

Since the second half of 2011, the structure of the regional office in charge of both social and health matters has been modified. Before that, social and health matters were handled by two different regional offices.

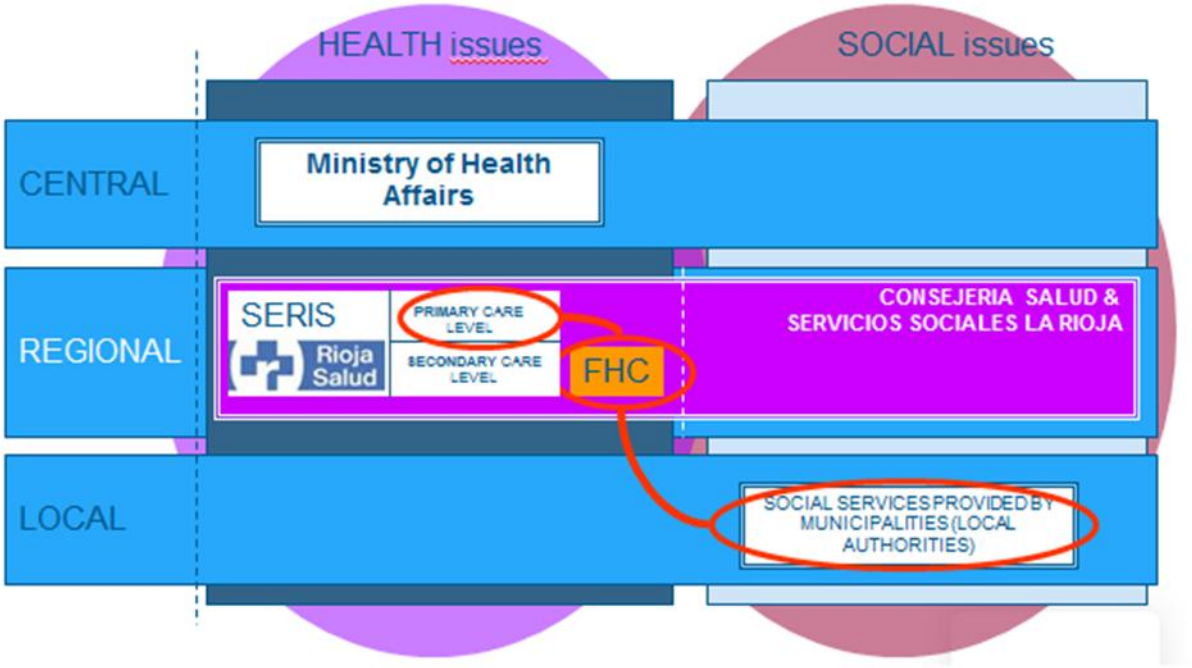

Figure 15: Diagram of the organizational structure of the regional office in charge of social and health matters.

Currently, a regional strategy is being developed for chronic patient care and the Personnel Director of FHC has had the opportunity to inform of some of the preliminary conclusions of the inCASA project.

The specialist in rehabilitation and the social worker are currently analysing the possible implications for its use as a screening tool with regard to potential problems for the patient, both health related and social. Prior to this project, no such interactions were reported. In fact, the social facet was not analysed except in certain cases where the problems had already manifested themselves at the time of discharge (i.e. lack of family, caregivers, or poor conditions in their place of residence).

The inclusion of the Actigraph has allowed inclusion of patients initially excluded in the pilot from the tele-rehabilitation programme for specific reasons related to both health and social factors. In relation to social factors, patients residing in nursing homes were thus excluded and in relation to health factors, patients whose state of health prevented them from carrying out the prescribed exercises or from learning how to use involved technology were also excluded from the pilot (Phase Two).

4.2.1 Pilot Structure

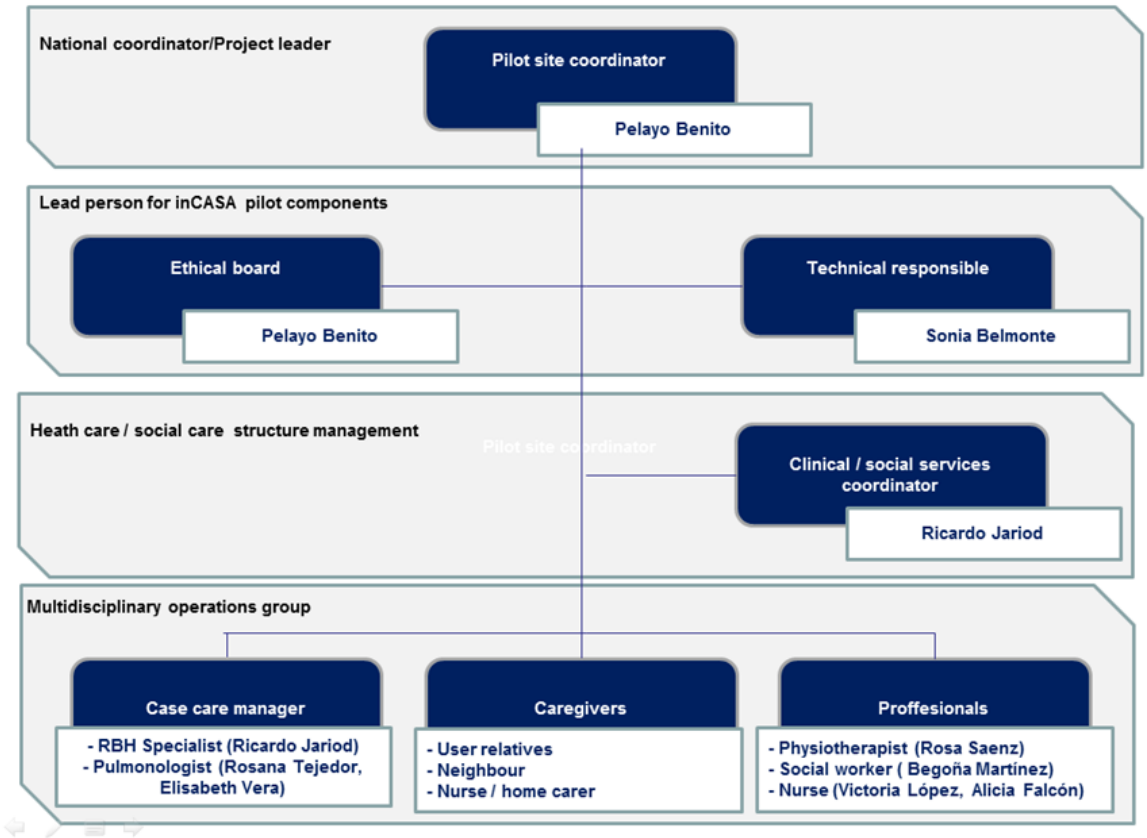

Figure 16: FHC pilot structure

The structure is unchanged compared to the 2nd phase (the pilot phase) that was described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2*. However, the role of the FHC social worker has now been more clearly defined and will be implemented in the 3rd phase of the pilot.

FHC Social Worker:
The FHC social worker is in charge of assessing the patient's needs and requesting appropriate action by health professionals at FHC as well as by other public services at regional and local level. The FHC social worker will carry out interviews with the patients based on the GIJON

assessment scale. The FHC social worker will carry out periodic calls and/or home visits to the patient as deemed necessary. Finally, the FHC social worker is responsible for analysing the results of the social assessment and produce reports documenting these.

4.3 Service Delivery Process

Selected patients who accept to take part in the treatment are trained at the hospital gym under direct supervision by a physiotherapist for a period of two weeks. They receive detailed instructions in using the devices (pulse oximeter, portable pedal machine, weights, and touch screen) and information related to the perception of fatigue according to the Borg Dyspnoea Scale. The FHC pilot will implement the following services/use cases:

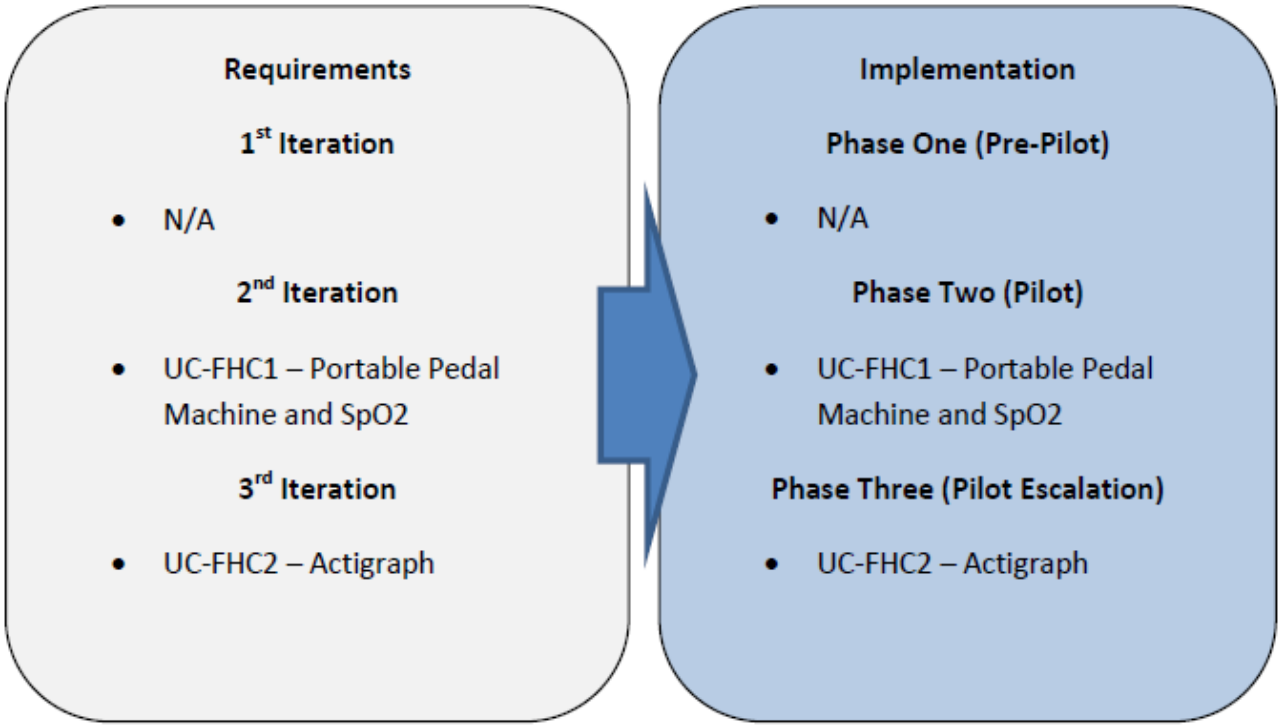

Figure 17: FHC Deployment Figure

FHC entered the project by the second iteration (Phase Two) of inCASA User Requirements consolidation and prioritisation, due to internal issues. The pilot started in December 2011 by implementing Use Case 1 Pedal Machine and SpO2 aimed at patients with COPD. The purpose of this use case is to decrease the level of CO_2 in blood and to increase pulmonary capability.

Phase Three has started and the Actigraph use case has been implemented; data from six patients has been obtained to date.

Two indicators were pre-selected to measure data from daily physical activity: R24 and a five-day profile. However, a final decision if these two indicators will be used or if other indicators facilitated by the Actigraph (e.g. PEM) will be used.

The transmission of rest/activity data captured by the Actigraph to the social services is currently in a very preliminary phase. It was submitted for revision given that it raised certain technical problems and problems related to information security. For now, we have chosen to handle this information internally between FHC professionals, both health and social.

The parameters that will be monitored are (accumulative):

Parameter	Phase
SpO2 (blood oxygen saturation level)	Pilot
Weight	
Heart rate	
Mobility of lower limbs (pedalling rate)	
Fatigue (pedalling curve)	
Rest-activity rhythm (Actigraph)	Pilot Escalation

Table 6: FHC Parameters

The implementation of the Actigraph in Pilot Escalation Phase will allow FHC to meet two new objectives:

- To improve the protocol used for the selection of the best candidates for participation in the tele-rehabilitation programme for COPD via Actigraph use (efficiency)
- To detect possible risk factors for social exclusion that complicate the COPD rehabilitation programme through social assessment of patients (effectiveness).

The Actigraph is an accelerometer used in our case to measure the level of activity in COPD patients. It is expected to be used in three ways:

- Before and after the completion of pulmonary rehabilitation treatment to detect if patient improvement was objectified by parameters in the quality of life test (SF36) or indicate that BODE correlates with an increase in the daily activity (movement) of the patient
- In cases where irregular circadian rhythm is suspected
- To detect the pattern of activity of patients who are candidates for rehabilitation treatment but who reject it for fear of the physical effort or for social reasons.

In order to define the utilization of the Actigraph, it was important to keep in mind a recent validation study on the correlation between caloric intake and the measurement of activity based on Actigraph.[8]

In addition, the use of incentive spirometers[9] were included in the tele-rehabilitation programme at home to complete exercise for upper limbs (weights) and lower limbs (pedal machine) in order to allow the patient to do pulmonary exercises.

Figure 18: FHC Integrated Solution with the "Patient's Kit"

[8] Van Remoortel H, et al., Validity of six activity monitors in chronic obstructive pulmonary disease: a comparison with indirect calorimetry, Faculty of Kinesiology and Rehabilitation Sciences, Department of Rehabilitiation Sciences, Katholieke Universiteit Leuven, and Respiratory Division, UZ Gasthuisberg, Leuven, Belgium.

[9] An incentive spirometer is a medical device used to help patients improve the functioning of their lungs.

4.3.1 3rd Phase Use Cases

The use case implemented in the 2nd phase is on-going and will be combined with a new use case in the 3rd phase, Use Case 2 Actigraph. Use cases 1 is described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* and can also be found in Appendix C.

The following describes the new use case that includes the use of Actigraph:

Use Case 2: Actigraph

Overview: Each patient practises the assigned exercises according to his health; first at the hospital gym in order to learn how to use the devices used in the pilot in an appropriate way and after that at home every day.

Before beginning and finalizing the treatment an Actigraph is delivered to patients during a period of approximately 5 days to measure possible variations in their activity level. Each patient is interviewed by a social worker to assess social risk factors.

Purpose: Patients, who do not have a family, live alone, and/or without significant contact to their family, may receive visits from a social worker who is aware of their health and social situation and who can warn the healthcare services as necessary.

Procedure: The system sends the information collected to the FHC personnel who process and analyse it in depth in order to determinate the patient's response to the exercises.

Analysis: Analysis of the data received from the kit at the patient's home by the FHC personnel.

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

Alerts: May be created by the hospital personnel in case the actual results of the exercise differ from those expected when considering the patient's condition. The social worker will carry out periodic calls to the patient.

Feedback to user and relatives: Yes; at the end of treatment by the rehabilitation specialist.

Personalisation: Yes.

Devices: Actigraph, pulse oximeter, tactile screen, bicycle, weights and spirometer.

4.3.2 Intervention Protocols

The collected data will be analysed and compared with set values based on the individual patient's level of COPD as well as on variables such as the ratio between weight and physical capabilities. If values are outside the fixed ranges the following intervention may occur:

- A specialist will consider alternative treatment and/or change the recommended exercise plan
- A social worker may visit to assess the presence of any social problems/issues affecting the patient's ability to do the prescribed exercises
- Control phone calls twice a month during the period of six weeks while the patient does prescribed exercises at home.

4.3.3 Health and social integration scenario

The following scenario describes how a COPD patient could benefit from remote rehabilitation enabled by inCASA.

Coping with COPD

Luis C., a 70 year old with chronic obstructive pulmonary disease (COPD), lives with his wife in a small village with no more than 2.500 inhabitants. The village is 45 kilometres from the main village where the county hospital is located. His weight has been increasing quite quickly recently, in fact ever since he stopped going for him and his wife, Rita's usual long walks in the forest surrounding

the village because his health was deteriorating. These days he spends most afternoon watching TV. He gave up smoking some time ago but still longs for a cigarette especially after meals; he loves his wife's home made cooking and he has a healthy appetite. Too healthy perhaps.

Luis has had to give up driving because of his poor health condition. His wife doesn't drive either so they use public transport to get to and from the hospital for Luis' appointments there. Recently, just walking to and from the bus station, which is only 10 minutes away, makes him tired. Luis if finding it very hard to accept that his health is deteriorating and he feels less and less able. His wife is concerning that he's becoming depressed on top of everything.

When he complained to the doctor about how he gets tired and has no energy to even walk to the bus station he was told that regular exercise would actually have a positive effect on his condition, or at the very least help avoid that it got worse. Luis finds this hard to believe and aside from his walks he has never practised any kind of exercise in his life. The doctor then asks him how he's feeling otherwise, if he's feeling depressed. Luis is not happy to admit but yes, he's feeling like his condition makes life impossible to live, he feels useless and a weakling.

Luis reluctantly agrees to give exercise a try but only on the condition that he can do it at home because he can't face having to go to the hospital several times a week just to do exercise. He's told that the idea of the rehabilitation programme at the hospital is precisely to allow COPD patients to do their exercises at home using a bicycle and free lifting weights. He just needs to come in for a training session to teach him how to do the exercise. Based on Luis' reluctance, the doctor also suggests that he get extra support to help him be motivated and really follow through with the programme. He explains that it really only means that Luis also has an Actigraph which transmits data about his rest/activity levels. If deemed necessary, a social worker will support him dealing with any non-health issues that may make it difficult for him to comply with his prescribed exercises. Rita is thrilled; Luis is less enthusiastic but accepts to give it a try for a month.

A couple of days later, a technician arrives to install the inCASA platform that allows for the remote monitoring and transmission of health data. He is also bring the portable pedal machine, which to Luis and Rita's great relief is small and handy and not like the big exercise bicycles they had imagined. While the installation is going on, Luis has now started the home rehabilitation programme. Rosa, his home nurse, visits him each week to see if he is doing the exercises accurately as prescribed by Ricardo, the rehabilitation specialist. Ricardo can monitor the length and the rhythm of Luis' training activities, as well as his clinical status, simply by connecting to his computer at the hospital and looking at Luis' SpO2 data.

A few days ago, Luis talked to Maria, the hospital's social worker, on the phone. They arranged a meeting for tomorrow to talk how he's coping with his condition and the rehabilitation programme. In fact, these last couple of weeks, Luis has followed his exercise plan 100% and he has even gone out for a few afternoon walks in the forest with his wife instead of just watching TV. He is feeling better physically and psychologically, and he feels like at last he is getting the medical attention that he needs to cope with his condition. His wife also says he hasn't been this happy since he was first diagnosed with COPD.

4.4 Integrated Telehealth/Telecare Business Processes and Workflows

The figure below illustrates the overall business processes and workflows in FHC for the integrated social and health services (implemented in August 2012 with the inclusion of the FHC social worker and the Actigraph use case):

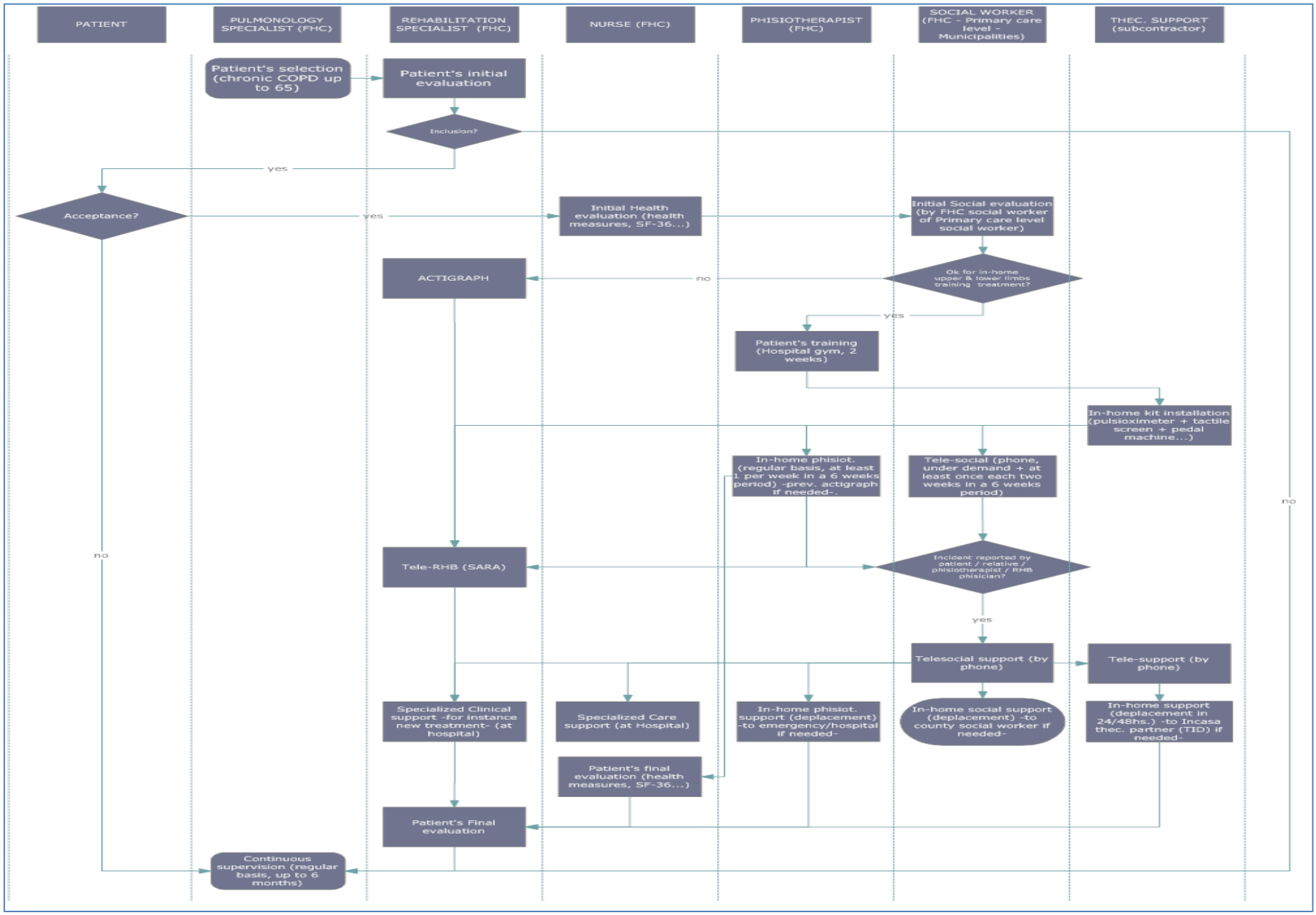

Figure 19: FHC Integrated Business Processes and Workflow Model

The following gives an overview of the workflow processes in the 3rd phase of the FHC pilot with a focus on using the Actigraph to assess whether social intervention may be called for. The two figures illustrate two different scenarios: A) The user is not willing and/or capable to do exercises at home, and B) The user is capable to do exercises at home:

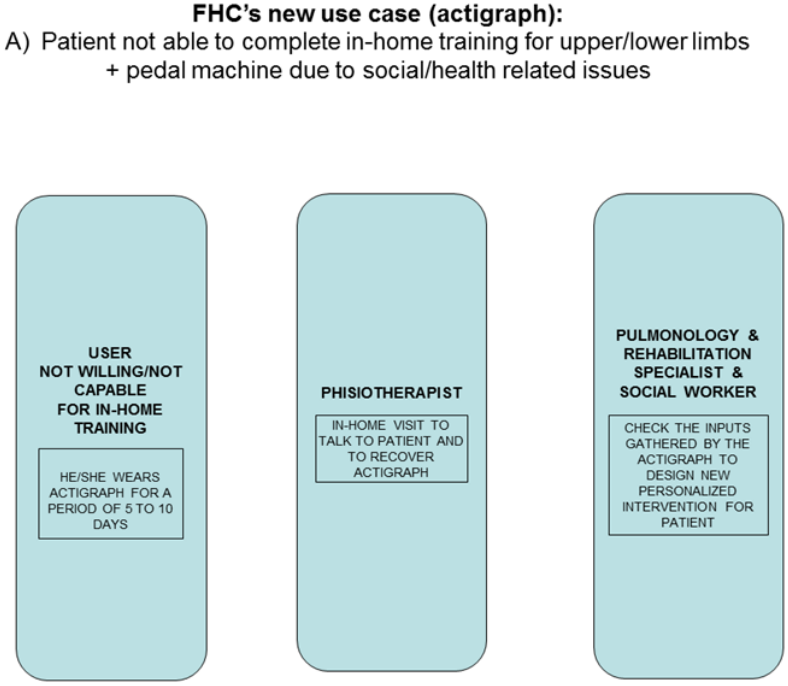

Figure 20: FHC Workflow Process Use Case 1 and 2

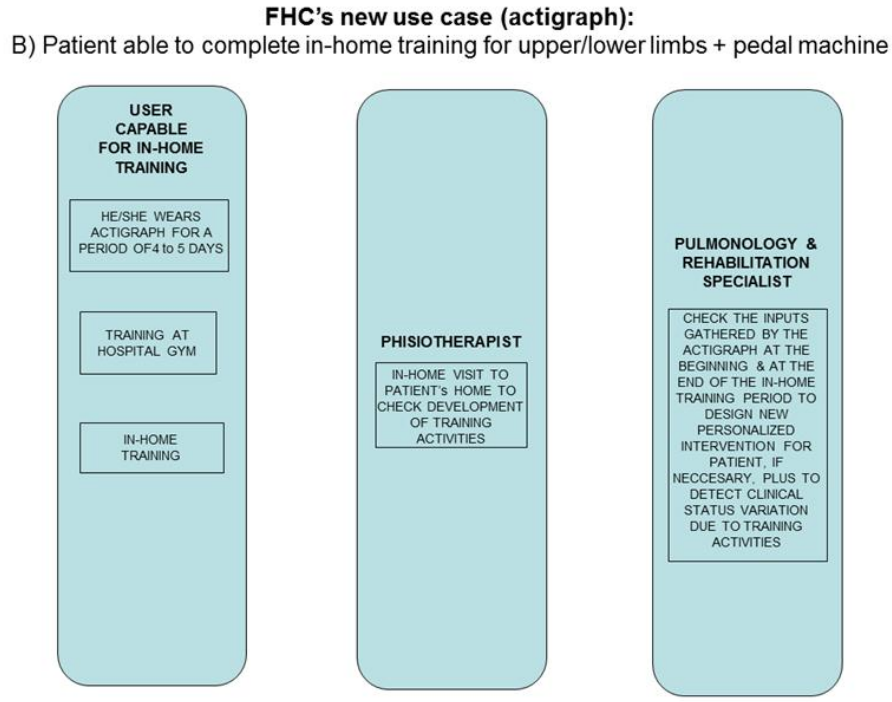

Figure 21: FHC Workflow Process Use Case 1 and 2

4.5 Schedule

The following table provides an overview of the FHC pilot schedule:

Date	Action
May 2010	Project ethics approved by the Committee for Ethics in Clinical Research in La Rioja (CEICLAR)
September 2010	Equipment acquisition and parameterisation completed
December 2011	Pilot started (Phase 2)
August 2012	Actigraph use case implemented for 6 patients
November 2012	Integrated Telehealth and Telecare service commences (Pilot Escalation Phase)
December 2012	Analysis and evaluation begins
April 2013	Pilot ends
June 2013	Evaluation Report D6.6

Table 7: FHC Pilot Schedule

4.5.1 Updates since Iteration 2

With respect to use case 1, it was decided to substitute pedal machines for bicycles since they are much cheaper and easier to transport.

Weight does not have its own use case, but it is one of the measurements used to calculate the patient's Body Mass Index (BMI) (see parameter Table 6).

Heart rate is part of the initial use case and is measured with a pulse oximeter. Remote measuring can be done during the execution of exercises which enables you to compare cardiac frequency and the level of oxygen saturation (SpO2) at a given moment.

The use of a pulse oximeter will continue as originally described but in addition patients will also do exercises with free lifting weights and use an incentive spirometer (while wearing the pulse oximeter).

Based on the recommendations from the reviewers, it was decided to increase the number of participating patients. The FHC pilot will thus include at least 34 patients:

- 28 patients have already been included in the pilot, and 12 of them have finished or are about to finish the programme.
- 4 more patients are in the Control Group. They have completed only the first part of the programme in the hospital gym and now they can complete their participation doing the exercises at home for a period of six weeks.
- 2 new patients over the age of 65 and diagnosed with COPD have been identified as suitable for participation by the pulmonologist.

In addition, 7 other potential patients have been approached but their participation has not been confirmed at this moment:

- 5 patients who initially rejected but who may join the pilot as a result of the new social evaluation report done by the FHC social worker.
- 2 candidates who were initially excluded because they live in a retirement home but who may join now as a result of the new social evaluation report done by the FHC social worker (the kit can be installed without any problem and it would strengthen the integration of tele-care with a social component).

The technical requirements relevant for FHC have been updated as necessary. A complete report of all the updated requirements can be found in Chapter 7.

5 INSERM

This chapter presents the 3rd phase of the INSERM pilot, the Pilot Escalation Phase. It focuses on the organisational aspects, service delivery processes, and business processes relevant for this 3rd phase.

One new use case has been identified which will enable the integration of Telehealth and Telecare services. The use case describes the new business process and organisation which aims to improve the coordination of healthcare and social care professionals involved with the patient. This involvement will be based on all the data collected in the patient's home using telecare and telehealth devices.

The technical requirements relevant for INSERM have been analysed and updated as necessary as part of the third iteration. A complete report of all the requirements can be found in Chapter 7.

5.1 Aims and Objectives

Cancer chronotherapy is delivered at home using programmable pumps and help avoid familial and social disruptions. Since cancer is a complex disease associated with co-morbidities, many healthcare and social care providers are involved. This leads to a large burden on the healthcare system as well as a complex situation for patients and their family. By integrating social and medical care and using Telehealth monitoring, patients can be supported on more than one level in efficient ways.

The aims and objectives of the pilot include:

- Support for of a holistic approach to care for cancer patients; care is currently handled by several social and medical care providers who usually interact separately with the patient.
- Early detection of drug-related adverse events or disease exacerbations through close monitoring of the health condition in order to prompt relevant intervention thus reducing hospitalisation.
    - This approach includes the daily self-rating of the symptoms that reflects impaired behavioural or biological functions, as well as body weight and circadian rest-activity pattern through non-invasive rest-activity monitoring.

This will result in improved quality of life and patient prognosis through facilitating healthcare coordination, controlling patient symptoms and enhancing circadian robustness.

Patients are recruited from the outpatient Chronotherapy Unit of the Department of Medical Oncology (Dr Francis Lévi) at Paul Brousse Hospital (Villejuif) and are followed as outpatients.

If selected patients meet the eligibility criteria, and if they agree to be enrolled in the study and to use the system at home, an appointment is made for the installation.

Pilot inclusion criteria:

- Male or Female
- Suffering from cancer (any type of cancer)
- Age + 65 years
- Ambulatory
- Living at home (alone or with spouse)
- Affiliated to a social security system
- Written consent to participate in the study signed and dated.

5.1.1 Rationale

The patients are recruited for a study period of minimum 6 weeks, which corresponds to two or three chronotherapy courses and ensures a good follow-up before, during and after treatment.

5.2 Organisational Aspects

In conventional care, healthcare services and social services are separated and there is no cooperation between the hospital nurses, the homecare nurse, the general practitioner and other healthcare or social care professionals. When the patient requires healthcare or social services, he/she contacts the relevant professional him/herself.

With the inCASA solution, the nurses are the primary access point who directly interact with the patient and if necessary signal the health problems at an early stage to the oncologist, the GP, the local nurse or other relevant healthcare professionals. Early detection of worsening of cancer or early detection of adverse events on chronotherapy followed by immediate appropriate action could prevent health deterioration, hospitalisation and/or death. Depending upon the type of deterioration (e.g. symptom, body weight, rest-activity), as indicated with reference to a pre-set threshold eventually completed with a patient interview, the nurse refers the patient to the relevant healthcare or social care professional (oncologist, geriatrist, general practitioner, psychologist, dietician, physical therapist or social worker). The patient can then check the appointments with the healthcare or social care professional directly in the diary displayed on the electronic platform at his or her home. When a patient has medical questions or requires social services, the nurses can be contacted by phone during office hours.

To facilitate cooperation between professionals, it was agreed that during the initial evaluation that the nurses will collect information about the patients' environment, including the details of the carers. This information will then be reported on the web portal. The intervention of professionals will be coordinated by the LVL Medical homecare company. They will organise a consultation with a dietician at home at the beginning of the study in order to have an initial check-up and prevent undernutrition.

5.2.1 Pilot Structure

The INSERM pilot structure is illustrated below:

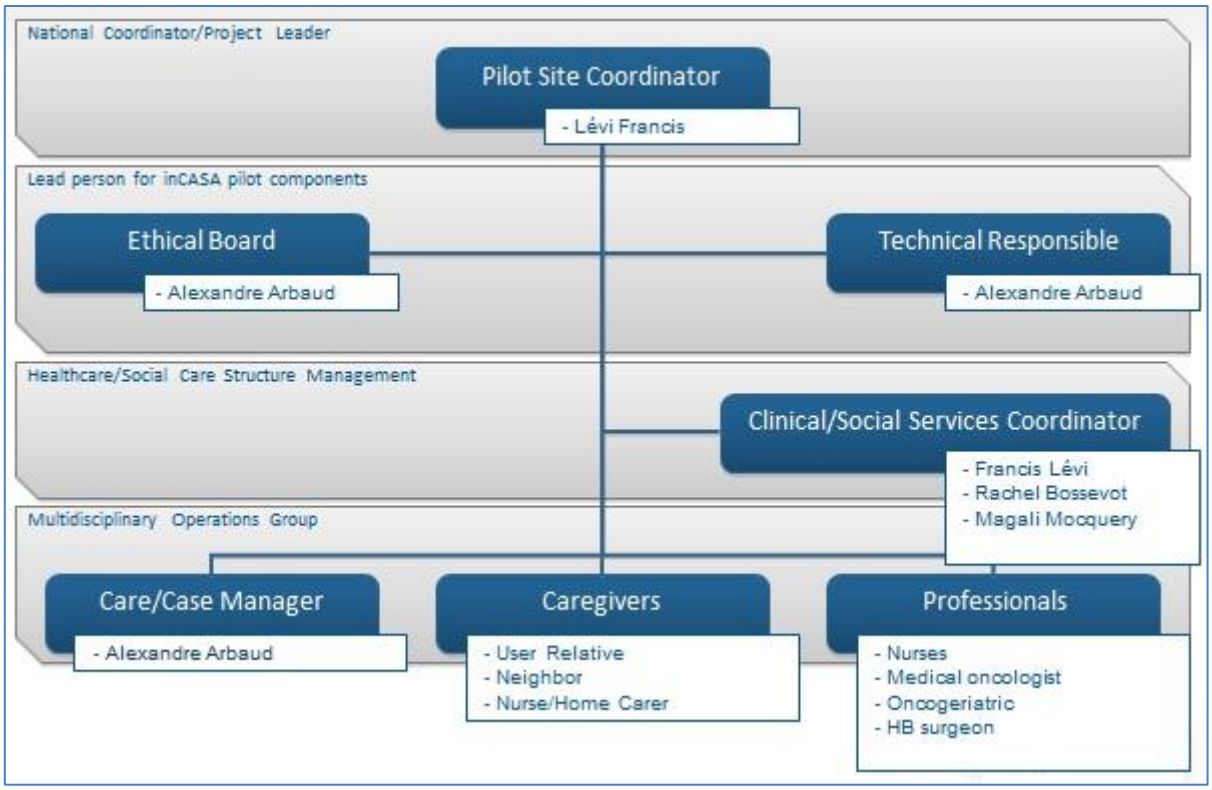

Figure 22: INSERM Pilot Structure

The structure is unchanged compared to the 2nd phase (the pilot phase) that was described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2*.

5.3 Service Delivery Process

The service will be installed and configured in the users' homes with the appropriate devices and infrastructure. The INSERM pilot will implement the following services/use cases:

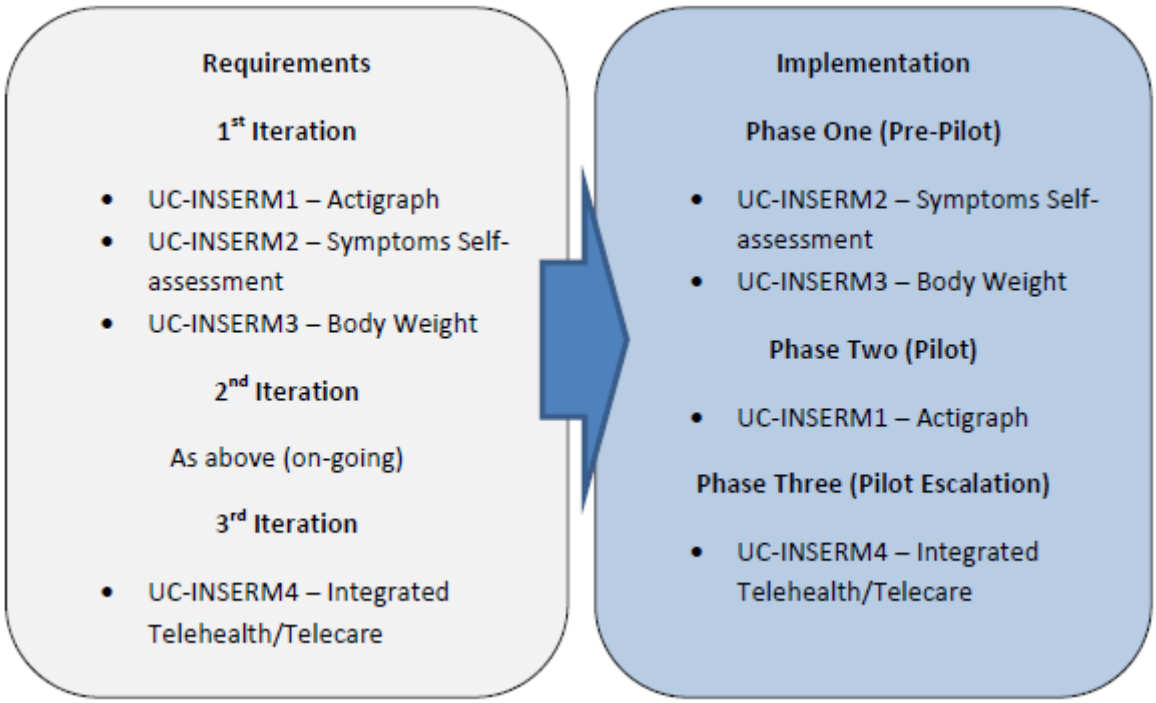

Figure 23: INSERM Deployment Figure

Phase One started in November 2011 by introducing symptoms self-assessment and body weight monitoring through the SARA's platform.

In Phase Two, the use cases were extended with the introduction of the infrared Actigraph and the set of monitoring devices was thus completed.

The equipment provided to the patients is composed of an electronic Bluetooth weight scale, an infrared Actigraph (wrist-watch accelerometer) and an all-in-one PC with a touch screen with the SARA application installed. The computer is connected to the internet through the Wi-Fi or 3G network if no internet connection is available at home.

The equipment is installed at the patient's home by the case manager at the beginning of the inclusion period for a minimum of six weeks. Patients are asked to use it every day for body weight measurement, symptoms self-assessment through the M.D. Anderson Symptom Inventory questionnaire, and rest-activity rhythm recording. During the installation of the platform at home the patients are trained in using the equipment.

In Phase Three, INSERM will integrate healthcare and social care services. Fully integrated inCASA services will apply for patients recruited from October 2012 until pilot conclusion.

The single parameters that will be monitored are (accumulative):

Parameter	Phase
Body weight	Pre-pilot
Symptoms self-assessment	
Rest-activity (Actigraph)	Pilot
As above (on-going)	Pilot Escalation

Table 8: INSERM Parameters

In the 3rd Phase (Pilot Escalation) no new single parameters will be added and no additional sensors or devices were necessary for the healthcare and social care integration as changes are mainly in the organisational aspects and processes.

5.3.1 3rd Phase Use Case

The use cases related to the integrated services are the same as the use cases described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* but can also be found in Appendix D. No additional sensors or devices were necessary for healthcare and social care integration as changes are mainly in the organisational aspects and processes. Moreover, body weight and symptoms self-assessment are Telehealth parameters, whereas Actigraphy is a Telecare parameter as it provides quantitative information on the regular activity and rest patterns of the patient both at home and outside.

Use Case 4: Integrated Telehealth/Telecare

Overview: To achieve the integration of Telecare and Telehealth services, INSERM will involve the hospital nurses as a primary access point for the patients. They will directly interact with the patient and point out any health problems at an early stage to the oncologist, the GP, the local nurse and/or other relevant healthcare professionals.

Purpose: By integrating healthcare and social care, a network of social and medical professionals is built around the patient. This will result in the most appropriate care being delivered in the

shortest time possible and minimising also the burden on informal carers (mostly partners or family of the patient).

Procedure: To facilitate cooperation between professionals, it was agreed that during the initial evaluation the nurses will collect information about the patients' environment, including the details of the carers. This information will then be reported on the web portal. The intervention of professionals will be coordinated by the LVL Medical homecare company. They will organise a consultation with a dietician at home at the beginning of the study in order to have an initial check-up and prevent undernutrition.

Analysis: Depending upon the type of deterioration (e.g. symptom, body weight, rest-activity), as indicated with reference to a pre-set threshold eventually completed with a patient interview, the nurse refers the patient to the relevant healthcare or social care professional (oncologist, geriatrist, general practitioner, psychologist, dietician, physical therapist or social worker).

Data fusion: The patient can check the appointments with the healthcare or social care professional directly in the diary displayed on the electronic platform at his or her home.

Alerts: Depending on the type of deteriorated monitored parameter (symptom, body weight, rest-activity etc.), as indicated by a level below a pre-set threshold and her interview of the patient, the nurse will refer the patient to the relevant health professional (oncologist, geriatrist, general practitioner, homecare nurse, psychologist, dietician, physical therapist or social worker). The appointments of the patients will be managed and displayed on the SARA platform.

Feedback to patients and relatives: Yes.

Personalisation: Yes.

Devices: SARA platform.

5.3.2 Intervention Protocols

While monitoring the data, an incident is detected when:

- Body weight decreases by 5% or more (grade 1)
- Symptoms severity or interference with daily life increase above 7
- Rest-activity rhythm dichotomy index decrease below 97.5%
- No data are received during more than 48h.

As soon as an incident is detected, the nurses call the patient to check the technical aspects and patient's condition. If needed, the nurses request the intervention of relevant healthcare or social care professional or technical support. If an appointment with a professional is taken, the nurses update the diary of the patient. Subsequently they check that all the parameters come back to their baseline level.

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5.3.1 Telehealth and Telecare Integration Scenario

The following describes three different envisioned scenarios related to the integration of healthcare and social services in the INSERM pilot.

Scenario 1: Chronotherapy delivery at home

Michel is followed by his oncologist at Paul Brousse hospital in Villejuif for metastatic colorectal cancer. He is treated with three-drug chronotherapy delivered at home using programmable pumps four days every three weeks. Michel is relieved because with such treatment modality he can stay at home with his wife despite the complexity of the chemotherapy protocol. Yet he is also anxious

about the pump operation and the follow-up of his health condition during chemotherapy delivery because of the risk of side effects.

A SARA platform is installed at his own home in order to collect his own data. For this purpose, Michel weighs himself every morning on a Bluetooth weight scale and scores his symptoms himself on an electronic version of a widely used worldwide questionnaire about health and quality of life for cancer patients using a touch screen. His rest-activity pattern is automatically recorded by an Actigraph worn on the wrist like a watch. He simply sends the recorded data once a day using infrared communication by pressing a button on the Actigraph and on the SARA platform. Michel feels safer with this equipment as he knows that his health status is monitored and that the hospital nurses who check the data daily will be able to react promptly if his health condition worsens. He also knows that he may contact the nurses at any time for social needs or medical or technical assistance.

Every three weeks when Michel attends hospital for a medical consultation with his oncologist, Sandrine, the hospital nurse, programs a pump to deliver the drugs as prescribed. She connects the pump to the implanted venous access port of the patient. Sandrine makes sure that Michel is visited whenever needed by a nurse employed by a homecare company so as to properly and quickly alleviate symptoms, handle technical issues and check that the pump is operating well. Upon treatment course completion, the nurse removes the pump from the implantable port and administers the required care.

All the appointments are reported by Sandrine on the web portal and Michel can see his diary updated directly on the SARA platform. He can call the hospital nurse if any change is required.
Michel is happy that everything has been arranged for him. He feels comfortable to be at home when he knows he is being monitored while on intensive chronotherapy, and has one central point that he can call if he needs either medical or social support.

Scenario 2 – Medication adjustment
During the second day of her chronotherapy, Catherine rates her pain at 8 out of 10 on the MDASI scale whereas she rated the pain below 3 the previous days. Sandrine the hospital nurse is alerted and calls Catherine who confirms that her pain and fatigue have suddenly increased. Sandrine contacts the oncologist who decides to prescribe painkillers. Then, Sandrine faxes the prescription to the local pharmacy and tells Catherine that the pharmacy will deliver the medicine at her home. The next day, the score of pain rated by Catherine, decreases back to its baseline level. Catherine feels much better and she is grateful to Sandrine and the pharmacist that they could react so promptly.

During the next medical consultation, her oncologist checks the data on the web portal and he realizes that Catherine had pain and fatigue exacerbations during the previous chronotherapy course and that she also had lost 4 kg within two weeks. Therefore, he decides to reduce the dose of the drugs delivered by the pump in order to decrease the side effects and increase tolerability.

Scenario 3: Preventing hospitalisation
When checking the data on the web portal, Sandrine is alerted that several functions recorded for François are out of range. She looks into the medical record of François. She finds out that he has been followed by the hospital for 6 months for his cancer and that he received his last chronotherapy course last week. She notices that François' weight has decreased by 6% within one week and that his rest-activity rhythm is severely altered. She decides to call the GP.

The GP also looks at the data on the web portal and decides that a home visit is needed. Sandrine calls François to let him know that the GP will make a home visit and updates his diary. The wife of François answers the phone and she confirms that François's condition is getting worse. He has no appetite and has difficulties sleeping.

The GP visits François, who is really in trouble, as a result of a complete lack of appetite for the past week. The GP prescribes parenteral nutrition at home for three days and decides that no hospitalization is needed. He informs the home care company of his prescription using the inCASA web services. Later the home care company implements the prescription at François' home and informs Sandrine accordingly. François' wife calls the hospital nurse the next day to inform her that François is doing better and he is well taken care of at home.

When the GP makes a home visit three days later they discuss the condition of François, which is improving. However, François' wife tells the GP that François is often feeling down and worried. The GP, François and his wife discuss this thoroughly and François agrees that he feels depressed and would need counselling. Together they call the hospital nurse. She takes action and makes an appointment for François with a psychologist and updates the SARA diary.

A few months later, the home care nurse makes one of her regular visits to François. She finds him in a good condition. The evolution of his cancer is stable and François and his wife confirm that he is in much higher spirits lately. He has obviously accepted his condition and is complying with his medication.

5.4 Integrated Telehealth/Telecare Business Processes and Workflows

The figure below illustrates the overall business processes and workflow in the INSERM pilot for the integrated social and healthcare services:

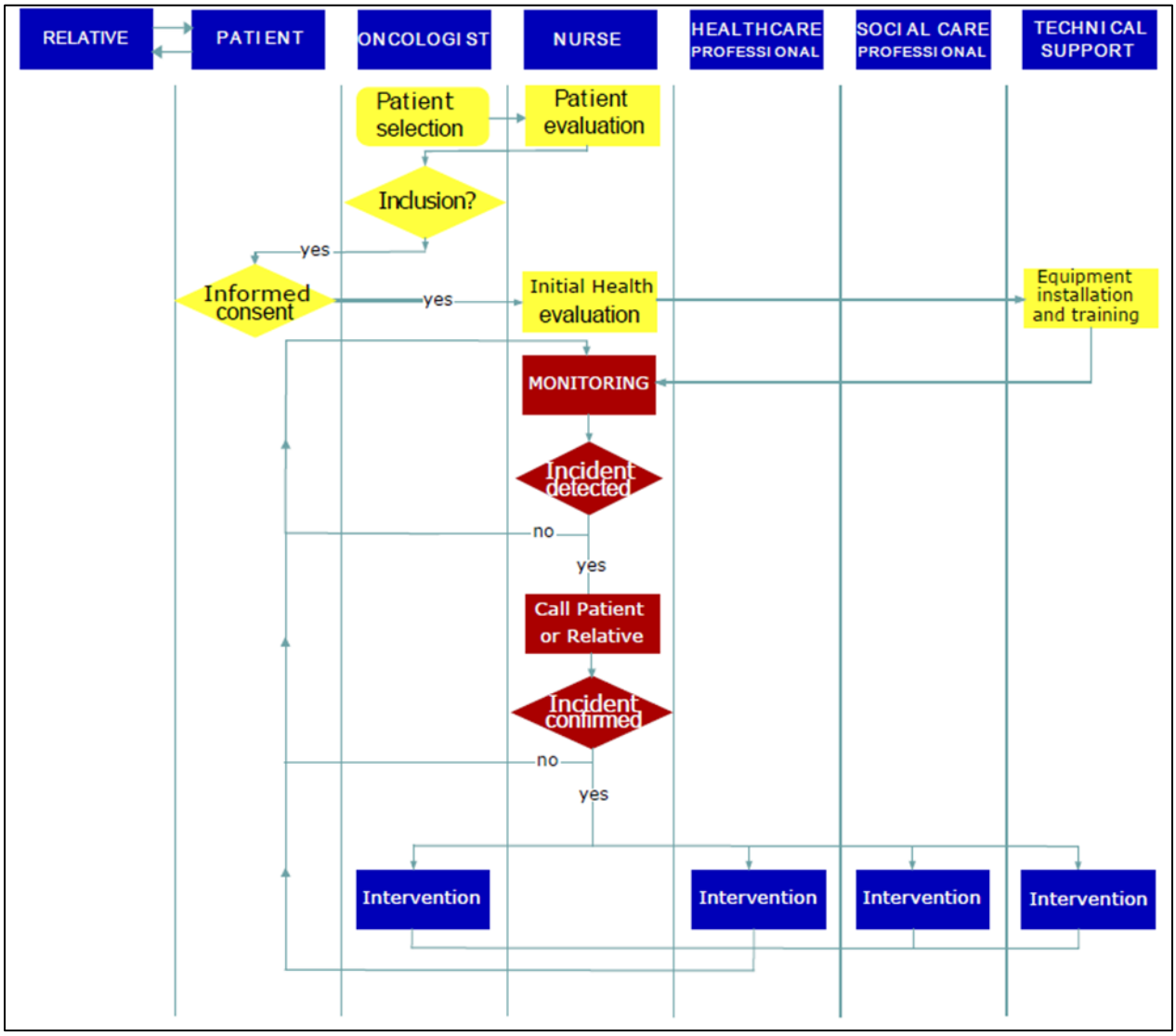

Figure 24: INSERM Business Processes and Workflow Model

As illustrated above, after patient selection, user acceptance, equipment installation and training, the hospital nurses ensure data monitoring. As soon as an incident is detected and confirmed, they alert the adequate professional who provides the required care.

The next figure demonstrate the stakeholders[10] and organisations involved in the INSERM pilot:

[10] The use profiles of some of the stakeholders have been updated since the 2nd iteration (D2.4). These are described in Chapter 5.5.1 below.

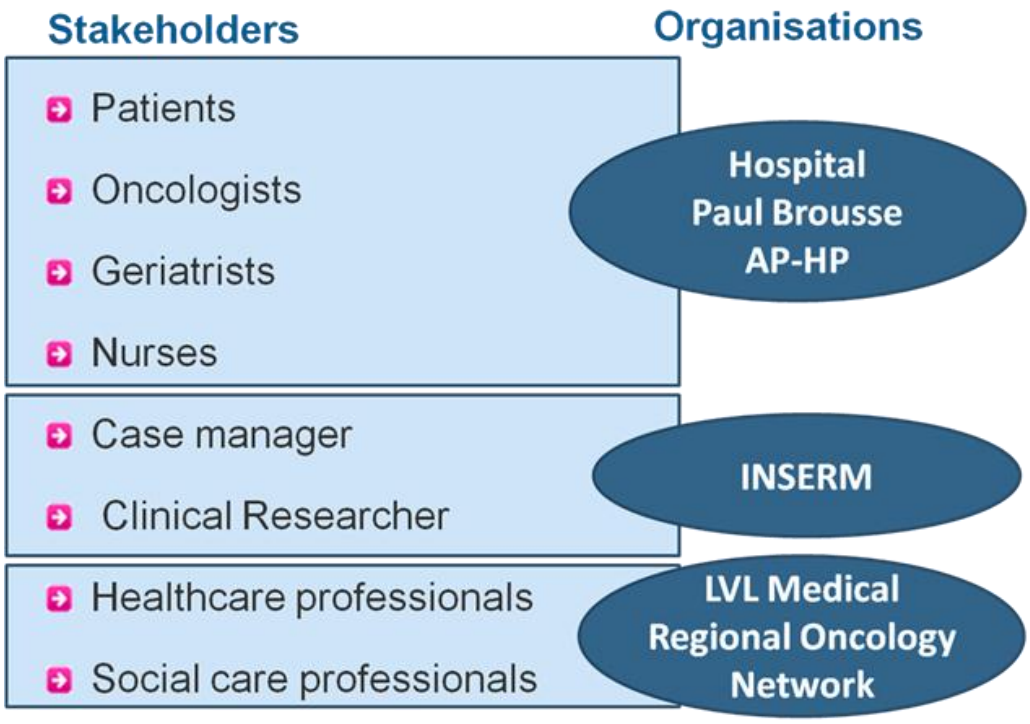

Figure 25: INSERM Stakeholders and Organisations

5.5 Schedule

The following table provides an overview of the INSERM pilot schedule:

Date	Action
May 2011	Project approval by the INSERM Clinical Research and Regulatory Aspects Committee, which assumes official sponsor responsibilities for the project.
July 2011	Equipment acquisition and parameterisation
July 2011	Information meeting in Paul Brousse hospital about the inCASA solution to all the hospital staff
October 2011	Selection of patients and patient acceptance signatures
November 2011 – February 2012	Equipment installation (PC platform and weight scale), data collection and evaluation. Pre-Pilot phase start with 5 patients.
March 2012	Pre-pilot ends. Pilot activities start.
October 2012	Deployment of integrated Telehealth and Telecare service (Pilot Escalation Phase)

March 2013	Completion of pilot deployment in 40 patients and preliminary analysis and evaluation report.
June 2013	Full evaluation report and integration into global pilot activities report.

Table 9: INSERM Pilot Schedule

5.5.1 Updates since Iteration 2

The integration of Telehealth and Telecare services enabled by the inCASA platform has been finalised and a new use case (Use Case 4) defined. This use case will use the already implemented inCASA services and use the monitored data to create a network of social and medical professionals around the patient. The nurse will play an active role by facilitating referrals to the relevant professional, whether it is a GP, oncologist or social worker. This will result in the most appropriate care being delivered in the shortest time possible and minimising also the burden on informal carers (mostly partners or family of the patient).

In relation to this new use case, the following user profiles have been updated:

Hospital nurses
The hospital nurses program and prepare the drug delivery chrono-pump that will administer chronomodulated chemotherapy. They interview the patient before the oncology consultation. They check the data sent by the patients daily through the InCASA platform and can be contacted by phone at any time. They alert the oncologist, other healthcare professional, social care professional or the case manager or a relative (informal carer) if an incident is detected.

Social care professional
The social care professional can be a psychologist, a dietician, a social worker, a home help, etc., alerted by the hospital nurse, depending on the social needs of the patients.

Case manager
The case manager is responsible for the enrolment of the patients in the study, the equipment installation at home and provision of technical support as necessary.

The technical requirements relevant for INSERM have been updated accordingly. A complete report of all the updated requirements can be found in Chapter 7.

6 KGHNI

This chapter presents the 3rd phase of the KGHNI pilot, the Pilot Escalation Phase. It focuses on the organisational aspects, service delivery processes, and business processes relevant for this 3rd phase.

Five new use cases focusing on behavioural and environment monitoring have been defined and will be implemented in this 3rd phase of the pilot. The technical requirements relevant for KGHNI have been updated accordingly. A complete report of all the updated requirements can be found in Chapter 7.

6.1 Aims and Objectives

The aim of the KGHNI pilot is to integrate social and healthcare services in order to enhance the support offered to patients with Congestive Heart Failure (CHF) who live in their own home. The integrated services are designed to complement the already established pilot's medical services and aim to provide doctors with early signs of a patient's deterioration (clinical) and to enhance the patient's quality of life (psychologically and functionally in the home and in everyday activities).

Both components contribute to improving CHF patients' prognosis while effectively reducing the risk of re-hospitalisation and avoiding non-required visits to the hospital's out-patient clinic. To this end, additionally to the clinical measurements, the activity of CHF patients at home will also be monitored (developing a habits model) since they generally suffer from reduced mobility. A reduction in their average daily mobility or change in their habits is a strong indicator of a worsening clinical status. Another explanation for this reduced activity could be the onset of depression which is something very common for this particular patient group.

With regards to the risk of depression, expert psychologists will review each patient case and conduct proper periodical evaluations using the results of standardised depression monitoring questionnaires. Additionally, they will have access to information about any monitored habit changes of the patient and will be able to interview the patient in person. Finally, the psychologist will intervene therapeutically, when deemed necessary, using non-pharmacological interventions, such as cognitive behaviour therapy (CBT), or prescribe anti-depression medication after consulting the assigned cardiology doctor.

When a patient has also been proven to have significant social problems (poor and/or frail and/or without strong familial support), the internal Hospital Social Care service will be able to intervene by offering direct assistance or by referring the patient to a nation-wide or regional social service (i.e. the "Help at Home" programme). The offered social services may include visits at home by social workers, family assistants and doctors/psychologists.

The objectives of the Pilot Escalation Phase can be summarised as follows:

- improving the speed of delivery and the quality of the provided healthcare services while at the same time reducing costs
- reducing the medical risks for the patients due to their continuous monitoring
- reducing patients' anxiety about their medical condition
- understanding the health condition of CHF patients in the context of their daily life at home by analysing the pilot results
- discovering correlations between the patients' medical condition and everyday habits, thus enabling the consolidation of the latter as early indicators of a worsening clinical status
- demonstrating that the active involvement of relatives and the assistance provided by social workers contribute to the patients' overall quality of life

- prolonging elderly patients' independence by supporting them in their own home
- enabling early discharge of patients
- improving medical therapy in order to decrease the risk of hospital readmission;
- detecting and/or preventing depression
- facilitating organisational cooperation between the participating units of the hospital in the inCASA project: The Cardiology Clinic, the Psychiatric Clinic and the Social Service.

6.1.1 Rationale

Certain issues were taken under consideration while designing the Pilot Escalation Phase to ensure that the above objectives are fully met, e.g. the number of overall users, duration of participation, and the added value of combining services. These issues are described below.

The pilot will gradually escalate to a total number of 40 users. The increased number of end-users will enable a full deployment of the combined socio-health services during the extended pilot period. To meet the requirements of enlarged installations (up to 10 patients simultaneously participating) additional equipment is currently procured and purchased (Activity Hubs, touch screen PCs, medical devices, and Telecare sensors) to meet the targeted capacity by the end of 2012.

Each patient will participate in the Pilot Escalation Phase for approximately 3 months. Experience gathered during the main pilot phase, where the patient groups rotated every 2 months, clearly indicated that this timeframe can accommodate the proper evaluation of the health-related inCASA services and interventions. It is expected that the extended participation period will enable the gathering of evidence of potential changes of the psychological condition of the patients, the majority of whom have suffered recently from cardiac episodes and are in need to cope with the anxiety introduced by these life-changing events. Finally, the new timeframe allows measuring the efficiency of the social support services whether provided using internal hospital resources or serviced from nation-wide programmes such as "Help at Home".

The true potential of the inCASA solution is realized when effectively combining healthcare and social care services. For the Greek pilot case it made sense to deliver a solution that addresses also the psychological condition of elderly CHF patients. Several studies have already suggested that the prevalence of depression increases sharply with the severity of heart failure symptoms while major depressive incidents are also a stronger predictor of mortality than minor incidents. Moreover, depression has been found to have a negative impact on every dimension of health-related quality of life, including physical-social functioning and mental health.

Additionally, in these studies it was shown that annualized adjusted total costs were significantly higher for depressive CHF patients and that inpatient/outpatient service utilization was also found to be greater. The overall quality of life issues are addressed at the pilot level by providing social care services to patients facing adverse societal conditions. Within this integrated scheme the use of the inCASA combined monitoring facilities can be viewed as a starting point for mobilising Social Care services (internal or external to the hospital) and Psychiatric Clinic resources to offer needed assistance to the CHF patients.

6.2 Organisational Aspects

From an operational point of view, the KGHNI organizational units directly involved in the delivery of the healthcare and social care integrated inCASA services are the Cardiology Clinic, Social Services and the Psychiatric Clinic.

The KGHNI pilot is coordinated by the Cardiology Clinic of the hospital. The appointed cardiologists and nurses participating in the project will have the overall case management for

every CHF patient monitored via the inCASA solution. Some of their tasks are: measurements monitoring, trend analysis, alerts management, interventions, medication change decisions etc.

Specifically, the KGHNI cardiologists coordinate the pilot's activities. They are responsible for patient recruitment, data monitoring, alerts processing, interventions and pilot evaluation. As they coordinate all activities, they should also report any raised ethical issue to the hospital's ethical committee as well as to the inCASA Ethical Board.

Nurses are responsible for continuous remote monitoring of the patient through the Web Interface of the Consumer Applications. They should report immediately to the assigned cardiologist any alert produced by the system. Nurses also participate in the patient's initial and final evaluation through health questionnaires (dementia, frailty, SF36).

KGHNI social workers will have an active role in the framework of the inCASA project. They are responsible for the communication with patients and for making them feel that the inCASA solution is as user-friendly as possible. The social workers may call the patient asking him/her to come to the hospital if doctors judge so. Moreover, they are asked to perform phone conferences with the patients to determine their psychological status and alert the doctors/psychologists if necessary. This will be achieved via the usage of specific questionnaires, produced by experts from the Psychiatric Clinic, which will make it possible to extract useful information about the patient's mental and social well-being. Furthermore, social workers will offer services at home to people who need social support and/or help them register with nation-wide social care services such as "Help at Home".

KGHNI psychiatrists/psychologists define the questions posed to the patients by the social workers during their meeting. These questions are formed with respect to the scientific standards of this domain. They are responsible for the psychological status assessment and for the habits change alerts assessment based on the analysis of the inCASA platform data. Last but not least, they perform face-to-face interviews with patients having non-negligible social and psychological difficulties.

6.2.1 Pilot Structure

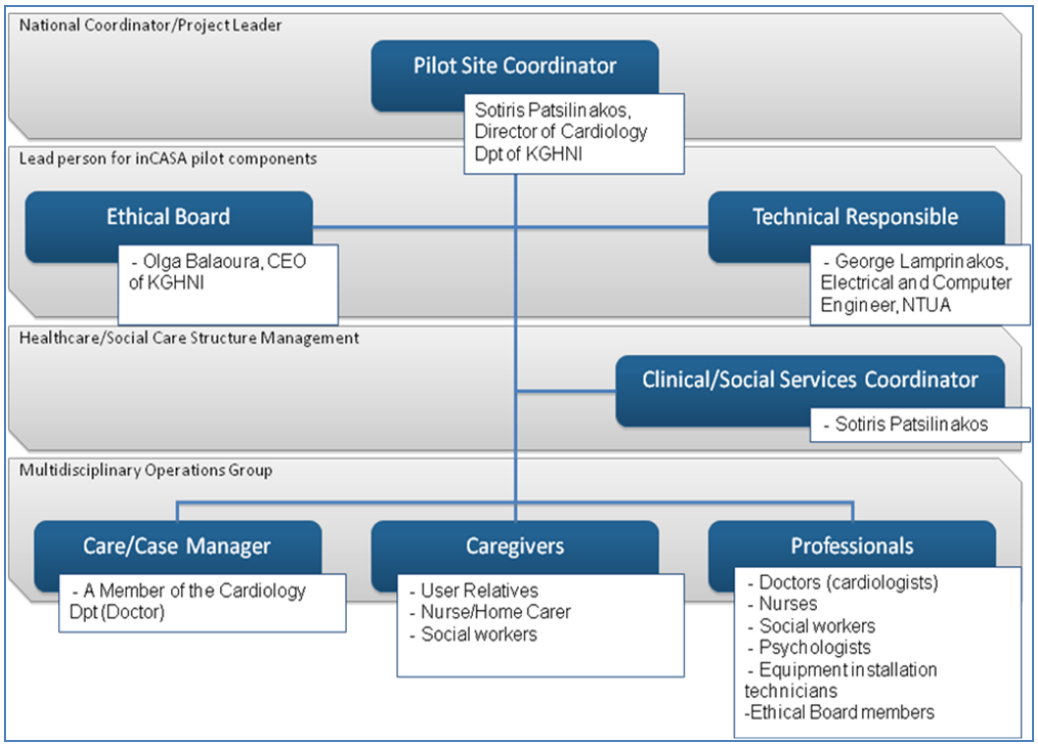

Figure 26: INSERM Pilot Structure

The structure is unchanged compared to the 2nd phase (the pilot phase) that was described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2*. However, it is important to note the role of the KGHNI Ethical Board who, in cooperation with the inCASA Ethical Board, will monitor the pilot execution, making sure that the conditions of the informed consent form are not violated at any point.

6.3 Service Delivery Process

The main inCASA server will be installed at the well-equipped KGHNI Cardiac Care Unit and will make use of the existing infrastructure. In order to achieve the pilot's goals, the inCASA Telehealth and Telecare data monitoring facilities have been deeply integrated at platform level to support unified modes of message exchange, reasoning on measured data and based on automatically built and/or personalised habit profiles, and forwarding alerts to the appropriate actors and professional end-users. The KGHNI pilot will implement the following services/use cases:

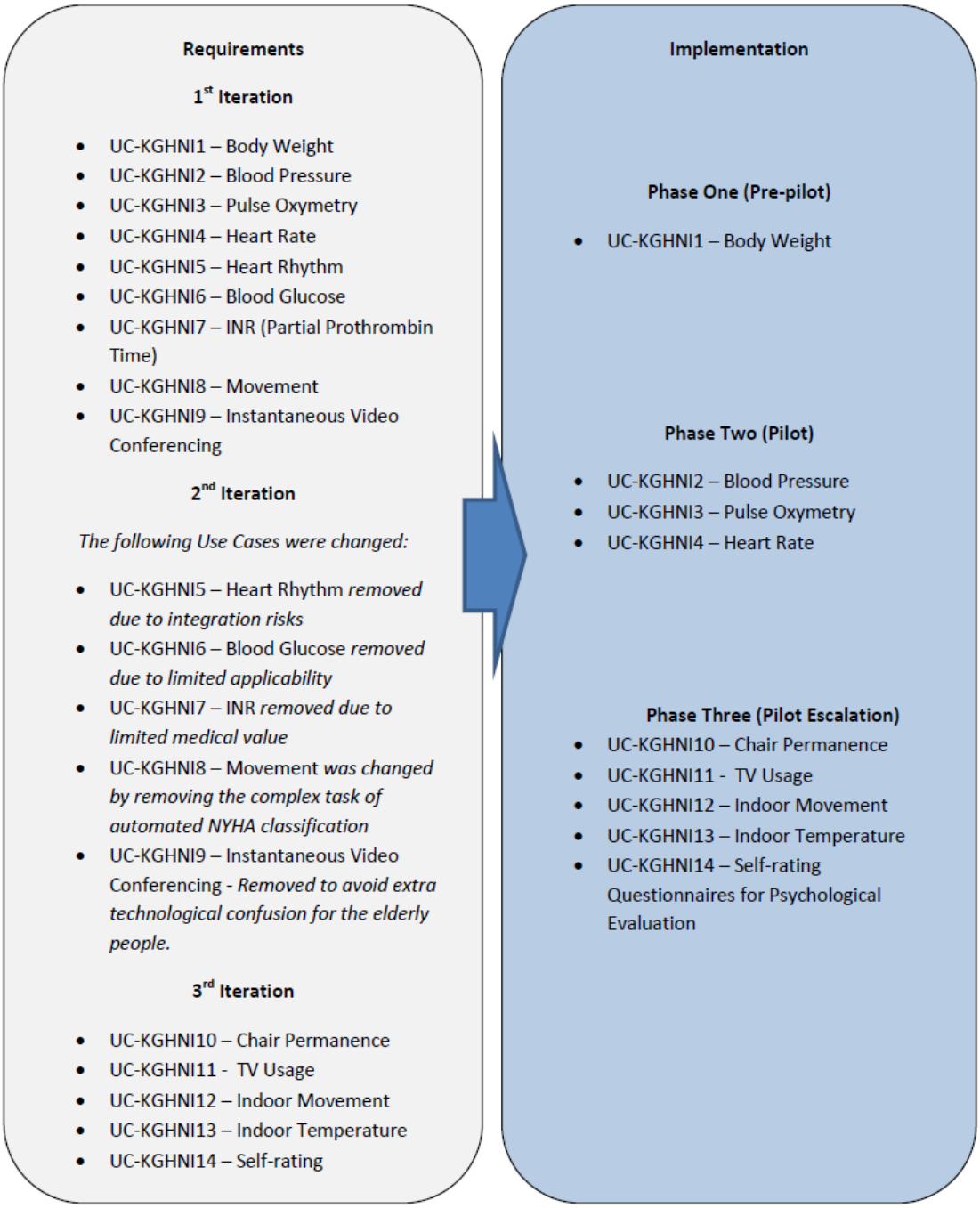

Figure 27: KGHNI Deployment Figure

KGHNI implemented one of the use cases (Body weight) in Phase One (Pre-Pilot). Body weight measurement was selected as it is the most common use case among the inCASA pilots providing a common feature in the first phase.

In Phase Two (Pilot Phase), three additional use cases focusing on measuring and monitoring health parameters were introduced. In the 2nd iteration, it was decided not to implement use cases 5 to 8.[11]

The aim of the integrated use cases introduced during the Pilot Escalation Phase is to allow the clinicians to concurrently view clinical and habits monitoring data[12] and observe any correlation between change in usual habits and decline in physical health. To achieve this, chair permanence, TV usage and motion sensor data will be continuously monitored and used to produce a habits profile for each participating patient.

Furthermore, an extra use-case is incorporated into the Greek pilot allowing the clinicians to monitor the psychological condition and state of depression of the CHF patients, using standard self-rating questionnaires:

- Zung Self-Rating Depression Scale (SDS): weekly administered to patients via phone conference initiated from a KGHNI social worker in order to timely detect any changes in their psychological condition.
- Beck Depression Inventory (BDI): rating scale to assess the severity of depressive symptoms; to be administered to patients when joining and when leaving a pilot group in order to gather enough evidence for a comparative study.

The parameters[13] that will be monitored are (accumulative):

Parameter	Phase
Body Weight	Pre-pilot
Blood Pressure	Pilot
Pulse Oxymetry	
Heart Rate	
Chair Permanence	Pilot Escalation
TV Usage	
Indoor Movement	
Indoor Temperature	

Table 10: KGHNI Parameters

The threshold values for the clinical parameters are personalised in order to adapt more precisely to the status of each patient. For all clinical parameters, except body weight, an alert is raised in case of measurements outside thresholds. In the specific case of body weight monitoring, an alert is generated when there is more than i.e. 1 Kg (default threshold value) increase of the patients' weight over the last 2 observation days.

During the Pilot Escalation Phase (Phase Three), the KGHNI pilot will thus focus on establishing common views that will materially help clinicians detect trends and possibly observe correlations

[11] For further detail on reasons for this, please refer to D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2.

[12] Both clinical and habits monitoring data visualized in tabular and graphical format; prioritization of patients' display according to their clinical needs and alerts severity.

[13] The threshold values and definition of alerts for each of the clinical parameters are described in detail in the deliverable *D6.3 All Pilot Installation Report*.

between changes in usual habits and decline in physical health. This is an ambitious goal set to counteract deficiencies in treatment and follow-up chronic CHF patients' treatment and follow-up. Specifically, empirical data indicate that sometimes a chronic patient's condition is getting worse for no apparent reason and that people close to the patient often fail to recognise these signs of deterioration. They are usually able to identify such signs in retrospect, after a serious incident has taken place – often dismissing too easily complaints from the elderly patient.

The capitalisation on the contextual Telecare data (personalised habits models) is expected to bring added value to the delivered care, emphasising the prevention of potentially life-threatening incidents and the reduction of re-hospitalisations, while at the same time reinforcing the sense of security of the patients and the people close to them.

6.3.1 3rd Phase Use Cases

As noted above, the use cases implemented in the 3rd Phase of the pilot focus on habits/behavioural monitoring and comparing the data with data from the clinical monitoring, thus providing integrated Telehealth/Telecare services. Use cases 1 – 4 are described in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2* and can also be found in Appendix E.[14]

UC-KGHNI10: Chair permanence

Overview*:* A contact sensor detects when and for how long the user is sitting on the designated chair/sofa (i.e. to watch television, to use their PC, to rest etc.).

Purpose*:* Detecting deviations from normal habits assists doctors in identifying early on the deterioration of individual patients' health and helps prioritizing the provision of psychological and social support. The monitoring period of approx. 3 months is adequate to build personalized habits models based on the monitored Telecare parameters while also providing an appropriate timeframe for engaging the combined socio-health interventions and measure their effectiveness.

Procedure*:* The sensor data processed by the system are when the user sits down and for how long. These different patterns will be processed in order to generate alert messages.

Analysis*:* Analysis of differences between the user's habits and actual monitored chair permanence.

Data fusion*:* All data are stored in a database connected to the system and accessible by the Consumer Application, i.e. the Clinical Web Portal which provides a single point of access for the operators (nurses, doctors, psychologists) to the platform's data. Chair sensor data is used as input to automatically build a profile of the patient's habits during the first 2 weeks of deployment; no computations whatsoever are made at the platform level to establish correlations between the data feeds of the Telecare sensors.

Alerts*:* A message will be displayed on the Consumer Applications monitored by the cardiology clinic nurses or doctors when a patient is sitting in the designated chair/sofa for comparatively prolonged times on a daily basis. The full description of the alert will be available at the Alerts Tab of the portal, where all alerts will be stored at a combined interface. The operators also have access to the history of all Telecare-related or Telehealth-related alerts.

Feedback to user and relatives: In case of an alarming situation (strong deviation from the habitual profile), the patient may be called by the social worker or psychologist for deeper investigation into

[14] Use cases 5-9 have been removed in the 2nd iteration. A description of these use cases can be found in the deliverable *D2.1 Preliminary Requirement Investigation_v2.2*.

the issue. As an outcome, a visit to the hospital may be scheduled for the patient where an intervention could be decided according to the KGHNI workflow and decided through a process that involves the multi-disciplinary KGHNI monitoring team.

Personalisation*:* Yes.

Devices*:* Funkstuhl Transmitting Chair Sensor.

UC-KGHNI11: TV Usage

Overview: An activity sensor will be installed at the TV power socket to detect when the TV is turned and for how long.

Purpose: Detecting deviations from normal habits assists doctors in identifying early on the deterioration of individual patients' health and helps prioritizing the provision of psychological and social support. The monitoring period of approx. 3 months is adequate to build personalized habits models based on the monitored Telecare parameters while also providing an appropriate timeframe for engaging the combined socio-health interventions and measure their effectiveness.

Procedure: The sensor data processed by the system are when the user turns on the TV and for how long. These different patterns will be processed in order to generate alert messages.

Analysis: Analysis of the difference between the user's habits and actual monitored TV usage.

Data fusion: All data are stored in a database connected to the system accessible by the Consumer Applications (web front-end). TV usage data is used as input to automatically build a profile of the patient's habits during the first 2 weeks of deployment; no computations whatsoever are made at the platform level to establish correlations between the data feeds of the Telecare sensors.

Alerts: A message will be displayed at the Consumer Applications monitored by the cardiology clinic nurses when a patient has the TV turned on for prolonged times on a daily basis.

Feedback to user and relatives: In case of an alarming situation (strong deviation from the habitual profile), the patient may be called by the social worker or psychologist for deeper investigation into the issue. As an outcome, a visit to the hospital may be scheduled for the patient where an intervention could be decided according to the KGHNI workflow and decided through a process that involves the multi-disciplinary KGHNI monitoring team.

Personalisation: Yes.

Devices: Activity sensor (Power Socket with Power Consumption Monitoring), e.g.Netvox Z-800.

UC-KGHNI12: Indoor Movement

Overview: A motion sensor is installed in the patient's living room to detect when the user is moving (standing-up, walking, entering/exiting the room).

Purpose: Detecting deviations from normal habits assists doctors in identifying early on the deterioration of individual patients' health and helps prioritizing the provision of psychological and social support. The monitoring period of approx. 3 montsh is adequate to build personalized habits models based on the monitored Telecare parameters while also providing an appropriate timeframe for engaging the combined socio-health interventions and measure their effectiveness.

Procedure: The input processed by the system is the frequency of the user movements within the living room. These different patterns will be processed in order to generate alert messages.

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

Data fusion: All data are stored in a database connected to the system accessible by the Consumer Applications (web front-end). Motion data is used as input to automatically build a profile of the patient's habits during the first 2 weeks of deployment; no computations whatsoever are made at the platform level to establish correlations between the data feeds of the Telecare sensors.

Alerts: A message will be displayed at the Consumer Applications monitored by the cardiology clinic nurses when a patient shows too little or too much movement within the living room on a daily basis. The assigned cardiology doctor also has access to the history of Telecare-related alerts.

Feedback to user and relatives: In case of an alarming situation (strong deviation from the habitual profile), the patient may be called by the social worker or psychologist for deeper investigation into the issue. As an outcome, a visit to the hospital may be scheduled for the patient where an intervention could be decided according to the KGHNI workflow and decided through a process that involve the multi-disciplinary KGHNI monitoring team.

Personalisation: Yes.

Devices: Motion Detector/Temperature Sensor, e.g. Netvox Z-B01C.

UC-KGHNI13: Indoor Temperature

Overview: The motion sensor in the patient's living room also measures indoor room temperature.

Purpose: Temperature is monitored to assess the level of comfort within the patient's house; this is an important parameter for the well-being of elderly people suffering from CHF. Specific focus is on the high temperatures encountered in Greece during the summer period as this may adversely affect the clinical state of a CHF patient.

Procedure: The input processed by the system is the temperature in degrees Celsius during the day.

Analysis: Deviation from upper/lower temperatures considered comfortable.

Data fusion: All data are stored in a database connected to the system accessible by the Consumer Applications (web front-end).

Alerts: When the temperature deviates significantly from pre-set comfort levels an alert is automatically generated and displayed at the Consumer Applications, monitored by the cardiology clinic nurses.

Feedback to user and relatives: Patient will be called when temperature exceeds thresholds and informed of the possible impact of excessive indoor temperatures on their health.

Personalisation: Yes.

Devices: Motion Detection/Temperature Sensor, e.g. Netvox Z-B01C.

UC-KGHNI14: Self-rating questionnaires for psychological evaluation

Overview: To better support the patients' everyday life, psychological evaluation questionnaires (**SDS**) are administered to the patients once per week via a phone conference initiated from a KGHNI social worker. KGHNI psychologists subsequently score them to track their condition and detect if there are any signs of depression.

Procedure: The social worker arranges once per week a phone conference with each patient to complete the self-evaluation procedure. Questionnaire results are forwarded to psychologists who subsequently score them and post the results on the Consumer Application web-front-end.

Analysis: Scoring and review of the questionnaires results is conducted by the psychologists; they decide on the specifics of the intervention always in collaboration with the KGHNI cardiologists.

Data fusion: None; expert doctors score the questionnaires. The results of the psychological questionnaires are published in Consumer Applications accessible by all carers.

Alerts: No alerts are generated by the system. Questionnaires results are co-evaluated with other monitored parameters to allow carers to decide whether an intervention is needed.

Feedback to user and relatives: In case that scoring reveals early or advanced depression, a proposal will be made to the patient for a psychological session at the hospital. It will be explained to the patient that this could improve their overall situation.

Personalisation: Yes.

Devices: Phone, paper, pen.

6.3.2 Telehealth and Telecare Integration Scenario

The following describes integrated Telehealth/Telecare scenarios by describing the pathways of the different levels of intervention (intervention protocols) when new health-related symptoms are consolidated from observed deviations in the patient's habits or additional psychological/social factors are deduced to having a detrimental influence on their quality of life and everyday activities.

UC-KGHNI10, 11 and 12: Chair permanence, TV Usage and Motion Sensors

This scenario describes the sequence of actions when the installed Telecare sensors detect reduced patient activity at home, i.e. TV usage and chair permanence increase over a short period of time and/or motion detector readings indicate reduced movement in the premises.

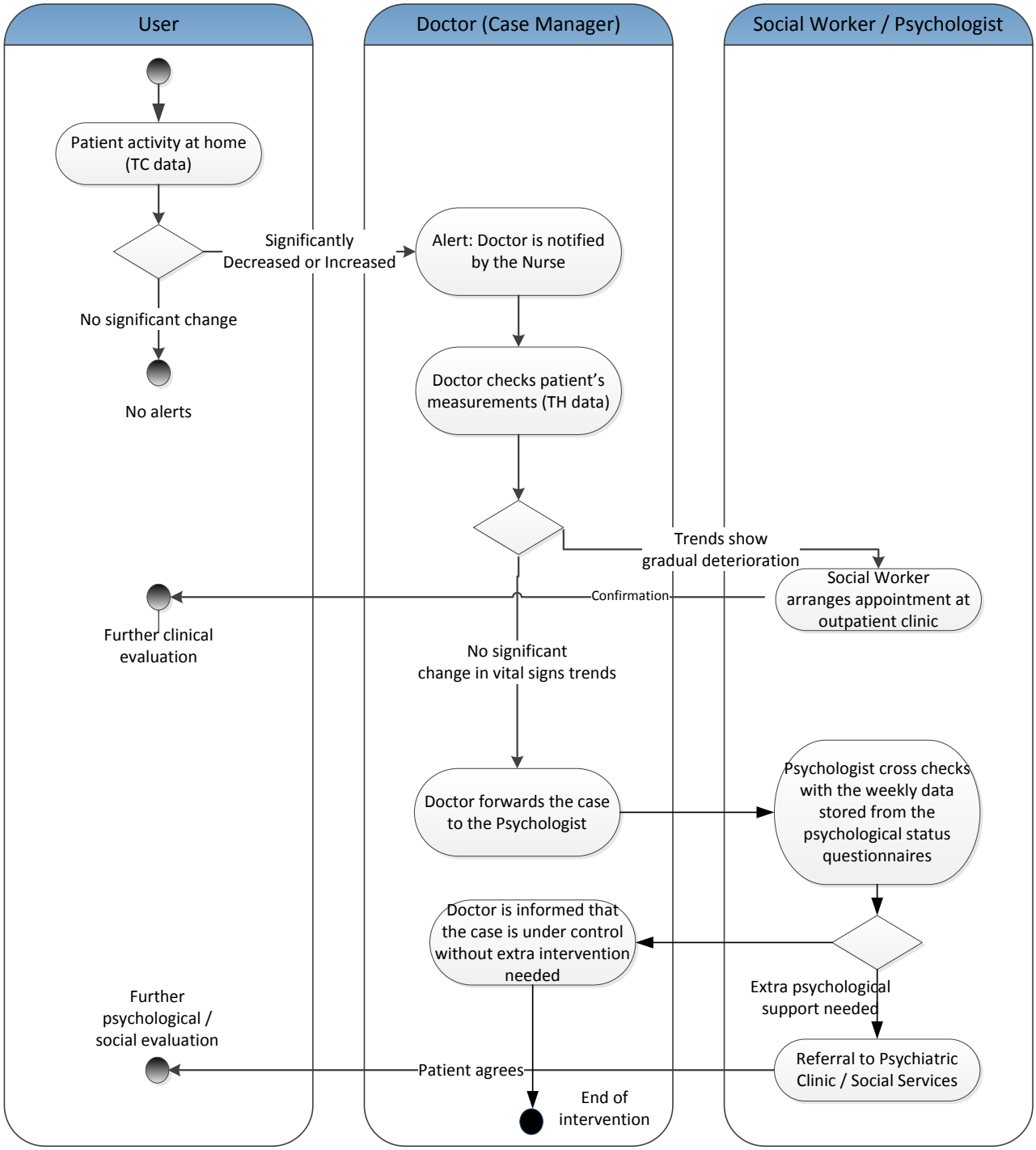

Figure 28: KGHNI Activity Diagram for Habits Monitoring

As can be seen in the above Activity Diagram, when a deviation from the normal user habits is automatically detected by the platform the following actions are taken:

1. The inCASA platform will forward the pertinent alert to the NTUA Consumer Applications.
2. A nurse at the care centre will notify the assigned doctor (Case Manager).
3. The doctor will review the history of Telehealth measurements by accessing the web-interface of the Consumer Applications.
4. If the trends of the health-related measurements over the past few days indicate a gradual deterioration of the patient's clinical state, the doctor can decide to arrange an appointment with the patient at the Outpatient Clinic for further medical examinations.

5. If no material change is detected by the doctor, the case is forwarded to the assigned psychologist who can also co-factor other contextual data such as the recent self-assessment questionnaire scores, indicative of the patient's state of depression, and recently recorded interventions (i.e. medication change) that could have an effect on the patient's activity.
6. Based on the above evidence, the psychologist can decide to refer the patient to an expert psychologist within KHGNI and/or encourage the patient to meet with the social worker.

UC-KGHNI13: Indoor Temperature

This scenario describes the sequence of actions when the temperature sensor detects that the indoor temperature value in the user's home is not within a pre-established range considered comfortable.

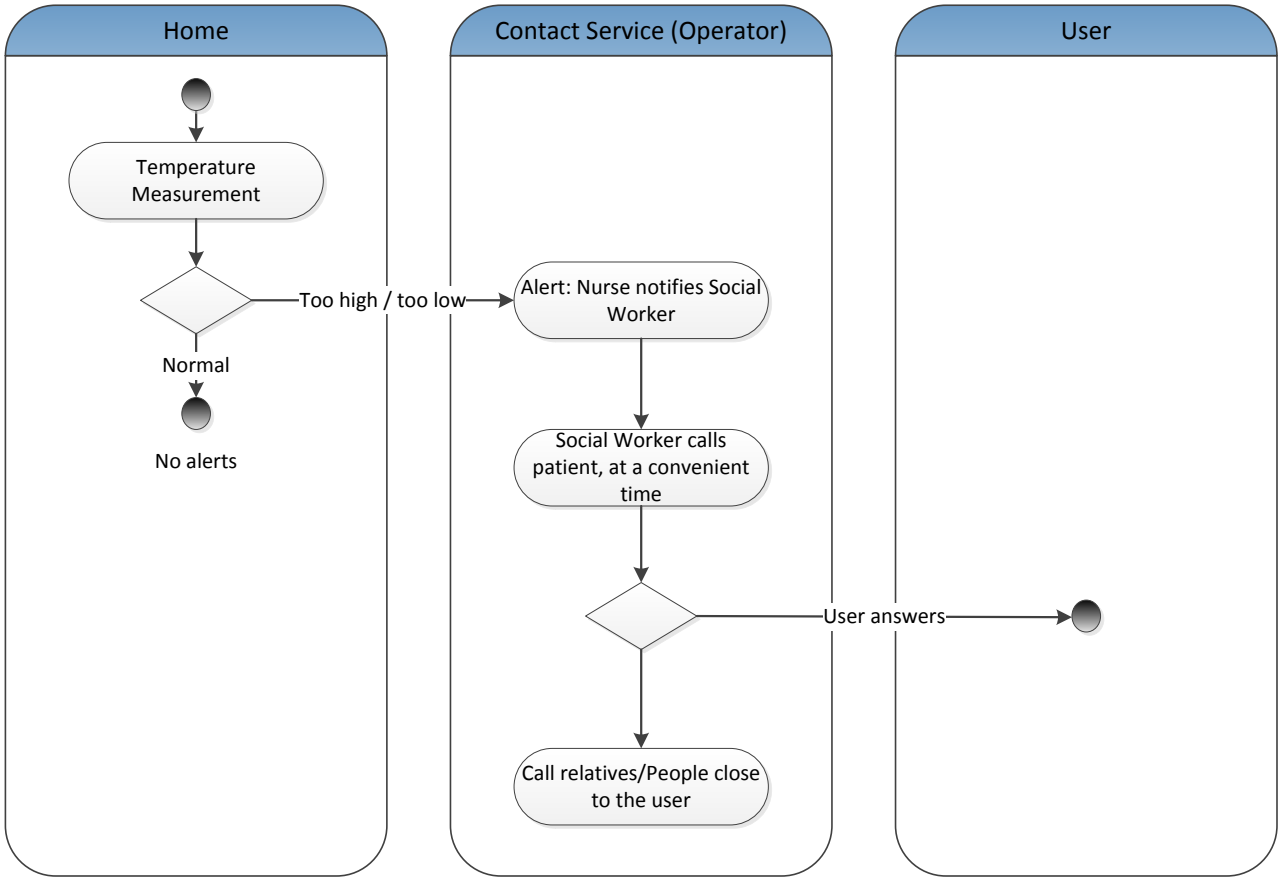

Figure 29: KGHNI Activity Diagram for Indoor Temperature Measurements

As can be seen in the above Activity Diagram, when the temperature sensor detects a temperature out of range (too low or too high) the following actions will be taken:

1. inCASA platform will send an alert to the Contact Centre, through the NTUA Consumer Applications.
2. The nurse will notify a social worker to check on the patient by phone.
3. If user doesn't answer the phone, Contact Centre's operator will try to contact a relative of or other people close to the patient.

UC-KGHNI14: Self-rating questionnaires for psychological evaluation

This scenario describes the sequence of actions when the self-evaluation questionnaire results indicate that the patient may be suffering from a depressive episode.

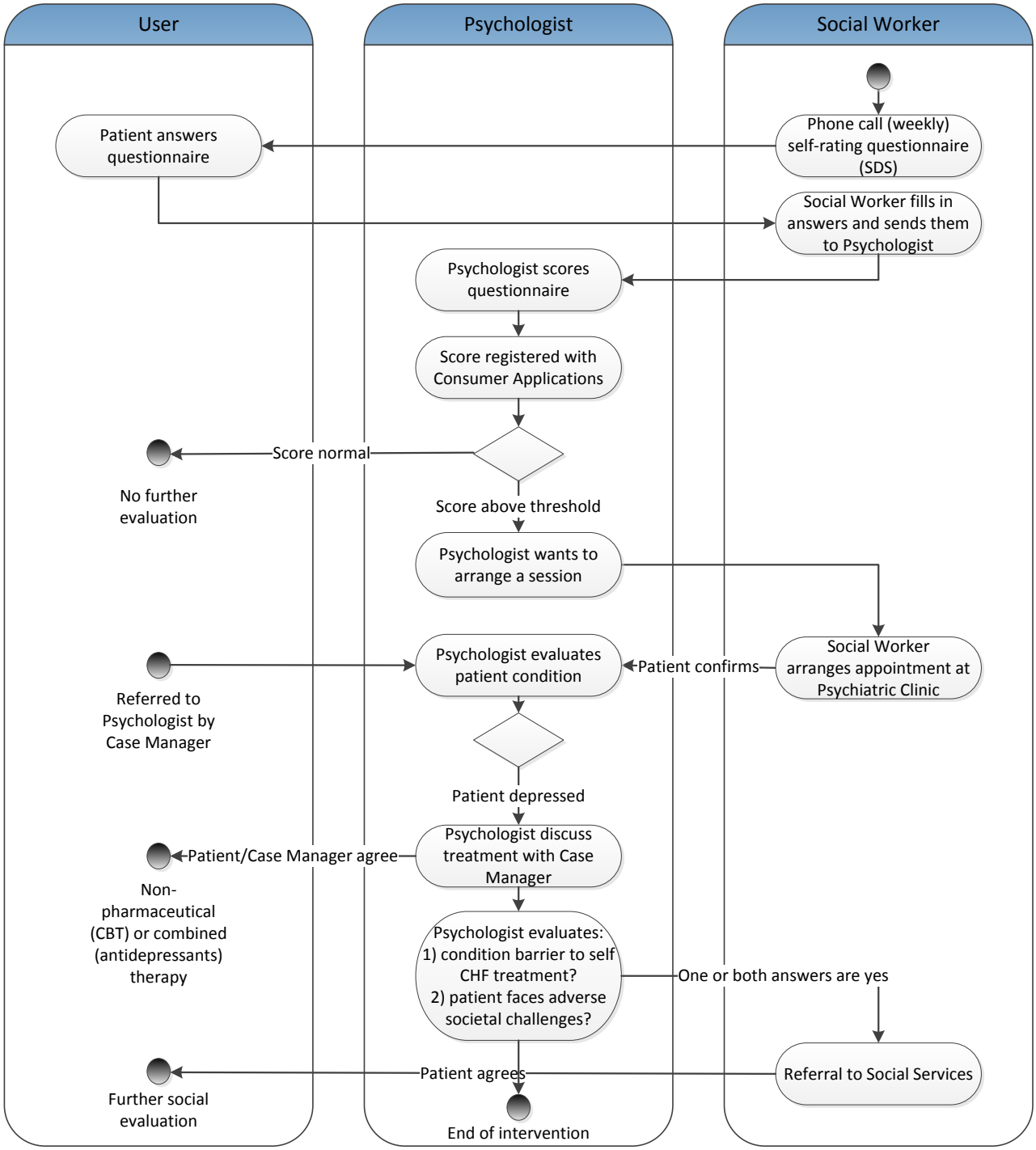

Figure 30: KGHNI Activity Diagram for Psychological Evaluations

As can be seen in the above Activity Diagram, when there are reasonable indications that the patient is depressed (i.e. from the questionnaire results or through direct contact with the patient) the following actions are taken:

1. The psychologist notifies the social worker to arrange a session with the patient.
2. The patient is examined by the psychologist responsible for determining a treatment.
    a. Non-pharmacological such as cognitive behaviour therapy (CBT)
    b. Anti-depressants prescribed after consulting the assigned cardiology doctor to minimize the risk of medication side effects.

3. The psychologist may also determine that a patient is facing adverse social challenges and/or his/her condition constitutes a barrier to effective heart failure self-care; in this case the psychologist can notify the Social Services and people who are close to the patient.

6.3.3 Intervention Protocols

The intervention protocols for the new use cases in Phase Three are described above with the scenarios. The clinical protocols related to health monitoring data have been detailed in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_version 2.*

6.4 Integrated Telehealth/Telecare Business Processes and Workflows

The figure below illustrates the overall business processes and workflow in the KGHNI pilot for the integrated social and healthcare services:

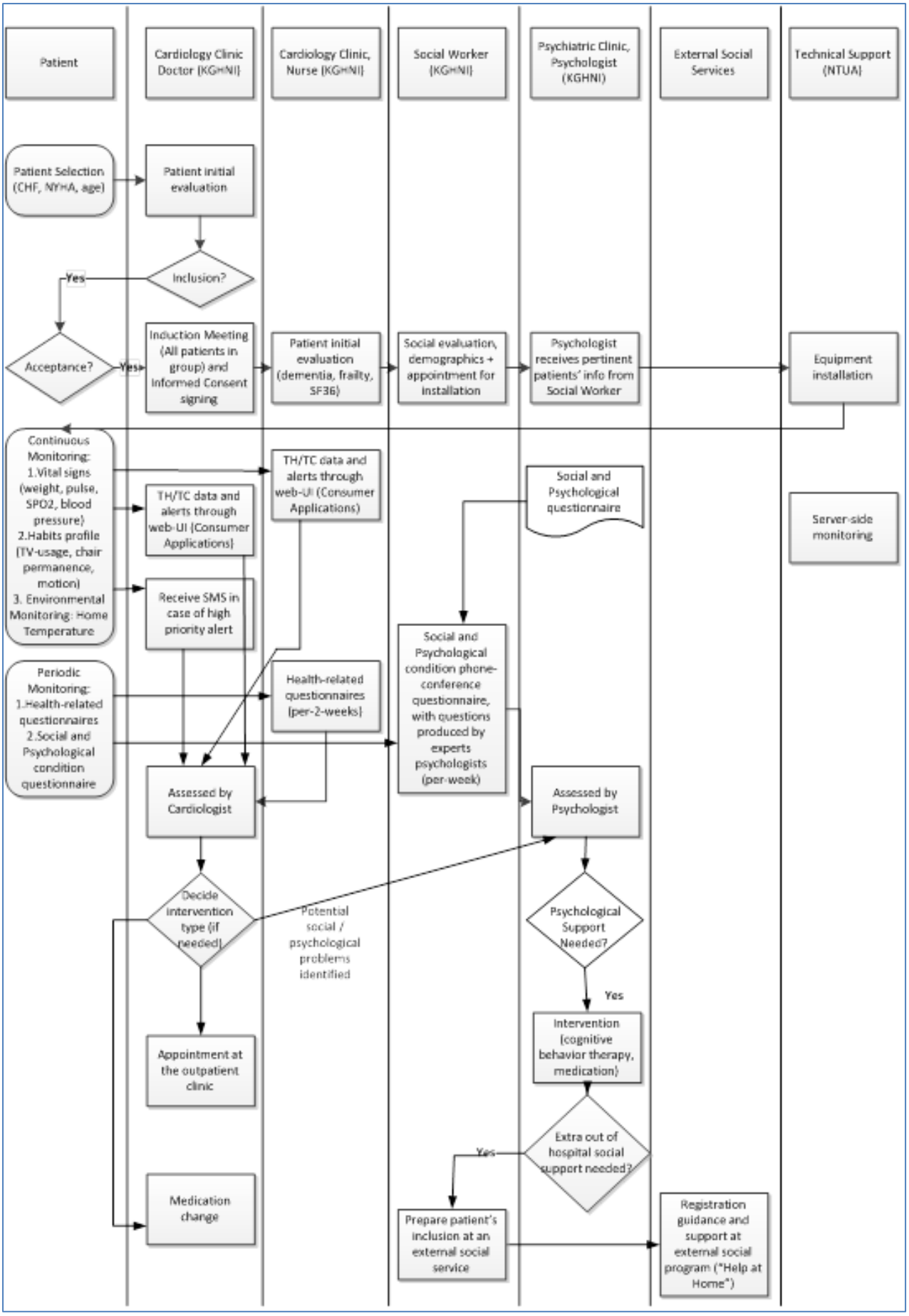

Figure 31: KGHNI Business Processes and Workflow Model

6.5 Schedule

The following table provides an overview of the KGHNI pilot schedule:

Date	Action
March 2011	Pre-Pilot activities start
October 2011	Pre-Pilot equipment installation, testing and running
October – December 2011	Pre-Pilot Platform is running. Platform usability tested and improvements proposed
January - February 2011	1st Evaluation of inCASA installation, usability and Pilot procedures.
March 2012	Pilot Start (Pilot Phase): User home inspection, consent forms (Group 1: 5 patients), equipment installation, training and testing, patient questionnaires, 1st group commenced
April 2012	End of participation for Group 1
May 2012	Group 2 commenced
June 2012	End of participation for Group 2
July 2012	Group 3 commenced
August 2012	Testing Integrated Telehealth/Telecare inCASA platform (1 patient)
August 2012	End of participation for group 3
September 2012	Pilot with Integrated Telehealth/Telecare services begins Group 4 commenced
December 2012	End of participation for Group 4
December 2012	Group 5 commences (10 patients)
March 2013	End of participation for group 5
March 2013	Group 6 commences (10 patients)
May 2013	Final Evaluation
June 2013	Conclusion of pilot monitoring and evaluation

Table 11: KGHNI Pilot Schedule

The Greek Pilot Phase started in March 2012 with its Telehealth phase, after a successful conclusion of the pre-pilot and its evaluation. The pilot will be concluded by June 2013, when the evaluation of all pilot activities will have been completed. So far, 20 out of the projected total of 40

CHF patients have been included in the Pilot. Five of them (Group 4) are currently active while the remaining 15 have already ended their participation in the program.

September 2012 was a milestone for pilot activities since the combined Telehealth and Telecare services (Phase Three) have been successfully introduced. It stands as the final solution provided by KGHNI in the framework of the inCASA project.

6.5.1 Updates since Iteration 2

The use cases in this 3rd and final phase of the pilot have been further defined and intervention protocols and scenarios defined. As reported in iteration 2, several originally planned use cases have been removed and the deployment figure (Figure 27) has been updated accordingly.

The technical requirements relevant for KGHNI have been updated accordingly. A complete report of all the updated requirements can be found in Chapter 7.

7 Technical Requirements Consolidation and Prioritisation

The method used for the consolidation and prioritisation of technical requirements has been described in detail in *D2.2 Requirements Consolidation and Prioritisation Iteration 1_v2.5* and *D2.4 Requirements Consolidation and Prioritisation Iteration 2_v1.0*. The following chapters use the same method and present the updates and changes made to technical requirements (classified as functional or non-functional) in this 3rd iteration.

7.1 Use Case Coding

In the first Iteration (*D2.2 Requirements Consolidation and Prioritisation Iteration 1_v2.5*), the approach taken to consolidate the requirements was to extract single requirements among common and singular use cases. A first coding of requirements was thus achieved.

Continuing with the same approach, we here report the changes made for this 3rd and final iteration. Changes are marked in red.

Use Case (Input)	Description	Pilot	Common Description	Name	Code (Output)
UC-INSERM3	10 Bluetooth weight scales directly connected to the inCASA platform.	INSERM	The user should be provided with a Bluetooth Weight Scale measuring in Kg	Weight Scale	R01
UC-KGHNI1	For example A&D UC-321-PBT Electronic Scale. Bluetooth interface to gateway. One device for each patient in the group.	KGHNI			
UC-ATC10	A weight scale (should record the measurements in KG)	ATC			
UC-CHC2	A weight scale (should record the measurements in KG)	CHC			
~~UC-KGHNI1~~	~~It could be considered to have a reminder send to the patient~~	~~KGHNI~~	~~The system could send a reminder (sms or tablet alert) to the user to take measurement~~	~~Weight measurement Reminder~~	~~R02~~
UC-INSERM3	Patients body weight will be recorded once a day (early morning)	INSERM	The system should allow professional users to set the usual timing of measurement (from hh:mm to hh:mm) and the number of measurements per day and should accept extemporary measurements provided by the patient	Frequency and Timing of weight measurements	R03 R04
UC-KGHNI1	Measure every morning after visit to the toilet.	KGHNI			
UC-KGHNI1	~~It is a requirement that the~~ The service should be personalised to each individual patient in terms of time of day and increment of the weight measurements.	KGHNI			

UC-CHC2	Patient to take one measurement per day – preferably by 11am.	CHC			
UC-CHC2	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.	CHC			
UC-ATC10	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.	ATC			
UC-ATC10	Patient to take one measurement per day – preferably by 11am.	ATC			
UC-INSERM3	Weight measurements are compared over several days.	INSERM	The system should allow measurement data visualization and extraction organized per day/per week/per month	Weight measurements Analysis	R05
UC-KGHNI1	Weight measurements are compared over two consecutive days.	KGHNI			
UC-ATC10	The data will then be analysed using the management system to track the patients weight	ATC			
UC-KGHNI1	If there are several measurements per day, the data from approximately the same time in the morning are compared.	KGHNI			
UC-CHC2	The data will then be analysed using the management system to track the patients weight	CHC			
UC-INSERM3	All the data should be store in a dedicated computer with permanent internet connection to the inCASA server.	INSERM	All data should be stored on the inCASA Repository through a permanent internet connection	Weight measurement Data Storage	R06
UC-KGHNI1	All data should be stored in a suitable Electronic Healthcare Record.	KGHNI			

UC-KGHNI1	All the data should be stored locally in a dedicated computer with internet connection to the inCASA server. In case of connectivity issues measurements can be forwarded to server when the connection is restored.	KGHNI			
UC-INSERM3	If the body weight decreases by 5% or more between several data points, the nurse is alerted	INSERM	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurements, absolute or across time. The system should allow professional users to set rules: the number of measurements to compare; the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert	Alerts for Weight	R07
UC-KGHNI1	If there is a consistent increase in body weight of more than 1 kg between three data points, the responsible doctor is alerted.	KGHNI			
UC-ATC10	The clinician will be alert when there is a variance away from the desired or expected	ATC			
UC-ATC10	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.	ATC			
UC-CHC2	The clinician will be alert when there is a variance away from the desired or expected	CHC			
UC-CHC2	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.	CHC			
UC-KGHNI3	~~Several pulse oximetry devices exist in the Continua alliance list.~~ For example Nonin Onyx II 9560 pulse oximeter.	KGHNI	The user should be provided with a wireless pulse oximeter	Pulse Oximeter	R08

	Bluetooth interface to gateway. One device for each patient in a the group.				
UC-ATC11	A pulse oximeter	ATC			
UC-CHC3	A pulse oximeter	CHC			
UC-KGHNI3	Measure the SO2 3 times daily e.g. in connection with blood pressure measurements.	KGHNI	The system should allow professional users to set the usual timing of measurement (from hh:mm to hh:mm) and the number of measurements per day and should accept extemporary measurements provided by the patient	Frequency and Timing of SpO2 measurements	R03 R04
UC-KGHNI4	Collect the pulse data from the oximeter in connection with SpO2 data transmission	KGHNI			
UC-CHC3	We will ask each patient to take one measurement per day – preferably by 11am.	CHC			
UC-CHC3	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.	CHC			
UC-ATC11	We will ask each patient to take one measurement per day – preferably by 11am.	ATC			
UC-ATC11	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.	ATC			
UC-KGHNI3	Values are pre-conditioned at the point of measurement. Trends of the values of SpO2 are derived from stored data.	KGHNI	The system should allow measurement data visualization and extraction organized per day/per week/per month	SpO2 measurements Analysis	R05
UC-ATC11	The data will be analysed using the management system to track the patients' SpO2	ATC			

UC-CHC3	The data will be analysed using the management system to track the patients' SpO2	CHC			
UC-KGHNI3	All data should be stored in a suitable Electronic Healthcare Record.	KGHNI	All data should be stored on the inCASA Repository through a permanent internet connection	SpO2 measurement Data Storage	R06
UC-KGHNI3/4	All the data should be stored locally in a dedicated computer with internet connection to the inCASA server. In case of connectivity issues, measurements can be forwarded to the server when the connection is restored	KGHNI			
UC-KGHNI3	Doctors are alerted of deteriorating condition	KGHNI	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurements, absolute or across time. The system should allow professional users to set rules: the range of normality and the limit of the variation to send the alert	Alerts for SpO2	R07
UC-CHC3	The clinician will be alerted when there is a variance away from the desired or expected	CHC			
UC-CHC3	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	CHC			
UC-ATC11	The clinician will be alerted when there is a variance away from the desired or expected	ATC			
UC-ATC11	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	ATC			
UC-KGHNI1/2/3/4	Confirmation of changes of medication or desired vital signs measurements schedule (i.e. weight measurement once per day at 08.00) shown on display.	KGHNI	The system could allow professional users to update the medication or/and the vital signs measurements schedule. The	Display of medication and measurements	R10

~~UC-KGHNI3~~	~~Call for visits to the outpatient clinic can be confirmed by SMS to the patient and relatives~~	~~KGHNI~~	changes could be shown on patient's display.	schedule on the user's screen	R11
UC-KGHNI2	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.	KGHNI	The user should be provided with a Bluetooth blood pressure Monitor measuring in mmHg with pulse metering capabilities	Blood Pressure Monitor	R12
UC-CHC1	Blood Pressure monitor that will record systolic, diastolic (mmHg) and pulse.	CHC			
UC-ATC9	Blood Pressure monitor that will record systolic, diastolic (mmHg) and pulse.	ATC			
UC-KGHNI2/4	Measurements shall be performed at least twice a day, e.g. in connection with SpO2 measurements ~~e.g. 3 times a day.~~	KGHNI	The system should allow professional users to set the usual timing of measurement (from hh:mm to hh:mm) and the number of measurements per day and should accept extemporary measurements provided by the patient	Frequency and Timing of Blood Pressure measurements	R03
~~UC-KGHNI4~~	~~Collect the pulse data from the blood pressure monitor in connection with blood pressure data transmission.~~	~~KGHNI~~			
UC-CHC1	Patient will take one resting blood pressure measurement per day – preferably by 11am.	CHC			
UC-CHC1	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.	CHC			R04
UC-ATC9	Patient will take one resting blood pressure measurement per day – preferably by 11am.	ATC			
UC-ATC9	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.	ATC			

UC-KGHNI2/4	The average should be calculated	KGHNI	The system should allow professional users to set the number of measurements to compare and the formula (e.g. average) to be applied to the selected measurements	Blood Pressure Monitoring calculation	R13
UC-KGHNI2	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.	KGHNI			
~~UC-KGHNI2~~	~~The patient may be notified of the need to perform the measurement.~~	~~KGHNI~~	~~The system could send a reminder (sms or tablet alert) to the user to take measurement~~	~~Blood Pressure measurement Reminder~~	~~R02~~
UC-KGHNI2	Data should be analysed for correctness (should be within certain limits) before being sent 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.	KGHNI	The system should allow measurement data visualization and extraction organized per day/per week/per month	Blood Pressure Analysis	R05
UC-CHC1	The clinical teams will look to ensure a patients' Blood Pressure is within pre-defined limits e.g. 140/85.	CHC			
UC-CHC1	The data will then be analysed using the management system to track the patients current blood pressure measure.	CHC			
UC-ATC9	The clinical teams will look to ensure a patients' Blood Pressure is within pre-defined limits e.g. 140/85.	ATC			
UC-ATC9	The data will then be analysed using the management system to track the patient's current blood pressure measure.	ATC			
UC-KGHNI2	All data should be stored in a suitable Electronic Healthcare Record.	KGHNI	All data should be stored on the inCASA Repository through a	Blood Pressure Data	R06

UC-KGHNI2	All the data should be stored locally in a dedicated computer with internet connection to the inCASA server. In case of connectivity issues measurements can be forwarded to server when the connection is restored.	KGHNI	permanent internet connection	Storage	
UC-KGHNI2	If values are outside certain bands, the responsible doctor should be alerted.	KGHNI	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurements, absolute or across time. The system should allow professional users to set rules: the range of normality and the limit of the variation to send the alert	Alerts for Blood Pressure	R07
UC-CHC1	The clinician will be alerted when there is a variance away from the desired or expected	CHC			
UC-ATC9	The clinician will be alerted when there is a variance away from the desired or expected	ATC			
UC-INSERM2	10 pad interfaces directly connected to the inCASA platform.	INSERM	The user should be provided with a Wireless Tablet connected to the inCASA platform	Symptoms self-assessment device	R14
UC-INSERM2	Patients will self-assess their symptoms on a pad interface connected to the inCASA platform once a day (in the evening).	INSERM	The system should allow professional users to set the usual timing of assessment (from hh:mm to hh:mm) and should accept extemporary self-assessment provided by the patient	Frequency and timing of self-assessment	R03

UC-INSERM2	Symptoms will include pain, fatigue, nausea, disturbed sleep, distress, drowsiness, nausea, anorexia, and vomiting.	INSERM	The system should allow the professional users to introduce specific questions or questionnaires to be administered to the patient and assign value to each answer and then calculate scores	Self-assessment questionnaire	R15
UC-CHC5	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	CHC			
UC-INSERM2	If the self-assessed symptoms scores are worsening, an alarm will be generated	INSERM	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the score of assessment, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert	Self-assessment Alerts	R07
~~UC-KGHNI8~~ UC-KGHNI2	Wireless movement sensors are inexpensive and easy to install.	KGHNI	The user's house should be provided by battery operated wireless sensors to detect movement of the user inside the house, recording time and duration of detected movement events	Indoor movement sensors	R16
UC-CHC4	PIR motion detector. In addition the time and duration of each event will be recorded.	CHC			
UC-ATC2	contact/movement sensors	ATC			
~~UC-KGHNI8~~ UC-KGHNI2	~~All data should be stored in a suitable Electronic Healthcare Record.~~ The data will be sent and compared with the personalised habits profile established for each patient during the training period (first 2 weeks)	KGHNI	All data should be stored on the inCASA Repository through a permanent internet connection	Indoor movement data storage	R06

UC-ATC2	The data will be sent and processed	ATC			
~~UC-KGHNI8~~ UC-KGHNI2	~~Movements are continuously measured in different sections of the home.~~ Movements in the room where the sensor is installed are continuously monitored.	KGHNI	Movement inside the house is continuously monitored by the system	Frequency and Timing of indoor Movement monitoring	R03
UC-ATC2	The service will monitor the indoor movements of the user, in order to identify gaps and anomalies and to send alerts	ATC			
UC-CHC4	A PIR motion detector will also be placed in a location e.g. hall where foot traffic is the greatest.	CHC			
~~UC-KGHNI8~~	~~CHF patients have in general reduced mobility. 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.~~	~~KGHNI~~	The system should allow professional users to evaluate changes from a "Normal Habits", by building a "normal habits" profile across 2 weeks of monitoring	Movement Monitoring Analysis	R17
UC-KGHNI10	Significantly increase of chair permanence combined with passive activities (i.e TV usage) can signal the onset of depression. Monitoring habits will also help us to detect early signs of worsening clinical condition.	KGHNI			

UC-KGHNI11	Significantly increase of passive activities like TV usage can signal the onset of depression, something very common in CHF patients. Monitoring TV usage and other habits related to in-house movement will also help us to detect early signs of worsening clinical condition.	KGHNI			
UC-KGHNI12	CHF patients have in general reduced mobility. 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. It will also enable us to detect early signs of a worsening clinical condition.	KGHNI			
UC-CHC4	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.	CHC			
UC-ATC2	The service will monitor the indoor movements of the user, in order to identify gaps and anomalies and to send alerts	ATC			
UC-CHC4	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.	CHC			

UC-ATC2	User is not moving for several hours (> 50% of usual movement), or is moving inside his home abnormally, 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	ATC			
~~UC-KGHNI8~~	~~The NYHA system relates symptoms to everyday activities and the patient's quality of life. 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.~~	~~KGHNI~~	~~The system should correlate movements to an algorithm made to evaluate NYHA class of everyday activities, by taking into account the movements, the number of people in the home as well as subjective input from the patient.~~ The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert	~~Movement Monitoring calculation~~ Movement Alerts	~~R18~~ R07
~~UC-KGHNI8~~	~~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.~~	~~KGHNI~~			
~~UC-KGHNI8~~	~~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.~~	~~KGHNI~~			
UC-ATC2	A message (SMS/e-Mail/UI Alert) to the operator will be sent if data are out of normal habits	ATC			
UC-KGHNI12	Healthcare professionals are alerted if the level of movements is significantly decreased. These alerts are co-factored by professional with alerts produced regarding chair permanence or increased duration of passive activities (i.e. TV usage)	KGHNI			
UC-CHC4	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.	CHC	The user's house should be provided by battery operated wireless sensors to detect presence of the user on the bed, recording time and duration of bed permanence events	Bed Permanence sensors	R19
~~UC-KGHNI8~~	~~Steinbeis can provide bed sensors that measure the time the patient spends in bed.~~	~~KGHNI~~			

UC-ATC3	Bed contact/movement sensors	ATC			
UC-CHC4	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, lying in bed.	CHC	The user's house should be provided by battery operated wireless sensors to detect presence of the user on a chair, recording time and duration of bed permanence events	Chair Permanence sensors	R20
~~UC-KGHNI8~~	~~All data should be stored in a suitable Electronic Healthcare Record~~	~~KGHNI~~	All data should be stored on the inCASA Repository through a permanent internet connection	Bed Permanence data storage	R06
UC-ATC3	The data will be sent and processed	ATC			
UC-ATC3	The system will process some inputs like: User goes to bed; User stays on bed; User wakes up from bed; User doesn't go to bed. These different patterns will be processed in order to generate alert messages	ATC	The system should allow professional users to evaluate changes from a "Normal Habits", by building a "normal habits" profile across 2 weeks of monitoring	Bed Permanence Analysis	R17
UC-CHC4	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.	CHC			
~~UC-KGHNI8~~	~~A reduction in the average daily mobility (i.e. staying more hours in the bed) is a strong indicator of clinical status worsening.~~	~~KGHNI~~			
UC-ATC3	A message (SMS/e-Mail/UI Alert) to the operator will be sent if data are out of normal habit	ATC	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF	Bed Permanence Alerts	R07

			MEASURE) across X continuous measurements/over XX days) to send the alert		
~~UC-KGHNI5~~	~~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.~~	~~KGHNI~~	~~The user should be provided with a wireless heart rhythm Monitor with at least 3 electrodes measuring rhythm with a basic EKG as output~~	~~Heart Rhythm monitor~~	~~R33~~
~~UC-KGHNI5~~	~~Recordings can be either continuously or in regular time slots of at least 30 seconds each.~~	~~KGHNI~~	~~Data should be transmitted continuously to the inCASA platform or at least in 30" slots regularly~~	~~Frequency and timing of heart rhythm monitoring~~	~~R21~~
~~UC-KGHNI5~~	~~All ECG data should be registered in the existing telemetry system at the Cardiology Department of the KHGNI~~	~~KGHNI~~	~~Data should be stored on the standard cardiological repository of the KGHNI through integration with the inCASA platform~~	~~Heart Rhythm data storage~~	~~R22~~
~~UC-KGHNI5~~	~~ECG signals are analysed for arrhythmia and sinus rhythm. This is best done in an existing telemetry system.~~	~~KGHNI~~			
~~UC-KGHNI5~~	~~If heart rhythm has not returned to sinus rhythm within a set time, the resident doctor is alerted.~~	~~KGHNI~~	~~The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X~~	~~Heart Rhythm Alert~~	~~R07~~

			~~continuous measurements/over XX days) to send the alert~~		-
~~UC-KGHNI6~~	~~Roche AccuCheck BG devices can be used.~~	~~KGHNI~~	~~The user should be provided with a glucose monitoring device~~	~~Glucose Monitoring Device~~	~~R23~~
~~UC-KGHNI6~~	~~Blood glucose levels are measured in a blood sample using traditional stick methods.~~	~~KGHNI~~	-	-	
~~UC-KGHNI6~~	~~Diabetic patients measure their blood glucose levels 1 or 2 times per day. Non-diabetic patients do it once per week.~~	~~KGHNI~~	~~The system should allow professional users to set the usual timing of measurement (from hh:mm to hh:mm) and the number of measurements per day/week and should accept extemporary measurements provided by the patient~~	~~Frequency and timing of glucose monitoring~~	~~R03~~ ~~R04~~
~~UC-KGHNI6~~	~~all data should be stored in a suitable Electronic Healthcare Record.~~	~~KGHNI~~	~~All data should be stored on the inCASA Repository through a permanent internet connection~~	~~Glucose monitoring data storage~~	~~R06~~
~~UC-KGHNI6~~	~~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.~~	~~KGHNI~~	~~The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent~~	~~Glucose Monitoring Alerts~~	~~R07~~

UC-KGHNI6			variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert		
UC-KGHNI7	Home INR devices exist but are quite expensive. So there are sticks to be used.	KGHNI	The user should be provided with a INR monitoring device or provided with a UI to insert manually measurements done with sticks	INR monitoring device	R24
UC-KGHNI7	INR measurements are performed once per week.	KGHNI	The system should allow professional users to set the usual timing of measurement (from hh:mm to hh:mm) and the number of measurements per day/week and should accept extemporary measurements provided by the patient	Frequency and timing of INR Measurements	R03
UC-KGHNI7	All INR data should be stored in a suitable Electronic Healthcare Record.	KGHNI	All data should be stored on the inCASA Repository through a permanent internet connection	INR measurement data storage	R06
UC-KGHNI7	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.	KGHNI	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X	INR Measurements Alerts	R07

			~~continuous measurements/over XX days) to send the alert~~		
UC-INSERM1	10 Infrared wrist Actigraphs, 10 USB dongles connected between the Bluetooth Actigraph and the inCASA platform for the transmission of the Actigraphy data.	INSERM	The user should be provided with Infrared Actigraphs recording movement at a frequency of one signal per minute	Actigraphy Device	R25
UC-INSERM1	Data will be recorded continuously at the frequency of 1 per minute.	INSERM			
UC-INSERM1	The Actigraph will transmit the recorded data by transmission to the inCASA platform once a day.	INSERM	Data should be transmitted to the inCASA platform at least twice a day. This frequency should be customizable during the project.	Actigraphy Data Transmission	R32
UC-INSERM1	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.	INSERM	The system should allow professional users to set the usual timing of measurement (from hh:mm to hh:mm) and the number of measurements per day	Frequency and timing of Actigraphy	R03

UC-INSERM1	A filter generates an alarm to be sent to INSERM screen if I<O decreases below 97.5%.	INSERM	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert	Actigraphy Alerts	R07
UC-INSERM1	The system confirmed a consistent decrease of I<O below the alarm threshold (0.93) during a 24 hours span;	INSERM			
~~UC-KGHNI9~~	~~The company CareView (Denmark) has a video consulting service that runs over ADSL or 3G lines. Special buffering technology provides Quality of Service management.~~	~~KGHNI~~	~~The user should be provided with AV Conference platform to get in touch with the professional operators~~	~~AV Conference device~~	~~R26~~
~~UC-KGHNI9~~	~~Subjective input is provided via keyboard and video conferencing.~~	~~KGHNI~~			
~~UC-KGHNI9~~	~~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.~~	~~KGHNI~~	~~The system should allow the elderly user or the professional user to start a conference call~~	~~Frequency and timing of AV Connection~~	~~R27~~
~~UC-KGHNI9~~	~~Time and length of the video consultation is stored in a suitable Electronic Healthcare Record.~~	~~KGHNI~~	~~All data should be stored on the inCASA Repository through a permanent internet connection~~	~~AV Conference Data Storing~~	~~R06~~
UC-ATC1	Contact sensor	ATC	The user's house should be provided with wireless contact sensor to detect opening/closing of the front door	The front door sensor	R28

UC-ATC1	revelation of possible different patterns (User opens/closes the door; User goes out/stays in; User open the door, goes out and closes the door; User open the door, goes out without closing the door etc)	ATC	The system should allow professional users to evaluate changes from a "Normal Habits", by building a "normal habits" profile across 2 weeks of monitoring	Front door Analysis	R17
UC-ATC1	If the user forgets to close door, after going out or staying in, an sms message of alert will be sent to neighbour/relative/social worker; if the alert will not be successful, a an operator will be sent to close the door and to do a survey	ATC	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert. The system should allow professional users to customize the system to send a message to user/relatives/caregiver/neighbour if an emergency is detected	Front Door Alert	R07 R11
UC-ATC4	sensors of temperature and humidity	ATC	The user's house should be provided with wireless humidity and temperature sensors to detect temp/moisture variations	Comfort of the home sensors	R29
UC-ATC4	the data coming from the flat will be sent continuously or periodically to the server	ATC	The system should allow professional users to set the usual timing of measurement (from hh:mm to hh:mm) and the number of measurements per day/week	Frequency and timing of temperature and humidity monitoring	R03

UC-ATC4	analysis of the gap between normal levels and revealed temperature and humidity	ATC	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert	Comfort of the home alerts	R07
UC-ATC5	specific sensors	ATC	The user's house should be provided with wireless Gas-Water leak/CO-Smoke Presence sensors to detect emergency events	Technical emergency sensors	R30
UC-ATC5	The service shall provide an automatic set of alerts in case of water or gas leaks, or from accidental fires, to avoid danger for the security of the tenant/user	ATC	The system should provide a continuous monitoring of the technical emergency sensors, forwarding the emergency signal in seconds after the event is detected	Frequency and timing of Technical Emergency monitoring	R31
UC-ATC5	If an emergency event is detected (water or gas leaks, smoke) an immediate alert will be send through the Call centre to the closest team of intervention or fireman service.	ATC	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if an event is revealed. The system should allow professional users to customize the system to send a message to user/relatives/caregiver/neighbour if an emergency is detected	Technical emergency alerts	R07
UC-ATC5	SMS, e-mail to the operator and acoustic/visual alert on the operator UI	ATC			R11
UC-ATC5	A message to the user/relatives/caregivers/neighbour can be sent if there is an alert. This should be set by the operator	ATC			

UC-ATC8	The sensors will record each time a person switch on/switch off the TV. In addition the time and duration of each event will be recorded.	ATC	The sensor will monitor if there is an abnormal use of the TV. Staying more than usual in chair/bed with TV switch on could be a warning of illness or uneasiness that could necessitate an intervention by the social worker.	The TV	R34
UC-CHC6	The system should register when medication is removed from the dispenser and when it is not.	CHC	Dependent on individual patient's health or social requirements a patient may be provided with a medication compliance dispenser. The medication dispenser will provide social and health professionals information about a patients medication intake. A difference in expected medication usage will provide complaince information.	Medical Compliance	R35
UC-KGHNI13	Temperature sensor	KGHNI	The user's house should be provided with wireless humidity and temperature sensors to detect temp/moisture variations	Comfort of the home sensors	R29

UC-KGHNI13	The data coming from the flat will be sent continuously or periodically to the server	KGHNI	The system should allow professional users to set the usual timing of measurement (from hh:mm to hh:mm) and the number of measurements per day/week	Frequency and timing of temperature	R03
UC-KGHNI13	Analysis of the gap between normal levels and revealed temperature	KGHNI	The system should send an alert (On Screen Alert/SMS) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurement, absolute or across time. The system should allow professional users to set rules about the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert	Comfort of the home alerts	R07
UC-KGHNI14	The system should allow clinicians and other involved carers to access the weekly psychological questionnaires scoring results; this is a crucial factor in detecting correlations with health and habits related data.	KGHNI	The system should allow measurement data visualization and extraction organized per day/per week/per month	Self-rating psychological condition questionnaires	R05

7.2 Basic Requirements

The next table shows the list of basic inCASA requirements as modified during the third iteration. This list of requirement provides an update to the basic and common layer of requirements to the inCASA platform which will impact on the architecture within WP3 activities. Changes are marked in red.

Abbreviations	
TH	Telehealth
TC	Telecare
Tech	Technological Requirement[15]
Func	Functional Requirement

Code	Type	Description	TH	TC
R01	Tech	The user should be provided with a Zigbee/Bluetooth Weight Scale measuring in Kg	X	
R02	Func	The system could send a reminder (sms or tablet alert) to the user to take measurement	X	
R03	Func	The system should allow professional users to set the usual timing of measurement/assessment (from hh:mm to hh:mm) and the number of measurements/assessments per day	X	X
R04	Func	The system should accept extemporary measurements provided by the user/patient	X	X
R05	Func	The system should allow measurement data visualization and extraction organized per day/per week/per month	X	X
R06	Tech	All data should be stored on the inCASA Repository through a permanent internet connection	X	X
R07	Func	The system should send an alert (On Screen Alert/SMS/e-mail) to the operator (Nurse/Clinician/Case Manager) if there is a consistent variation on the measurements or on the score of assessment, absolute or across time, or if an emergency event is revealed	X	X
R08	Tech	The user should be provided with a Zigbee/Bluetooth pulse oximeter measuring in %	X	
R09	Func	The system should allow professional users to set rules: the number of measurements to compare; the range of normality and the limit of the variation (rough limit) to send the alert; the limit of the variation (if more than XX UOM (UNIT OF MEASURE) across X continuous measurements/over XX days) to send the alert	X	X
R10	Func	The system could allow professional users to plan for single coded activities (e.g. medication change, appointment)	X	X
R11	Func	The system should be able to send SMS and e-mails. The system should allow professional users to customize the system to send a message to user/relatives/caregiver/neighbour if an event is revealed or an alert is triggered	X	X
R12	Tech	The user should be provided with a Zigbee/Bluetooth blood pressure Monitor measuring in mmHg with pulse metering capabilities	X	

[15] Technological requirements are functionality needed purely because of the chosen technology. If the designer had selected a different technology to handle this part of the work, the result would be different.

R13	Func	The system should allow professional users to set the number of measurements to compare and the formula (e.g. average) to be applied to the selected measurements	X	X
R14	Tech	The user should be provided with a Wireless Tablet connected to the inCASA platform	X	X
R15	Func	The system should allow the professional users to introduce specific questions or questionnaires to be administered to the patient and assign value to each answer and then calculate scores	X	
R16	Func	The user's house should be provided by battery operated wireless sensors to detect movement of the user inside the house, recording time and duration of detected movement events		X
R17	Func	The system should allow professional users to evaluate changes from a "Normal Habits", by building a "normal habits" profile across 2 weeks of monitoring	X	X
~~R18~~	~~Func~~	~~The system should correlate movements to an algorithm made to evaluate NYHA class of everyday activities, by taking into account the movements, the number of people in the home as well as subjective input from the patient.~~	~~X~~	~~X~~
R19	Tech	The user's house should be provided by battery operated Zigbee sensors to detect presence of the user on the bed, recording time and duration of bed permanence events		X
R20	Tech	The user's house should be provided by battery operated Zigbee sensors to detect presence of the user on a chair, recording time and duration of chair permanence events		X
R21	Func	Data should be transmitted continuously to the inCASA platform or at least in 30" slots regularly or some times a day. This frequency should be customizable by the operator.	X	X
~~R22~~	~~Tech~~	~~Data should be stored on the standard cardiological repository of the KGHNI through integration with the inCASA platform~~	~~X~~	
R23	Tech	The user should be provided with a glucose monitoring device	X	
~~R24~~	~~Func~~	~~The user should be provided with a INR monitoring device or provided with a UI to insert manually measurements done with sticks~~	~~X~~	
R25	Func	The user should be provided with Infrared actigraphs recording movement at a frequency of one signal per minute	X	X
R26	Tech	The user should be provided with AV Conference platform to get in touch with the professional operators	X	X
R27	Func	The system should allow the elderly user or the professional user to start a conference call	X	X
R28	Tech	The user's house should be provided with Zigbee contact sensor to detect opening/closing of the front door		X
R29	Tech	The user's house should be provided with Zigbee humidity and temperature sensors to detect temp/moisture variations		X
R30	Tech	The user's house should be provided with specific sensors to detect technical emergency events		X
R31	Func	The system should provide a continuous monitoring of the technical emergency sensors, forwarding the emergency signal in seconds after the event is detected		X
R32	Func	Data should be transmitted to the inCASA platform with a customizable frequency.	X	X
~~R33~~	~~Tech~~	~~The user should be provided with a wireless heart rhythm Monitor with at least 3 electrodes measuring rhythm with a basic EKG as output~~	~~X~~	

R34	Tech	The user's house should be provided by battery operated Zigbee sensors to detect the use of TV, recording time and duration of chair permanence events		X
R35	Tech	The user should be provided with a medication dispenser	X	

The next table shows the MoSCoW scoring related to the basic requirements.[16] Changes made in this 3rd iteration are marked in red writing.

Code	KGHNI	INSERM	CHC	FHC	ATC
R01	5	5	5	1	5
R02	1	1	0	1	5
R03	3	5	0	1	3
R04	1	3	3	1	3
R05	5	5	5	5	3
R06	5	5	5	5	5
R07	5	5	5	3	5
R08	5	0	5	5	5
R09	5	5	5	5	3
R10	3	1	1	3	1
R11	3	3	0	0	5
R12	5	0	5	0	5
R13	3	5	5	1	3
R14	NA	5	0	3	0
R15	NA	5	0	3	0
R16	5	1	5	0	5
R17	5	1	5	0	5
~~R18~~	~~0[1]~~	~~0~~	~~5~~	~~0~~	~~1~~
R19	0	3	5	0	5
R20	5	1	5	0	5
R21	5	5	5	5	5
~~R22~~	~~0[4]~~	~~NA~~	~~0~~	~~0~~	~~0~~
~~R23~~	~~1~~ (5)	~~0~~	~~0~~	~~0~~	~~0~~
~~R24~~	-	-	-	-	-
R25	0	5	0	5	0
R26	1	3	0	0	0
R27	1	1	0	0	1
R28	0	1	0	0	5
R29	3	NA	0	0	5
R30	NA	NA	0	0	3
R31	NA	NA	0	0	0
R32	1	5	5	3	5
~~R33~~	~~0[10]~~	~~0~~	~~0~~	~~0~~	~~0~~
R34	5	0	0	0	5
R35	0	0	4	0	0

[16] MoSCoW is a method to prioritise requirements popularised by the DSDM community. Please refer to *D2.4 Requirements Consolidation and Prioritisation Iteration 2_v2.5* further information on this method.

7.3 Specific Requirements Consolidation and Prioritisation

This section reports the specific Telecare, Telehealth and Merged Telecare/Telehealth requirements consolidation and prioritisation. Each pilot site has evaluated the requirements and defined each as either relevant (R) or not relevant (NR). Changes made during this 3rd iteration are marked in red.

Abbreviations	
FR-TC	Functional Requirement – Telecare
FR-TH	Functional Requirement – Telehealth
FR-MG	Functional Requirement – Merged Telecare/Telehealth
R	Relevant
NR	Not relevant

7.3.1 Telecare Specific Functional Requirements

Changes made in this 3rd iteration are marked in red.

Requirement		Relevant (R)/Not Relevant (NR)				
Code	Description	ATC	CHC	KGHNI	INSERM	FHC
FR-TC01	The System should register the opening/closing of the front door including the time stamp of the variation event and calculate DeltaT of the opening/closing or closing/opening event.	R	NR	NR	NR	NR
FR-TC02	The system should register if a certain person is passing through a door from inside to outside or from outside to inside.	R	NR	NR	NR	NR
FR-TC03	The System should check the identity of the person passing through a door (user/not user).	R	NR	NR	NR	NR
FR-TC04	The system should start a buzzer if a monitored door stays open for too long (the interval should be configurable from 1 to 60 minutes) without persons passing through. The system should store an alert to the EPR Repository if a monitored door stays open for too long (the interval should be configurable from 1 to 60 minutes).	R	NR	NR	NR	NR
FR-TC05	The System should allow the check of the status of a door (open/closed)	R	NR	NR	NR	NR
FR-TC06	Every sensor check should be available at the least with a query in the EPR Repository	R	NR	R	R	R
FR-TC07	The System should register every passage of a single person from one to another room including the time stamp of the variation event.	R	NR	R	NR	NR
FR-TC08	The System should register the bed sensors status at every variation, including the time stamp of the variation event.	R	R	NR	R	NR
FR-TC09	The System should allow the check of the bed permanence on-demand.	R	NR	NR	NR	NR

FR-TC10	The System should register the presence of gas/smoke/CO on the air or water on the floor, including the time stamp of the event.	NR	NR	NR	NR	NR
FR-TC11	The System should allow the check of the sensor status on demand (power/battery status/functionality test).	R	R	R	R	R
FR-TC12	The System should register the measurements of indoor temperature and humidity including the time stamp of the event of measurement.	R	NR	R	NR	NR
FR-TC13	The System should allow professional users to set range of normality of temperature and humidity (min-max)	R	NR	R	NR	NR
FR-TC14	The System should register any single action coming from the User's house for a week (the time frame should be configurable), including the time stamp of the events.	R	NR	R	NR	NR
FR-TC15	The System should organize data per time/per day/per week	R	R	R	R	R
FR-TC16	The System should create a profile of actions and pathways defined as "Normal Habits Model", by measuring and profiling the next actions/pathways:	R	R	R	NR	NR
FR-TC16a	Going to bed/Wake up: time stamp for going to bed and getting up from bed with DeltaT between the time stamps.	NR	NR	NR	NR	NR
FR-TC16b	Going out from home: time stamp for going out of home/coming back to home with DeltaT between time stamps	NR	NR	NR	NR	NR
FR-TC16c	Moving inside home: number of movements inside the house and time stamp/location of each movement detected by sensors	R	R	R	NR	NR
FR-TC17	The System should check the variations of the Normal Habits Model for 2 weeks after the first profiling to allow a first iterative "tuning" of the model.	R	R	R	NR	NR
FR-TC18	The system should allow the manual management of the Model by changing the range of "Normal Habits Model" of user habits.	R	R	R	NR	NR
FR-TC19	The System should describe alerts with: identification – name – description – priority – severity.	R	R	R	R	NR
FR-TC20	The System should consider as priority: non urgent – mild urgent – urgent – very urgent – emergency.	R	NR	R	R	NR
FR-TC21	The System should show a list of the users and related alert ordered per priority/per severity/per time.	R	R	R	R	NR
FR-TC22	The System should enable a method on the GUI to mark the alert as "forwarded to (select role)" or "solved".	NR	NR	R	R	NR

FR-TC23	The System should permit the opening of an user dedicated page on which single alert is described.	R	R	R	R	NR
FR-TC24	The System should allow the operator to send specific SMS to predetermined numbers (e.g. relative, caregiver, neighbour, social worker, clinician, etc.), by introducing also contact info and roles as a system parameter	R	NR	R	R	NR
FR-TC25	The System should register the event and generate an alert characterized by priority=1 – Emergency.	R	NR	R	R	NR
FR-TC26	The System should trigger a visual highlighted alarm on the User Interface.	R	R	R	R	NR
FR-TC27	The System should trigger an emergency acoustic alarm on the Operator's workplace.	R	NR	R	R	NR
FR-TC28	The System should integrate a method to "silence" the alert without hiding it.	R	NR	R	R	NR
FR-TC29	The System should send a SMS to Case Manager/relative/neighbour/caregiver indicating the source of alert and timestamp of trigger (e.g.: "inCASA Alert – CO DETECTED at 21:30 25/04/2011 - Mario Rossi – Corso Vittorio Emanuele II n. 31 – Torino – phone no. +39 011 6602521").	R	NR	R	R	NR
FR-TC30	The System should register the presence of a person (if possible wearing a personal id device) in the room at every variation including the time stamp of the variation event.	NR	NR	R	NR	NR
FR-TC31	The System should allow the check of the room permanence for every room.	NR	NR	R	NR	NR
FR-TC32	The System should register the chair sensor status at every variation, including the time stamp of the variation event	R	R	R	NR	NR
FR-TC33	The System should allow the check of the chair permanence on-demand.	NR	NR	R	NR	NR
FR-TC34	The System should register the opening and closing of the fridge door, including the time stamp of the variation event and should calculate DeltaT of the On/Off or Off/On event.	NR	NR	NR	NR	NR
FR-TC35	The System should allow the check of the open/close status on-demand.	NR	NR	NR	NR	NR
FR-TC36	The System should allow the check of the on/off status on-demand.	R	NR	R	NR	NR
FR-TC37	The system should register the presence of the user on the same room where the device is, including the time stamp of the variation event (near/not near).	R	NR	R	NR	NR

FR-TC38	The system should register when medication is removed from the dispenser and when it is not.	NR	R	NR	NR	NR
FR-TC39	The system should allow registering of the scoring of standardised depression-monitoring questionnaires and should be able to graphically represent their trend. For KGHNI, the questionnaires will be conducted via phone-conferences	NR	NR	R	NR	NR

The next table shows the MoSCoW scoring related to the functional Telecare requirements. Changes made in this 3rd iteration are marked in red.

Requirement	**MoSCoW (NA=Not Applicable)**				
Code	**ATC**	**CHC**	**KGHNI**	**INSERM**	**FHC**
FR-TC01	5	NA	NA	NA	NA
FR-TC02	5	NA	NA	NA	NA
FR-TC03	3	NA	NA	NA	NA
FR-TC04	5	NA	NA	NA	NA
FR-TC05	5	NA	NA	NA	NA
FR-TC06	5	NA	5	5	5
FR-TC07	3	NA	1	NA	NA
FR-TC08	5	5	NA	3	NA
FR-TC09	5	NA	NA	NA	NA
FR-TC10	5	NA	NA	NA	NA
FR-TC11	3	3	5	3	3
FR-TC12	5	NA	3	NA	NA
FR-TC13	3	NA	3	NA	NA
FR-TC14	3	NA	5	NA	NA
FR-TC15	3	5	5	5	5
FR-TC16	3	5	3	NA	NA

FR-TC16a	1	NA	NA	NA	NA
FR-TC16b	1	NA	NA	NA	NA
FR-TC16c	3	5	3	NA	NA
FR-TC17	3	5	5	NA	NA
FR-TC18	3	5	3	NA	NA
FR-TC19	5	5	5	5	NA
FR-TC20	3	NA	3	3	NA
FR-TC21	3	5	3	3	NA
FR-TC22	0	NA	5	5	NA
FR-TC23	3	5	5	5	NA
FR-TC24	5	NA	3	3	NA
FR-TC25	5	NA	5	5	NA
FR-TC26	5	5	5	5	NA
FR-TC27	3	NA	5	5	NA
FR-TC28	3	NA	5	5	NA
FR-TC29	5	NA	5	3	NA
FR-TC30	0	NA	3	NA	NA
FR-TC31	1	NA	3	NA	NA
FR-TC32	5	3	5	NA	NA
FR-TC33	1	NA	5	NA	NA
FR-TC34	1	NA	NA	NA	NA
FR-TC35	1	NA	NA	NA	NA
FR-TC36	3	NA	5	NA	NA
FR-TC37	3	NA	5	NA	NA

FR-TC38	NA	3	NA	NA	NA
FR-TC39	NA	NA	5	NA	NA

7.3.2 Telehealth Specific Functional Requirements

Changes made in this 3rd iteration are marked in red.

Requirement		Relevant (R)/Not Relevant (NR)				
Code	**Description**	**ATC**	**CHC**	**KGHNI**	**INSERM**	**FHC**
FR-TH01	The System should allow the scheduling of measurements by professional users and forward automatic reminders (sms or tablet alert) to the patient.	NR	NR	R	R	NR
FR-TH01a	The System should allow professional users to set the usual timing of measurements (from hh:mm to hh:mm), conducted by the patient.	NR	NR	R	R	R
FR-TH01b	The System should allow professional users to set the number of measurements per day (frequency), when the measurement device is wearable and the measurements are automatic.	NR	NR	NR	R	R
FR-TH02	The System should enable professional users to ask the patients to repeat a measurement in a day or allow them to send a second reading at another point during the day. The System should accept these extemporary measurements.	R	R	R	NR	R
FR-TH03	The System should assist the patients through the measurement process by providing visual or audio cues.	NR	R	R	R	R
FR-TH04	The System should provide a customizable client GUI to enable the manual input of measurement values when the device used is not wireless or the wireless link fails.	NR	NR	R	R	R
FR-TH05	The System should validate a set of measurements in accordance to predefined rules. The System should allow the customization of the appropriate filtering procedure for each type of measurement.	R	R	R	R	NR
FR-TH05a	The System should allow the patient to perform up to 3 blood pressure measurements each day and average them. In select cases, the System should allow the exclusion of the first	NR	NR	R	NR	NR

	measurement before averaging.					
FR-TH05b	The System should allow the preconditioning of the pulse oximetry measurements.	NR	NR	R	NR	R
FR-TH06	The System should allow the local storage of measurements, to facilitate their review by the patients and to allow their transmission at a later time.	NR	NR	R	R	R
FR-TH06a	The System should locally store Actigraphy data continuously recorded at a frequency of 1 per minute and the automatic transmission to the platform twice a day (early morning and late afternoon).	NR	NR	NR	R	R
FR-TH07	The System should store measurements in a centralized repository along with any contextual information necessary to enable further data processing, alerting and reporting.	R	R	R	R	R
FR-TH08	Every clinical measurement should be available at the least with a query in the EPR repository.	NR	NR	R	R	R
FR-TH09	The System should store measurements in the EPR repository as soon as they are transmitted, to enable the timely derivation of trends over historical data and the near real-time evaluation of the rules that fire the clinical alerts when deviating from normalcy.	NR	NR	R	R	R
FR-TH010	The System should update the snapshots view in accordance to type/date/time of measurement.	R	R	R	R	NR
FR-TH11	The System should automatically execute an appropriately defined query to select past measurements used in the evaluation of the pertinent trends.	R	R	R	R	NR
FR-TH11a	The System should allow professional users to define the time/sampling window or other filtering criteria used to select historical measurements.	R	R	R	R	NR
FR-TH11b	The System should allow the retrieval of the daily body weight measurements to enable the computation of their average.	R	NR	R	R	NR
FR-TH11c	The System should allow the retrieval of the past two days weight measurements' daily average values, to allow the detection of sharp increases/decreases.	NR	R	R	R	NR

FR-TH11b	The System should allow the retrieval of a predefined number of pulse oximetry values to assess increasing or decreasing trends over a given period of time.	NR	R	R	NR	R
FR-TH11c	The System should allow the retrieval of the rest-activity rhythm data to compute the daily I<O index.	NR	NR	NR	R	R
FR-TH12	The System should apply the appropriate processing algorithm over the query results to update the trends view.	R	R	R	R	NR
FR-TH12a	The System should allow professional users to alter the formulation for determining trends over selected/filtered measurements.	R	R	R	R	NR
FR-TH12b	The System should enable the computation of the daily body weight average.	R	R	R	R	NR
FR-TH12c	The System should enable the computation of differences between daily average body weight values according to the formula d(0)-d(-1) and d(-1)<d(-2), where d(0) is the current and d(-1) is the previous day.	NR	NR	R	R	NR
FR-TH12d	The System should enable the computation of differences of body weight values from a target value according to the formula d-aim, where d is the current day and aim is the target value.	NR	NR	R	R	NR
FR-TH12e	The System should enable the computation of difference values between a predefined number of consecutive body weight measurements.	NR	NR	R	R	NR
FR-TH12f	The System should enable the computation of differences between consecutive pulse oximeter values to determine their trend over the predefined timeframe.	R	R	R	NR	R
FR-TH12g	The System should enable the computation of the I<O index based on daily rest-activity rhythm data.	NR	NR	NR	R	R
FR-TH12h	The System should update the trend of the I<O index over the initial 3 weeks monitoring period.	NR	NR	NR	R	R
FR-TH13	The System should invoke the SPP rules engine to determine automatically whether the pertinent alerts should be fired, as soon as the snapshot and trends view are updated. The rules determine if the measurement value or trend is within prescribed/personalized range or deviates significantly from	NR	NR	R	R	R

	expected values					
FR-TH13a	The pre-set, personalized or automatically derived (after the calibration period) thresholds and normalcy ranges for the respective measurement are retrieved from the platform.	NR	NR	R	R	NR
FR-TH13b	The System should evaluate whether a patient's daily average body weight is consistently increasing (i.e. increase > 1 kilo/day for two consecutive days).	NR	NR	R	R	NR
FR-TH13c	The System should evaluate whether a patient's body weight is consistently decreasing over consecutive measurements.	NR	NR	R	R	NR
FR-TH13d	The System should evaluate whether a patient's body weight is diverging from the expected value.	R	R	R	R	NR
FR-TH13e	The System should evaluate whether a patient's blood pressure is diverging from the expected value.	R	R	R	R	NR
FR-TH13f	The System should evaluate whether a patient's blood pressure is within normalcy limits (systolic/diastolic < 140/85 mmHG).	NR	NR	R	R	NR
FR-TH13g	The System should evaluate whether the patient's average daily diastolic blood pressure is within normalcy range (80 mmHG < diastolic < 170 mmHG).	NR	NR	R	R	NR
FR-TH13h	The System should evaluate whether the patient's pulse oximetry is within normalcy limits (oximetry < 90%)	R	R	R	NR	R
FR-TH13i	The System should evaluate whether the patient's pulse oximetry is rapidly deteriorating	NR	NR	R	NR	R
FR-TH13j	The System should evaluate whether a patient's pulse oximetry is diverging from the expected value.	R	R	R	NR	R
FR-TH13k	The System should evaluate whether the patient's heart rate is within normalcy range (50 bpm < rate < 100 bpm).	NR	NR	R	R	R
FR-TH13l	The System should evaluate whether the patient's blood glucose is within normalcy limits (<200 mg/dl diabetic, <120 mg/dl non-diabetic patients).	NR	NR	R	NR	NR

FR-TH13m	The System should evaluate whether there is a consistent decrease of patient's I<0 (computed over a period of 24 hours) below the normalcy limits (<0.93 or other value determined during the monitoring period).	NR	NR	NR	R	R
FR-TH14	The System should automatically classify generated alarms depending on their criticality.	NR	NR	R	R	R
FR-TH14a	The System should communicate all alarms, as soon as they are generated, to the Consumer Application to notify the platform operators.	R	R	R	R	NR
FR-TH14b	The System should relay alarms with higher criticality via SMS to doctor and/or the patient's relatives/neighbours, in accordance to the prescribed clinical/intervention protocol.	NR	NR	R	R	NR
FR-TH15	The System should automatically send reminders to notify the elderly patients or people close to them that they missed a scheduled measurement or they didn't timely take their prescribed medicines.	NR	NR	R	R	R
FR-TH15a	The System should automatically detect that the patient did not take a scheduled measurement or did not receive his/her medication in time.	NR	R	R	R	R
FR-TH15b	The System should enrich reminders messages (indicating pending action) and recipient list (i.e. caregivers in addition to the patient) using contextual information.	NR	NR	R	R	NR
FR-TH15c	The System should be able to retrieve the required contextual information with a simple query to the EPR.	NR	NR	R	R	NR
FR-TH15d	The System should automatically register the reminder with the system scheduler and forward it to the messaging module of the platform.	NR	NR	R	R	NR
FR-TH15e	The System should prepare the reminder message in the most appropriate form (i.e. SMS, message in SARA client) in accordance to their devices of choice for interfacing with the platform.	NR	NR	R	R	R
FR-TH16	The System should provide a specialized UI for allowing doctors to ask patients to take extemporary	NR	NR	R	R	NR

	measurements.					
FR-TH16a	The System should integrate the pertinent view in the Consumer Applications.	NR	NR	R	R	NR
FR-TH16b	The System should provide a visualization of the current measurements schedule for the particular patient.	NR	R	R	R	R
FR-TH16c	The System should allow the doctor to select an available time slot within the same day to schedule the extemporary measurement.	NR	NR	R	R	NR
FR-TH17	The System should enable doctors to schedule appointments with patients or order changes in the doses/frequency of prescribed medicines (single-coded activities).	NR	NR	R	R	NR
FR-TH17a	The System should provide this functionality through an integrated view in the Consumer Applications web UI.	NR	NR	R	R	NR
FR-TH17b	The System should be able to retrieve the required contextual information to enrich this view via simple queries to the EPR and the Consumer Applications local database.	NR	NR	R	R	NR
FR-TH17c	If the doctor elects to schedule a new appointment, the System should show a subsequent screen where the doctor's scheduled appointments are displayed. Then the System should allow the doctor to select an available timeslot and schedule the new appointment; optionally the System should allow the doctor to specify a reason (i.e. indicating that a specific examination is in order).	NR	NR	R	R	NR
FR-TH17d	If the doctor elects to change the frequency/doses of a prescribed medication, the System should allow him/her to write a short message that describes the required change and update the contextual treatment information accordingly.	NR	NR	R	R	NR
FR-TH17e	After the submission of the single-coded activity, the System should automatically compile a notice for the appointment or the medication change that is forwarded to the messaging module of the platform	NR	NR	R	R	NR
FR-TH17g	The System should automatically decide on the most appropriate form of communicating the notice to the specified patient and include any other	NR	NR	R	R	NR

	additional recipients (i.e. caregivers, relatives).					
FR-TH17h	The System should forward the corresponding notice to the patient's device of choice (i.e. PC, cell phone), and optionally send a SMS message to additional recipients.	NR	NR	R	R	NR
FR-TH18	The system should allow professional users to quickly visualize the changes in symptoms and symptoms clusters through a graphical presentation	NR	NR	NR	R	R
FR-TH19	The system should compute and display for professional users the scores of symptoms severity and symptoms interference with life	NR	NR	NR	R	R
FR-TH20	The system should display for professional users the percentage change of weight on a scale ranging from -20% to +20%	NR	NR	R	R	NR
FR-TH21	The system should generate an alert when the weight has increased or decreased by 5% or more	NR	NR	NR	R	NR
FR-TH22	The system should generate an alert when the symptoms scores are out of range	NR	NR	NR	R	R
FR-TH23	The system should generate an alert when the I<O index is out of range	NR	NR	NR	R	R
FR-TH24	The system should allow professional users to quickly visualize the I<O index	NR	NR	NR	R	R
FR-TH25	The system should allow an easy download of the data recorded by the Actigraph	NR	NR	NR	R	R

The next table shows the MoSCoW scoring related to the functional Telehealth requirements. Changes made in this 3rd iteration are marked in red.

Requirement	**MoSCoW (NA=Not Applicable)**				
Code	**ATC**	**CHC**	**KGHNI**	**INSERM**	**FHC**
FR-TH01	NA	NA	5	5	5
FR-TH01a	NA	NA	5	5	5
FR-TH01b	NA	NA	NA	3	3

FR-TH02	5	5	5	NA	NA
FR-TH03	NA	5	3	3	3
FR-TH04	NA	NA	5	5	5
FR-TH05	5	5	3	3	3
FR-TH05a	NA	NA	5	NA	NA
FR-TH05b	NA	NA	5	NA	NA
FR-TH06	NA	NA	3	3	3
FR-TH06a	NA	NA	NA	5	5
FR-TH07	5	5	5	5	5
FR-TH08	NA	NA	5	5	5
FR-TH09	NA	NA	5	5	5
FR-TH010	5	5	5	3	3
FR-TH11	5	5	5	5	5
FR-TH11a	5	5	3	3	3
FR-TH11b	5	NA	5	5	5
FR-TH11c	NA	5	5	5	5
FR-TH11b	NA	3	5	NA	NA
FR-TH11c	NA	NA	NA	5	5
FR-TH12	5	4	5	5	5
FR-TH12a	5	4	3	3	3
FR-TH12b	5	4	5	5	5
FR-TH12c	NA	NA	5	3	3
FR-TH12d	NA	NA	1	3	3
FR-TH12e	NA	NA	3	3	3

FR-TH12f	5	4	3	NA	NA
FR-TH12g	NA	NA	NA	5	5
FR-TH12h	NA	NA	NA	5	5
FR-TH13	NA	NA	5	3	3
FR-TH13a	NA	NA	5	3	3
FR-TH13b	NA	NA	5	5	5
FR-TH13c	NA	NA	3	5	5
FR-TH13d	5	5	1	3	3
FR-TH13e	5	5	1	1	1
FR-TH13f	NA	NA	3	1	1
FR-TH13g	NA	NA	5	5	5
FR-TH13h	5	5	5	NA	NA
FR-TH13i	NA	NA	3	NA	NA
FR-TH13j	5	5	1	NA	NA
FR-TH13k	NA	NA	5	5	5
FR-TH13l	NA	NA	NA	NA	NA
FR-TH13m	NA	NA	NA	5	5
FR-TH14	NA	NA	3	3	3
FR-TH14a	5	5	5	5	5
FR-TH14b	NA	NA	3	3	3
FR-TH15	NA	NA	5	3	3
FR-TH15a	NA	5	5	5	5
FR-TH15b	NA	NA	5	3	3
FR-TH15c	NA	NA	5	5	5

FR-TH15d	NA	NA	5	5	5
FR-TH15e	NA	NA	3	5	5
FR-TH16	NA	NA	3	3	3
FR-TH16a	NA	NA	3	5	5
FR-TH16b	NA	5	3	5	5
FR-TH16c	NA	NA	3	3	3
FR-TH17	NA	NA	5	1	1
FR-TH17a	NA	NA	5	5	5
FR-TH17b	NA	NA	5	5	5
FR-TH17c	NA	NA	3	3	3
FR-TH17d	NA	NA	5	3	3
FR-TH17e	NA	NA	5	5	5
FR-TH17g	NA	NA	3	3	3
FR-TH17h	NA	NA	5	3	3
FR-TH18	NA	NA	NA	5	5
FR-TH19	NA	NA	NA	5	5
FR-TH20	NA	NA	1	5	NA
FR-TH21	NA	NA	NA	5	NA
FR-TH22	NA	NA	NA	5	5
FR-TH23	NA	NA	NA	5	5
FR-TH24	NA	NA	NA	5	5
FR-TH25	NA	NA	NA	5	5

7.4 Merged Telehealth and Telecare Specific Functional Requirements

Changes made in this 3rd iteration are marked in red.

Requirement		Relevant (R)/Not Relevant (NR)				
Code	**Description**	ATC	CHC	KGHNI	INSERM	FHC
FR-MG01	Should enable remote update of gateway and devices	R	R	R	R	R
FR-MG02	Gateway should Indicate when transmitting data	R	R	NR	R	NR
FR-MG03	Gateway should indicate when connected to mobile network	R	R	NR	R	NR
FR-MG04	Should be able to check mobile of Gateway Remotely	R	R	NR	R	NR
FR-MG05	Battery Life in devices should last for at least one month	R	R	R	R	R
FR-MG06	Motion Sensor timing should be changeable	R	R	R	NR	NR
FR-MG07	Should be able to mark patients active or not active on the clinical Portal	R	R	R	R	NR
FR-MG08	Data should be viewable of the patient portal within 5 minutes of transmission	R	R	R	R	NR
FR-MG09	Ability to export monitoring data into an excel file from the clinical portal	R	R	R	R	R
FR-MG10	Ability to export patient notes into a word document from the clinical portal	NR	R	R	NR	NR
FR-MG11	Add and edit patient details to the clinical user interface	R	R	R	R	R
FR-MG12	Ability to assign different devices to a patient on the clinical portal	R	R	NR	R	R
FR-MG13	Ability to assign a gateway to a patient on the clinical portal	NR	R	NR	R	NR
FR-MG14	Able to access clinical portal via internet URL	R	R	R	R	R
FR-MG15	Able to view prioritised and combined Telehealth and Telecare on clinical portal summary page	R	R	R	R	NR
FR-MG16	Ability to view Telehealth and Telecare data in individual patient summary page	R	R	R	R	R
FR-MG17	Ability to use algorithms to compare trend clinical measurements with habits monitoring	NR	R	NR	NR	NR
FR-MG19	Devices should provide feedback that data has been successfully transmitted	R	R	R	R	R
FR-MG20	Devices should indicate when they have paired with the gateway	R	R	R	R	R
FR-MG26	Clinical Portal should display all data on Today reading screen	R	R	R	R	NR

FR-MG28	Clinical portal should present a tabbed view separating Telehealth from Telecare data	R	R	R	R	R
FR-MG29	Clinical portal should present a unified view of both Telehealth and Telecare alerts, listed according to their time of occurrence or severity	R	R	R	R	R
FR-MG30	Clinical portal should enable the extraction of measurements (both TH/TC) to Comma Separated Values (CSV) and Excel (XLS) files	R	R	R	R	R
FR-MG31	Clinical portal should enable the building of configurable graph plots that combine data made available over both the TH/TC domains	R	R	R	R	R
FR-MG32	Clinical portal should summarize data from Telecare binary sensors (i.e. on/off) as time slices (event occurrence or not) over a configurable time period (i.e. daily, weekly etc.)	R	R	R	NR	R
FR-MG33	Clinical portal should provide a summary view of the habits model build for each individual patient over the "training" period	R	R	R	NR	R
FR-MG34	Clinical portal should enable the superimposition of alert events on both TH/TC graph pages	R	R	R	R	R
FR-MG35	Clinical portal should enable the summarization of Telecare events clearly indicating, preferably by the use of a composite score, that there was a significant overall deviation from the normal habits of a patient.	R	R	R	NR	R
FR-MG36	The patient portal should be accessed via a secure user name and password	NR	R	NR	NR	NR
FR-MG37	The patient portal should enable secure access to the patient portal via a URL and be accessed via any internet connected device	NR	R	NR	NR	NR
FR-MG38	The patient portal should display the patient trend tabular and graphical data	NR	R	NR	NR	NR
FR-MG39	The patient portal should enable a patient to answer activity and diet questionnaires	NR	R	NR	NR	NR

The next table shows the MoSCoW scoring related to the functional Merged Telehealth and Telecare requirements. Changes made in this 3rd iteration are marked in red.

Requirement	**MoSCoW (NA=Not Applicable)**				
Code	**ATC**	**CHC**	**KGHNI**	**INSERM**	**FHC**

FR-MG01	3	3	5	5	3
FR-MG02	3	3	1	3	0
FR-MG03	3	3	0	3	0
FR-MG04	3	3	0	3	0
FR-MG05	5	5	3	5	3
FR-MG06	3	3	3	NA	0
FR-MG07	5	3	3	5	0
FR-MG08	5	5	5	5	0
FR-MG09	5	5	5	5	5
FR-MG10	0	3	5	NA	0
FR-MG11	5	5	5	5	5
FR-MG12	5	5	0	5	5
FR-MG13	0		0	5	0
FR-MG14	5	5	5	5	3
FR-MG15	5	5	5	5	0
FR-MG16	5	3	5	5	5
FR-MG17	0	3	1	NA	0
FR-MG19	5	5	3	3	3
FR-MG20	3	5	3	1	3
FR-MG26	5	5	3	5	0
FR-MG28	5	5	5	3	3
FR-MG29	5	5	5	5	3
FR-MG30	5	5	5	5	3
FR-MG31	5	5	5	5	3

FR-MG32	5	5	5	0	3
FR-MG33	5	5	5	0	3
FR-MG34	5	5	5	3	3
FR-MG35	5	5	3	0	3
FR-MG36	0	3	0	0	0
FR-MG37	0	3	0	0	0
FR-MG38	0	3	0	0	0
FR-MG39	0	3	0	0	0

7.5 Non-Functional Requirements

Non-functional requirements are properties the functionality must have.[17] They specify criteria that can be used to judge the operation of the system rather than specific behaviours. Some of them can be linked directly to a functional requirement, some apply to the use cases, and some apply to the entire platform.

- Look and Feel:
  The essence of the product's appearance

- Usability and Humanity:
  The platform's ease of use and any special usability considerations needed for a better user experience

- Performance:
  How fast, how safe, how many, how available, and how accurate the functionality must be

- Operational:
  The operating environment of the solution, and any considerations that must be taken into account for this environment

- Maintainability and Support:
  Expected changes, and the time needed to make them; also specification of the support to be given to the platform

- Security:
  The security, confidentiality, and recoverability of the platform

- Cultural and Political:
  Special requirements that come about because of the culture and customs of people involved in the platform's operation.

[17] "Mastering the Requirements Process Second Edition", Suzanne Robertson, James Robertson, 2006. Addison-Wesley.

Abbreviations	
NFR	Non Functional Requirement
LF	Look and Feel
UH	Usability and Human
P	Performance
O	Operational
MS	Maintainability and Support
S	Security
CP	Cultural and Political

Changes made in this 3rd iteration are marked in red. Only CHC has made any changes since the 2nd iteration.

Requirement			MoSCoW (NA=Not Applicable)				
NFR	**Code**	**Description**	**KGHNI**	**INSERM**	**CHC**	**FHC**	**ATC**
Look and Feel Requirements	**NFR-LF1**	The main interface of the inCASA platform for the Operators will be Web Based and should give the user different options to move through the system, using navigation methods such as menus and buttons;	5	5	5	5	5
	NFR-LF2	The system should display and manage both the clinical monitoring data and habits monitoring data within the same application;	5	5	5	5	3
	NFR-LF3	One main button should allow the user to return to the main menu or home page from anywhere inside the application;	5	5	5	5	5
	NFR-LF4	The web site should be structured in a hierarchical manner containing various sub-interfaces;	5	5	5	5	5
	NFR-LF5	The sub-interface should have buttons which will link to different sub-interfaces depending on the privileges of the user;	5	5	5	5	5
	NFR-LF6	On each screen a home button should take the user back to the main interface screen;	5	5	5	5	5
	NFR-LF7	The Interface may include a small logo of inCASA	5	1	5	1	3

		project;					
	NFR-LF8	The colour to be used in the background should not induce stress to the user;	5	5	5	5	5
	NFR-LF9	the text should be black, no bright colours such red or orange would be used for background colours, however can be used to highlight text i.e. for Alerts.	5	5	5	5	5
Usability and Humanity Requirements	**NFR-UH1**	The inCASA platform will be very simple and easy to use;	5	5	5	5	5
	NFR-UH2	The overall system Interface would be easily used by people with basic computer systems training and with little understanding of English;	5	5	5	5	5
	NFR-UH3	The system should be designed in a way that makes it easy for user to remember the steps they should follow;	5	5	5	5	5
	NFR-UH4	Ideally, the system should be free of errors, but in case that the users do something wrong the errors messages should be indicated in plain English, in that way, it will be easier for users to understand what they are doing wrong when using the system;	5	5	5	5	5
	NFR-UH5	Where a patient/elderly user interface is involved, the system should be localised on the language of the users;	5	5	5	5	0
	NFR-UH6	Where a patient/elderly user interface is involved, the system should provide an interface that is large enough for an elderly person to view the screen clearly: Large display; Font size; Icons; Easily readable;	5	5	5	5	0
	NFR-UH7	Where a patient/elderly user interaction is needed, the system should provide clear instructions to the user/patient;	5	5	5	5	0
	NFR-UH8	Where a patient/elderly user interaction is needed, the system should be able to display simple list of questions for the chosen disease categories/social challenges;	5	5	5	5	0
	NFR-UH9	Where a patient/elderly user interaction is needed for taking measurements, the system should be able to display health monitoring feedback to the user/patient;	5	5	5	5	
	NFR-UH10	Where a patient/elderly user interaction is needed for	5	5	5	5	0

		taking measurements, the system should be able to provide a means for manual input of measurement data/responses to questions;					
	NFR-UH11	The system should be able to provide audible feedback for people with visual impairments.	3	3	5	5	3
Performance Requirements	**NFR-P1**	Interfaces will count on an advanced remote system that will allow a maximum response time of 10 seconds for the most complicated actions (Formulae application or data extraction).	5	5	3	5	5
	NFR-P2	The system will be very safe, International certification of EC is present on each of the off-shelf devices, and thus no risks are foreseen for the users, their homes or to the environment;	3	5	3	5	3
	NFR-P3	If prototypes are involved, a specific declaration of safety and conformity will be released by the partner who provides the prototype, declaring that no risks are foreseen risks for the users, their homes or the environment	3	5	5	5	3
	NFR-P4	The aim of the inCASA platform is to deliver a very reliable product with minimal degree of failures, therefore minimal maintenance is required;	5	5	5	5	5
	NFR-P5	The system will be available for use 24 hours per day, 365 days per year;	5	5	5	5	5
	NFR-P6	The operators will be available in accordance with local agreements.	5	5	5	5	5
	NFR-P7	Each device communicates wireless with the home gateway;	3	5	5	5	3
	NFR-P8	The devices should transmit data via the internet or mobile communications;	5	5	5	5	5
	NFR-P9	If interrupted during transmission, the home gateway will store the data until it is able to re-send data;	5	5	5	5	5
	NFR-P10	The system should operate on both main power and battery power;	3	3	5	5	3
	NFR-P11	In the event of a power outage the system should automatically reset without the need for user intervention.	3	3	5	5	3

	NFR-P12	The system should allow a maximum of 30 houses connected at the same time per pilot site (for the pilot duration). It will be designed to be able to connect simultaneously at least 500 users' houses at any time of the day.	5	3	5	1	3
	NFR-P13	In the event of a power outage the system should automatically reset without the need for user intervention.	3	3	5	3	3
	NFR-P14	Due to the nature of the system, the capacity of processing information is indefinite;	1	1	5	1	1
	NFR-P15	The system should be designed to ensure scalability and access to incoming new technologies like Cloud Computing;	5	3	5	5	3
Operational Requirements	**NFR-O1**	This system with its actual configuration must be installed indoor (sensors/devices);	5	5	5	5	5
	NFR-O2	The devices shall survive being dropped;	3	3	3	5	3
	NFR-O3	The devices shall conserve battery life;	3	3	5	5	3
	NFR-O4	The system will initially run on desktops or laptops with a minimum 512 of RAM and 40 GB and 400 MHz processor, with a Web Browser installed;	3	3	3	5	3
	NFR-O5	In the future the inCASA platform should be accessed through smart phones, palmtops, Tablets, etc., therefore increasing technological support should be taken into consideration during the design activities.	3	3	3	5	3
Mantainability and Support Requirements	**NFR-MS1**	The maintenance of the system should be ensured by a local network of technicians and the local availability of solution's parts;	5	5	5	5	5
	NFR-MS2	Devices should be assigned to the user by device serial number;	3	1	5	5	3
	NFR-MS3	For each device the location e.g. which room the sensors are placed, should be entered;	3	0	3	0	3
	NFR-MS4	A complete list of monitoring equipment should be available electronically, which can be sorted by: Device Type; Serial Number; Assigned; Unassigned; Faulty.	3	3	5	3	3
	NFR-MS5	The level of support this system will require should be very low;	5	5	5	5	5

	NFR-MS6	An help desk should be made available to provide the necessary support;	1	1	5	3	0
	NFR-MS7	The system should have some help tabs in the main User Interface.	3	3	3	3	3
	NFR-MS8	According to the fact that the system is web based with its target browser being MS Internet Explorer, it would be expected to run across various web browsers like Firefox or Safari.	5	5	3	1	5
Security Requirements	**NFR-S1**	The system shall ensure that only authorized users have access to the patient/user data;	5	5	5	5	5
	NFR-S2	All the authorized personnel will have access to the system, but only the Administrator will have rights to either add new users or delete the ones that are leaving;	5	5	5	5	5
	NFR-S3	The inCASA system web server shall be password protected where appropriate to allow only pertinent inCASA team members access;	5	5	5	5	5
	NFR-S4	The inCASA system shall deliver data in a manner that prevents further or second-hand use by unauthorized people.	5	5	5	5	5
	NFR-S5	The system should prevent its data from incorrect usage and prevent unintentional misuse by authorized users.	5	5	5	5	5
	NFR-S6	The system should preserve privacy of personal health care data both for user acceptance and for the credibility of the entire health systems;	5	5	5	5	5
	NFR-S7	Devices and inCASA platform will therefore have to comply with national legislation regarding access to patient data, both sensitive and non-sensitive.	5	5	5	5	5
and Cultural Requireme	**NFR-PC1**	The system shall not display religious symbols or words associated with mainstream religions;	5	5	5	5	5

	NFR-PC2	The system shall not use any terms or icons that might possibly be offensive	5	5	5	5	5

7.6 Requirements Risk Assessment

When combined, MoSCoW requirements prioritisation and Business Risk quantification give a very easily implemented but useful mechanism for managing an ordered set of inCASA user requirements. The application of Functional Risk may be used to regularise the criteria of prioritisation by considering technical effort.

7.6.1 Business Risks

Business Risk defines the impact on the business if the particular requirement is not delivered, or if a regulatory constraint or requirement is not met. For example if the system cannot meet a specific performance requirement and process the daily set of transactions then the business would be at risk of losing effectiveness, therefore customers and money. Criteria for Business Risk are listed on the next table:

Class	Criteria
High (Score: 5-4)	The requirement has direct impact on user/patient safety or system quality. Failure or inability to demonstrate compliance: o may result in non-working solution; o may have significant social/health hazard; o may cause a major financial loss due to a citation or legal action.
Medium (Score: 3-2)	The requirement may indirectly affect user/patient safety or system quality. Failure or inability to demonstrate compliance: o may result in repairable faults of the solution; o may not exist significant or permanent social/health hazard; o may cause some degree of financial loss due to losing of potential customers.
Low (Score 1-0)	The requirement has remote impact on user/patient safety or system quality. Failure or inability to demonstrate compliance: o will not result in social/health hazards or significant financial loss.

The following tables describe the changes made concerning the Business Risk assessment for the 3rd iteration. Only the requirements where changes have been made compared to the lists presented in chapter 5.5 in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_v.2.5* are presented here:

7.6.1.1 Basic Requirements Business Risk Assessment

Requirement			Business Risk	
Code	**Type**	**Description**	**Score**	**Note**
R05	Func	The system should allow measurement data visualization and extraction organized per day/per week/per month	4	Visualisation is an important feature for users
R15	Func	The system should allow the professional users to introduce specific questions or questionnaires to be administered to the patient and assign value to each answer	4	System flexibility to integrate new services is an important market factor

		and then calculate scores		
R32	Func	Data should be transmitted to the inCASA platform with a customizable frequency.	1	This is just a technical aspect with a non-immediate impact on business

7.6.1.2 Telecare Requirements Business Risk Assessment

Requirement		Business Risk	
Code	**Description**	Score	Note
FR-TC18	The system should allow the manual management of the Model by changing the range of “Normal Habits Model” of user habits.	5	The system flexibility is an important market factor

7.6.1.3 Telehealth Requirements Business Risks Assessment

Requirement		Business Risk	
Code	**Description**	**Score**	**Note**
FR-TH01b	The System should allow professional users to set the number of measurements per day (frequency), when the measurement device is wearable and the measurements are automatic.	5	Measurement options makes the systems more market attractive
FR-TH15	The System should automatically send reminders to notify the elderly patients or people close to them that they missed a scheduled measurement or they didn’t timely take their prescribed medicines.	5	This figure improve the quality of service of TH functions
FR-TH15e	The System should prepare the reminder message in the most appropriate form (i.e. SMS, message in SARA client) in accordance to their devices of choice for interfacing with the platform.	5	This figure improve the quality of service of TH functions
FR-TH16b	The System should provide a visualization of the current measurements schedule for the particular patient.	5	Visualisation is an important feature for users

FR-TH21	The system should generate an alert when the weight has increased or decreased by 5%	5	Improve the services offered
FR-TH22	The system should generate an alert when the symptoms scores are out of range	5	Improve the services offered by doctors

7.6.1.4 Telehealth/Telecare Merged Requirements Business Risks Assessment

Requirement		Business Risk	
Code	**Description**	**Score**	**Note**
FR-MG09	Ability to export monitoring data into an excel file from the clinical portal	5	Improve the business viability
FR-MG10	Ability to export patient notes into a word document from the clinical portal	5	Improve the business viability

7.6.1.5 Non-functional Business Risks Requirement

		Business Risk	
Code	**Description**	**Score**	**Note**
NFR-LF7	The Interface may include a small logo of inCASA project	5	This is an important marketing factor

7.6.2 Functional Risks

Functional Risks defines the amount of risk on the implementation of the project to meet a specific requirement. For example a MUST requirement stating that the system must ensure the monitoring of a specific parameter, is functionally a high risk if it's not possible to implement it without a great effort to integrate device to the inCASA platform. The criteria for Functional Risks are defined in the table below:

Class	Criteria
High (Score: 5-4)	Function/Requirement needs complex custom configuration or coding for integration or new development
Medium (Score: 3-2)	Function/Requirement needs custom configuration or coding for integration
Low (Score 1-0)	Function/Requirement doesn't need custom configuration or coding to be integrated

The following tables describe the changes made concerning the Functional Risk assessment for the 3rd iteration. Only the requirements where changes have been made compared to the lists presented in chapter 5.5 in *D2.4 Requirements Consolidation and Prioritisation Iteration 2_v.2.5* are presented here:

7.6.2.1 Basic Requirements Functional Risk Assessment

Requirement			Functional Risk	
Code	**Type**	**Description**	**Score**	**Note**
R35	Tech	The user should be provided with a medication dispenser	0	Dependent on patient's need

7.6.2.2 Telecare Requirements Functional Risk Assessment

Requirement		Functional Risk	
Code	**Description**	**Score**	**Note**
FR-TC38	The system should register when medication is removed from the dispenser and when it is not.	0	The SPP can provide that
FR-TC39	The system should allow registering the scoring of standardized depression-monitoring questionnaires and should be able to graphically represent their trend. For KGHNI, the questionnaires will be conducted via phone-conferences	0	Questionnaires scores are already provided by SARA platform

7.6.2.3 Merged Telehealth/Telecare Functional Risk Assessment

Requirement		Functional Risk	
Code	**Description**	**Score**	**Note**
FR-MG36	The patient portal should be access via a secure user name and password	0	User and password must be written down to use the application
FR-MG37	The patient portal should enable secure access to the patient portal via a URL and be accessed via any internet connected device	0	The patient portal is provided by an embedded app
FR-MG38	The patient portal should display the patient trend tabular and graphical data	0	That is already provided by SARA Gateway
FR-MG39	The patient portal should enable a patient to answer activity and diet questionnaires	0	Provided by SARA Gateway

Appendix A: ACT Use Cases 1-6 and 8

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 and 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.

Use Case 6: Chair Permanence
Overview: A contact sensor will be placed in a way to enable it to detect when the user is in the chair and how long.

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

Procedure: The sensors will record each time a person sits down/gets up from chair. In addition the time and duration of each event will be recorded.

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 patients and relatives: Yes.

Personalisation: Yes, all the user's habits are customised.

Devices: Contact/movement sensors.

Use Case 8: The TV
Overview: The sensor will monitor if there is an abnormal use of the TV.

Purpose: Staying more than usual in chair/bed with the TV switched on could be a warning of illness or uneasiness that could necessitate an intervention by the social worker

Procedure: The sensors will record each time a person switch on/switch off the TV. In addition the time and duration of each event will be recorded.

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

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

Alerts: Text message sent to the appropriate care worker.

Feedback to patients and relatives: Yes.

Personalisation: Yes, all the user's habits are customised.

Devices: TV usage sensor.

Appendix B: CHC Use Cases 1-5

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.

Data fusion: All data transmitted via the hub will be stored on the inCASA server.

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 4a,b,c: 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.

Data fusion: All data transmitted via the hub will be stored on the inCASA server.

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 patient's 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.

Data fusion: All data transmitted via the hub will be stored on the inCASA server.

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.

Appendix C: FHC Use Case 1

Use case 1: Portable bicycle and SpO2
Overview: The service will provide an exercise plan for the required exercises using a pedal machine and free weights for upper limbs.

Clinical purpose: To decrease the level of CO2 in blood and to increase pulmonary capability according to scientific evidence by SEPAR (Spanish society for neurology and thoracic surgery [www.separ.es])

Procedure: The patient will do the prescribed exercises daily and the collected data will be delivered to the healthcare professionals in charge of the patient (a rehabilitation specialist) to check their evolution. Data will be stored in a table and will become the basis for the definition of the exercises to be performed.

Analysis: A rehabilitation specialist and eventually a pulmonologist specialist will check the progress.

Data fusion: All data will be stored in a suitable electronic healthcare record.

Alerts: If values are outside certain ranges, the specialist will consider alternative treatments according to the patient's general situation, including a change on the recommended exercises.

Feedback to patients and relatives: Patients will receive feedback in the context of a regular visit to the hospital.

Personalisation: Yes. Personalisation will be based each patient's the level of COPD and more specifically on variables such us the ratio between weight and physical capability of the patient.

Devices: Pulse Oximeter, portable pedal machine, touchable screen and weights. The weights are not connected to any device and are used to do exercises with upper limbs.

Appendix D: INSERM Use Cases 1-3

Use case 1: Actigraphy

Overview: This service will allow daily transmission and analysis of rest-activity rhythm while patients receive chemotherapy thus enabling rapid intervention if necessary. The company Ambulatory Monitoring developed a new Actigraph with infrared transmission following INSERM requirement to be used in the inCASA project. This is a totally new service.

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

Procedure: Patients will receive the Actigraph at the beginning of the study and will wear it at least for 6 consecutive weeks. Data will be recorded continuously at the frequency of 1 per minute. The patients will transmit the recorded data by infrared transmission to the inCASA platform once a day.

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 6 weeks or more. The rhythm is considered as altered if the index decreases below 97.5%. 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: Actigraph files sent by patients are sent using LinkSmart Middleware, stored on CNET sever and accessible through the web portal.

Alerts: The system confirms a consistent decrease of I<O below the alarm threshold (0.975) during a 24 hours span; which will produce a specific alert on INSERM screen.

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: Yes

Devices: 10 Infrared wrist Actigraph.

Use case 2: Symptoms self-assessment

Overview: Rate daily self-assessed symptoms using the MD Anderson Symptom Inventory core items (MDASI scale) through the touch screen of the platform.

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: Data are sent to TID server and can be visualized through graphs on the web portal.

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. If deterioration persists over 24h, a contact between the patient and his/her physician is arranged on the same day by the nurse.

Feedback to patients and relatives: Yes

Personalisation: Yes.

Devices: 10 inCASA platform with touch screen.

Use case 3: Body weight

Overview: To measure body weight using a weight scale 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: Data are sent to TID server and can be visualized through graphs on the web portal.

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 by 5% or more, 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. If deterioration persists over 24h, a contact between the patient and his/her physician is arranged on the same day by the nurse.

Feedback to patients and relatives: Yes

Personalisation: Yes

Devices: 10 weight scales directly connected to the inCASA platform.

Appendix E: KGHNI Use Cases 1- 4

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 there 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 patient in the 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 patient in the 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: None.

Personalisation: None.

Devices: Nonin Onyx II 9560 pulse oximeter.

Use case 4: Heart rate

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

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: Nonin Onyx II 9560 pulse oximeter.