



# ACTOVAGE PROJECT

ACTivating InnoVative IoT smart living environments for AGEing well

## Detailed experiment plan IV DS4 RER contribution

<b>Deliverable No.</b>	D9.1	<b>Due Date</b>	30-SEP-2017
<b>Description</b>	Definition of the individual experiment plan for the DS4 in Regio Emilia Romagna.		
<b>Type</b>	Report	<b>Dissemination Level</b>	Public
<b>Work Package No.</b>	WP9	<b>Work Package Title</b>	LSP Deployment sites definition, execution and evaluation
<b>Version</b>	1.0	<b>Status</b>	Release 1

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# History

Date	Version	Change
02-Jun-2017	0.1	Structure of the document – first proposal
19-Jun-2017	0.2	ToC approved and contributions assigned
31-Jul-2017	0.3	Intermediate version
12-Sep-2017	0.8	Final - internal review
28-Sep-2017	0.9	Activage peer review
06-Oct-2017	0.10	Feedback of review included.
13-Oct-2017	1.0	Final version ready for release

# Key data

<b>Keywords</b>	Stroke; Monitoring; Habits;
<b>Lead Editor</b>	Name: Stefano nunziata Partner: C2K
<b>Internal Reviewer(s)</b>	Roberto Casas, TVES; Carsten Stockl�w; SL

## Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

# Table of contents

<b>TABLE OF CONTENTS</b> .....	<b>3</b>
<b>LIST OF TABLES</b> .....	<b>4</b>
<b>LIST OF FIGURES</b> .....	<b>4</b>
<b>1 DEPLOYMENT SITE ENVIRONMENT</b> .....	<b>5</b>
1.1 GEOGRAPHICAL INFORMATION .....	5
1.2 DEMOGRAPHIC INFORMATION.....	5
1.3 ALIGNMENT WITH STRATEGIC AND POLICY VISIONS (NATIONAL, REGIONAL, LOCAL LEVEL) .....	7
1.4 NEEDS OF THE TARGET POPULATION .....	8
1.5 CURRENT SERVICES ADDRESSING TARGET POPULATION NEEDS – GAPS AND LIMITATIONS .....	9
1.6 BACKGROUND EXPERIMENTATION – GAPS AND LIMITATIONS .....	9
1.7 DS ECOSYSTEM .....	1
<b>2 SELECTED UCS</b> .....	<b>4</b>
2.1 LOCAL UCS DESCRIPTION AND TARGETED COHORTS .....	4
2.2 DEFINITION OF LOCAL KPIS AND TARGETED COHORTS.....	19
2.3 TECHNICAL SOLUTION .....	21
2.3.1 <i>Architecture of proposed solution</i> .....	21
2.3.2 <i>IoT infrastructure</i> .....	22
2.3.3 <i>Scenarios specification</i> .....	23
2.3.4 <i>Data model and Information model</i> .....	25
<b>3 PROCEDURES</b> .....	<b>32</b>
3.1 LEGAL AND ETHICAL ASSESSMENT.....	32
3.2 USER RECRUITMENT AND CONSENT PROCEDURES .....	32
3.3 PROCUREMENT.....	34
3.4 INSTALLATION PROCEDURES .....	34
3.5 USER TRAINING AND SUPPORT.....	35
3.6 OPERATION PROCEDURES .....	36
3.7 TERMINATION PROCEDURES.....	37
3.8 KPIS EVALUATION PROCEDURES.....	37
3.9 DATA MANAGEMENT PROCEDURES .....	38
<b>4 DETAILED PLANNING</b> .....	<b>40</b>
4.1 DEFINITION PHASE.....	40
4.2 IMPLEMENTATION PHASE .....	41
4.3 LIVING LAB TESTING .....	41
4.4 DEPLOYMENT AND OPERATION .....	42

## List of tables

TABLE 1 STROKE AND HOSPITALIZATION - Yr 2016 .....	6
TABLE 2: CURRENT SERVICES ADDRESSING USER NEEDS. LIMITATIONS AND EXPECTED IMPROVEMENTS.....	9
TABLE 3: CURRENT AND PAST EXPERIMENTS. LIMITATIONS AND EXPECTED IMPROVEMENTS .....	11
TABLE 4 STAKEHOLDERS LIST - EXTRACT FROM D2.1_A.4_REQUIREMENTS_SPECIFICATION_FOR_AGEING_WELL_DS_RER_CONTRIBUTION_V1.DOC .....	4
TABLE 5 SERVICES DESCRIPTION .....	24
TABLE 6 DATA STAKEHOLDERS AND ROLES .....	25
TABLE 7 DATASET DSRER.01.RAWSENSORSDATA.....	27
TABLE 8 DATASET DSRER.02.MEASUREMENTSDATA .....	28
TABLE 9 DSRER.03.DATAFORANALYSIS .....	29
TABLE 10 DATASET DSRER.04.ANALYSISRESULTS.....	31
TABLE 10 TRAINING SESSIONS DETAILS.....	36

## List of figures

FIGURE 1 GEOGRAPHICAL POSITION .....	5
FIGURE 2 DEMOGRAPHIC DATA (2016).....	6
FIGURE 3 DS VALUE NETWORK .....	1
FIGURE 4 STAKEHOLDER ANALYSIS MAP .....	2
FIGURE 4 DS RER PARTNERS STAKEHOLDER ROLES.....	3
FIGURE 4 DS RER ARCHITECTURE.....	21
FIGURE 5: INFORMATION FLOW MODEL OF DS RER .....	25
FIGURE 6 WORKPLAN ACTIVAGE LIFECYCLE.....	37

# 1 Deployment site environment

## 1.1 Geographical information

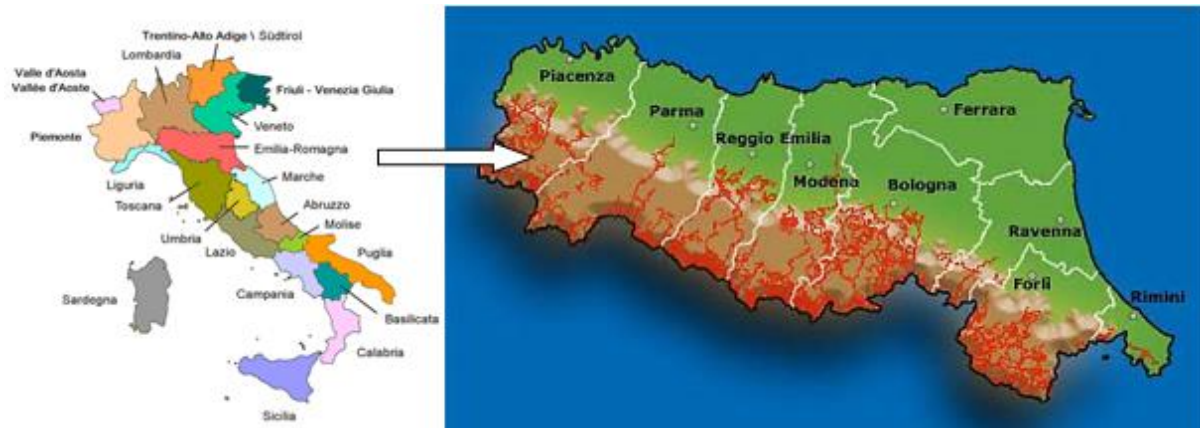


Figure 1 Geographical position

The Emilia Romagna region is located in northern Italy and is populated by 4.5 million inhabitants. The capital of the Region is Bologna and there are 9 provinces. The province of Parma, inhabited by 448,207 inhabitants is located in the northwestern part of the Region, it is delimited to the south by the Tosco-Emilian Apennines and north by the Po River.

The economy is predominantly agricultural and thanks to several world-recognized agri-food products has been defined and recognized as food-valley. There is also an important manufacturing industry in the food field.

In this context, there are two healthcare companies: the Parma Hospital-University Authority, which carries out emergency- tasks and the USL Parma Authority (LHA Parma), which has the role of assisting chronic and sub-acute.

The Emilia Romagna Region has programmed territorial welfare facilities that bring together the various services for health, rehabilitation, psychological, nursing and social services. The predominance of these structures is defined as Home of Health and the LHA Parma has been distinctly open to create more of the other provinces.

## 1.2 Demographic information

The constant and evolving element in the Region and in particular in the province of Parma is represented by the increase in the age of the population. The local administrative institutions constantly monitor the evolution of age of the population and then hand this analysis over to the care facilities and health facilities for the simultaneous increase of chronic degenerative diseases. Some methods of analysis are used in the tables below.

First of all, the number of people with stratification by age and gender as illustrated in the pyramid of the population. Moreover, for a more precise analysis, demographic indices are used to indicate the stratification of the population by dependency, particularly for the elderly population. Chronic diseases are the main cause of dependence.

MALE	FEMALE	TOTAL
218.022	230.185	448.207

DEMOGRAPHIC INDEX	
Old age index	173,7
Total dependency index	57,6
Youth dependency index	21,0
Senile dependency index	36,5
Pop structure index. att.	139,2
Pop Replacement Index. att.	134,6

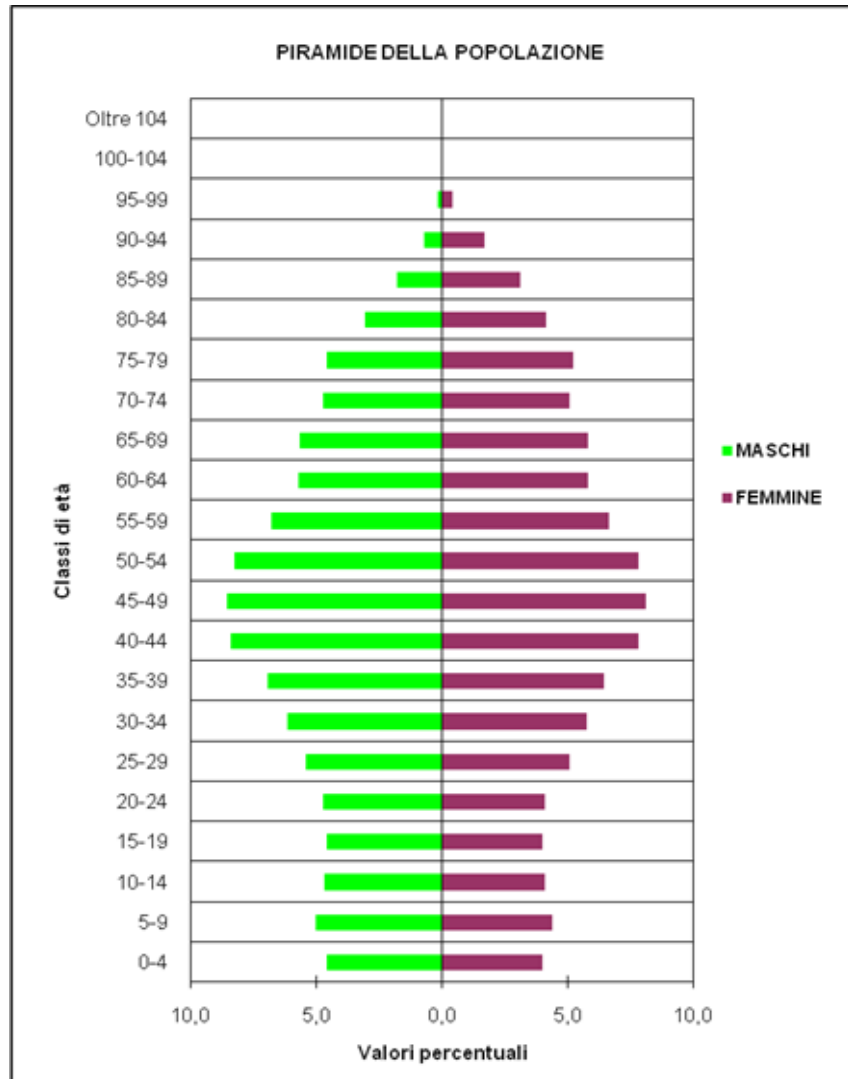


Figure 2 demographic data (2016)

Year 2016	Total
patient affected by stroke by admissions to hospital department resigned in 2016 Resident in the AUSL of Parma	692
"Acute" hospitalization following the first for any disease until May 2017 for admission department:	356
re-recovery rate (number of admissions after first recovery/ first recovery patient number)	33,38%

Table 1 Stroke and hospitalization - Yr 2016

The epidemiological study on the incidence of Stroke in the population of Parma highlights the hospitalization of 692 new cases in 2016 and a re-hospitalization of 356 persons for the specific pathology.

The analytical evaluation of these data indicates the percentage of about 30% of the re-hospitalization.

The ACTIVAGE Study intends to influence the phenomenon of re-hospitalization for a better quality of life and reduction of costs.

## 1.3 Alignment with strategic and policy visions (national, regional, local level)

The following are the health policy documents related to the problems of the elderly and then those related to stroke second at national, regional and local levels.

### Strategic and policy national visions



“Linee guida sociosanitarie rivolte a persone anziane e disabili in condizioni di fragilità” (Social health Guidelines for elderly people and disabled in frailty conditions)

Link : [http://www.projectaida.eu/wp-content/themes/thunderbolt/docs/AIDA\\_linee-guida-nazionali-per-lintegrazione-sociosanitaria\\_DEF.pdf](http://www.projectaida.eu/wp-content/themes/thunderbolt/docs/AIDA_linee-guida-nazionali-per-lintegrazione-sociosanitaria_DEF.pdf)



*Ministero della Salute*



*Agenzia Nazionale per i Servizi Sanitari Regionali*

Il Programma Nazionale Esiti (PNE) è sviluppato da AGENAS per conto del Ministero della Salute e fornisce a livello nazionale valutazioni comparative di efficacia, sicurezza, efficienza e qualità delle cure prodotte nell’ambito del servizio sanitario. Gli ambiti di valutazione sono, per quanto riguarda la funzione di produzione, le singole aziende ospedaliere/stabilimenti ospedalieri e, per quanto riguarda la funzione di tutela o committenza, le aziende sanitarie locali/province.

1

Link: [http://www.salute.gov.it/portale/temi/p2\\_6.jsp?id=2905&area=programmazioneSanitariaLea&menu=vuoto](http://www.salute.gov.it/portale/temi/p2_6.jsp?id=2905&area=programmazioneSanitariaLea&menu=vuoto)

Two documents have been identified, the first concerning assistance policies for elderly and disabled people, and the second on the outcomes of acute and chronic diseases of which stroke is the most important example.

### Strategic and policy regional vision



Progetti area cerebrovascolare “Il percorso integrato stroke care della Emilia Romagna”<sup>2</sup>.

<sup>1</sup> The National Successful Healthcare Programme is developed by AGENAS on behalf of the Ministry of Health and provides at national level comparative assessments of the efficacy, safety, efficiency and quality of care produced within the health service. As far as the production function is concerned, the assessment areas are the individual hospitals/hospital establishments and, as far as the protection or commissioning function is concerned, the local health care companies/provinces.

<sup>2</sup> Projects cerebrovascular area “The stroke care integrated pathway of Emilia Romagna”.



Link: <https://www.cochrane.it/sites/cochrane.it/files/public/uploads/note%20cochrane/Ferro.pdf>



Azienda USL di Parma “Documento di implementazione aziendale Stroke Care”<sup>3</sup>

Link: [http://www.ausl.pr.it/comunicazione\\_stampa/archivio\\_3/polo\\_neurologico\\_interaziendale.aspx](http://www.ausl.pr.it/comunicazione_stampa/archivio_3/polo_neurologico_interaziendale.aspx)

The regional and local policy is focused on stroke care.

The ACTIVAGE project is part of the regional planning for territorial and domiciliary assistance of chronic diseases and pathologies that lead to fragility. The creation of the experience of the Health Houses (Case della Salute) goes to this direction but the functionality of these new institutes in the territory must be based on an organization that is able to grasp the aspects of the everyday life of these diseases in order to create a continuous assistance and that captures sentinel events for the prevention of relapses and recurrences. As in COPD and heart failure, home care guidelines are being designed to increasingly avoid hospitalization and clinical deterioration. Stroke is a pathology with the same characteristics, with a high epidemiological incidence and the need to combine recovery and social reintegration.

The ministerial and consequently regional indications indicate that Stroke Care is a necessary tool to prevent not only clinical worsening but also hospitalizations and thus reduce both direct and indirect costs that the pathology is giving to the Regional and National Health Service. The ACTIVAGE project, which was planned by the Emilia Romagna region and in particular the 'Assessorato alla Salute e ai Servizi Sociali' (Department of Health and Social services), was decided to give effective planning to territorial services.

## 1.4 Needs of the target population

It is recognized that the experience of stroke impacts on the entire family, and nurses have a role to play in the assessment of the family and family caregivers.

The most important needs that arise in the outcomes of stroke are the maintenance of residual motor activity and the ability to maintain a quality of life that meets the needs of the intra-family relationship and social partners. Fundamental role is played by rehabilitation but it must be based on the stabilization of the clinical picture and the absence of acute or sub-acute events such as re-hospitalization to undergo rehabilitative projects. In this framework, the role of a family member or a care-giver is important. A decisive role is represented by the General Practitioner (Care Manager) who has to control the vital parameters of the person so that there are no decisive changes to stabilization. The nursing structure is crucial in providing the services needed for this maintenance and rehabilitation, which can be the figures of the psychologist, social worker and nurse.

<sup>3</sup> Local health Authority of Parma "Stroke Care Implementation Document".

## 1.5 Current services addressing target population needs – gaps and limitations

Stroke-related services are part of the chronicity programme at regional and local level, particularly in the geriatric fragility programme.

The emerging problems are linked to the multi-factuality of the pathology that needs to be observed over time and that is highlighted by the motor function and adaptation to the needs of everyday life.

The services created within the assistance network are more focused on solving crisis problems than on providing continuity of observation, which can draw attention from every phenomenon, especially addressed to the GPs (General Practitioners). With ACTIVAGE, this gap in continuous observation and handling is overcome.

SERVICE	LIMITATIONS	IMPROVEMENT REALIZED BY ACTIVAGE SOLUTIONS
Home of Health	New organisation in the Regional health system under evolvement	Increased service coordination
Nucleuses of Primary Cares	Aggregation of GPs not always structured	Increased General Practitioner intervention capacity
Nurse coordination	limited capability	Increased nursing capability
Home Care (ADI, Assistenza Domiciliare Integrata; domiciliary integrated assistance)	Temporary nursing	Continuity care
Rehabilitation	Periodicity and not continuity of observation	Improved movement control
Psychological assistance	Periodicity and discontinuity of observation	taken care

Table 2: Current services addressing user needs. Limitations and expected improvements

The services to the person are provided under the National Health Service (NHS) scheme by local health care companies through the organization of Health Care Houses, which comply with two principles:

- LEA (Essential level of assistance)
- Regional programming lines.

## 1.6 Background experimentation – gaps and limitations

The solution proposed in the RER DS was conceived on the basis of the previous experiences based on FISTAR and other internal projects. In particular, FISTAR aimed at monitoring COPD

patients in the province of Ferrara, using the existing SOLE network and regional eHR (FSE, Fascicolo Sanitario Elettronico), as point of storage and distribution of the information, and the FiWare infrastructure. In this implementation, we reused the concept for a different pathology reducing the impact on the assisted persons and basing the care on the Houses of Health (Case della Salute), the emerging territorial organization of the Regional Health System.

EXPERIMENT	CONCLUSIONS	IMPROVEMENT REALIZED BY ACTIVAGE SOLUTIONS
FISTAR	<p>Pneumologist of the Hospital of Copparo (FE) could monitor vital parameters (HR, blood oxygenation and respiratory parameters) and receive qualitative information by configured questionnaires.</p> <p>The project suffered from the youth of the FiWare technology and the difficulty in the use of the technology by assisted persons</p>	<p>The IoT devices used in ACTIVAGE aims at minimizing the impact on assisted person routines, in most cases the user does not have to interact with the devices.</p> <p>Informal care giver has been empowered and also formal care givers moved from the hospital physician to the House of Health, that includes a case manager and the GP as care manager.</p> <p>The FiWare components on which we base the platform are now more reliable and stable.</p>
WindTre Internal project	<p>Usage of new smart terminals - smartphone, wireless EEG, designed for contextualized research and advanced brain computer interface (BCI) applications - to integrate better disabled people in the home/office context. In particular one person verifies the new capabilities of the instrument.</p> <p>The internal activity has a very reduced perimeter, but it is important to demonstrate all the capability of the solution based on smart terminal to guarantee a better inclusion.</p>	<p>The ACTIVAGE solution extends the field of experimentation integrating more and more sensors to offer a set of services more complete and exhaustive compared to the final user's needs.</p> <p>The used approach suggested by the ACTIVAGE will allow a better integration with the current Wind Tre commercial offer “Home &amp; Digital Life” integrating smart terminals to deal with different contexts, as the Wellness context to track and check heart rate continuously or to control different parameters (e.g. Thermostat) or the context near the user (e.g. Nest Indoor Cam). ACTIVAGE will offer many elements to improve the “Home &amp; Digital Life” solution</p>
INTESA and SIDOREMI	<p>The INTESA project proposes a system able to capture the movement of the patient as well as the bed posture in an unobtrusive way. The proposed system is composed by a grid of forty-eight Force Sensing Resistor (FSR) sensor nodes,</p>	<p>We plan to extend such approach with different kinds of sensors requiring less configuration steps. The pressure sensor used does not need any specific setting. Moreover, the data collected will be analyzed in order to measure key-indicators of the quality of the sleep for post-stroke users.</p>

	<p>placed just on the staves of the bed.</p> <p>The SIDOREMI project aims at measuring and supporting children with autism disabilities. The project also measures the quality of the sleep by using wired sensors based on pressure.</p>	
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Table 3: Current and past experiments. Limitations and expected improvements

## 1.7 DS ecosystem

The following table shows the results of the stakeholder identification process (extract from D2.1\_A.4\_Requirements\_specification\_for\_ageing\_well\_DS\_RER\_Contribution\_v1.doc )

Stakeholder group	Profile	Identification of motivation and goals	Benefits from solution	Importance (high/low)	Influence (high/low)	Relations to other stakeholder groups
<b>Assisted person</b> - <b>Person with chronic conditions</b>	Person over 65yo, that suffered from a stroke, with informal caregiver, with good physical and cognitive conditions.	- remains independent living in his home - feeling safer and monitored	- intercept potential exacerbations - feeling safer and monitored	High	Low	Formal care giver - GP Formal care giver - Social Worker Formal care giver - Case manager Formal Care giver - Medical Therapist Informal Caregiver
<b>Formal care giver</b> - <b>General Practitioner (GP)</b>	Care manager of the assisted person	- monitors the trends of behaviour of the assisted person - check the assisted patient in case of strange behaviour	- strengthen the relationship with assisted person - reduces exacerbations	High	High	Assisted person - Person with chronic conditions Formal care giver - Case manager Formal Care giver - Medical Therapist Informal Caregiver Health care provider - casa della salute Health care provider – hospitals Developers - research institutions
<b>Formal care giver</b> - <b>Social Worker</b>	- social and health care workers (OOS Operatore Socio Sanitario) of the care giving cooperative that visit the assisted person and respond to non-technical-non clinical request at a call center	- gives support visiting the assisted person - gives support via a relationship help Desk to help assisted person on the services	- enlarge the target of users of their services monitoring assisted person in frailty situation	Low	High	Assisted person - Person with chronic conditions Formal Care giver - Medical Therapist Informal Caregiver Social services providers

<p><b>Formal care giver - Case manager</b></p>	<p>- the responsible for following the case of the assisted person in the Casa della Salute (home of Health). Monitors the situation and, having a clear view of the care system, activate the correct care service</p>	<p>- monitors the trends of behaviour of the assisted person - activate the correct patient care givers when needed</p>	<p>- The Home of Health is the organization in the Region that connects the health system and the citizens, integrating basic social care and health care under the same organization</p>	<p>high</p>	<p>high</p>	<p>Assisted person - Person with chronic conditions Formal care giver - General Practitioner (GP) Informal Caregiver Health care provider - casa della salute Authorities - Regional entities Developers - research institutions</p>
<p><b>Formal Care giver - Medical Therapist</b></p>	<p>- control the physical status of the assisted person using the videoconference with the help of a OOS at assisted person premise</p>	<p>- increase the level of assistance and reduces exacerbations</p>	<p>- He can visit more patient without physical displacement</p>	<p>high</p>	<p>low</p>	<p>Assisted person - Person with chronic conditions Formal care giver - GP Formal care giver - Social Worker Informal Caregiver Health care provider – hospitals Authorities - Regional entities Developers - research institutions</p>
<p><b>Informal Caregiver</b></p>	<p>- assist daily the primary user. - have access to the user apartment and have privileged communication with the user.</p>	<p>- increase his QoL, reducing the need of physical presence near the assisted person - He can check suspicious risky situations notified by the system and alert the case and/or care manager</p>	<p>- increase free time - feel that his care receiver is safer</p>	<p>High</p>	<p>low</p>	<p>Assisted person - Person with chronic conditions Formal care giver – GP Formal care giver - Social Worker Formal care giver - Case manager Formal Care giver - Medical Therapist</p>
<p><b>Health care provider - casa della salute</b></p>	<p>- The Home of Health is the organization in the Region that connects the health system and the citizens, integrating basic social care and health care under the same organization</p>	<p>- increase the relationship with assisted citizens - decrease inpatient for exacerbations - increase service to the population</p>	<p>- enlarge the target of users of their services - monitoring assisted person in frailty situation - intercept deterioration of frailty situations</p>	<p>High</p>	<p>High</p>	<p>Formal care giver - General Practitioner (GP) Formal care giver - Case manager Health care provider – hospitals Social services providers Authorities - Regional entities Developers - research institutions</p>

<b>Health care provider - hospitals</b>	- physicians and emergency room that take assisted person in charge when an health problem occurs	- keep the assisted person healthy as long as possible	- reduces ER admissions - reduces specialist visits	low	low	Formal care giver - General Practitioner (GP) Formal Care giver - Medical Therapist Health care provider - casa della salute Social services providers Authorities - Regional entities Developers - research institutions
<b>Social services providers</b>	- the care giving cooperative	- increase the services provided	- enlarge the target of users of their services monitoring assisted person in frailty situation	low	Low	Formal care giver - Social Worker Health care provider - casa della salute Health care provider – hospitals Authorities - Regional entities
<b>Authorities - Regional entities</b>	- the regional Health system	- keep citizens healthy and active as long as possible in an effective and efficient way	- decrease cost for chronic disease treatment - increase wellbeing of the citizens - contribute of the sustainability of health system	High	Low	Formal care giver - Case manager Formal Care giver - Medical Therapist Health care provider - casa della salute Health care provider – hospitals Social services providers
<b>Developers - SW</b>	- provide new AHA HW solutions	- provide solutions in a more effective and efficient way - use of standard and interoperable SW services	- faster and more effective design and implementation	low	high	Developers – HW Developers - research institutions Technology providers - Deployers
<b>Developers - HW</b>	- provide new AHA HW solutions	- provide solutions in a more effective and efficient way - use of standard to deploy new HW easily	- faster and more effective design and implementation	low	high	Developers - SW Developers - research institutions Technology providers - Deployers
<b>Developers - research institutions</b>	- provide innovative AHA technical solutions	- develop new solution that could be easily deployed into market	- Improve know how - research of the field	low	high	Formal care giver - General Practitioner (GP) Formal care giver - Case manager Formal Care giver - Medical Therapist Health care provider - casa della salute

						<i>Health care provider – hospitals</i> <i>Developers - SW</i> <i>Developers – HW</i> <i>Technology providers -</i> <i>Deployers</i>
<b>Technology providers</b> <b>Deployers</b>	- install and maintain the system	- install and maintain AHA solution in efficient and effective way	- easiness of installation of IoT devices - easiness of monitoring the IoT infrastructure - easiness of maintaining the IoT infrastructure	low	low	<i>Developers - SW</i> <i>Developers - HW</i> <i>Developers - research institutions</i>

Table 4 Stakeholders list - extract from D2.1.A.4\_Requirements\_specification\_for\_ageing\_well\_DS\_RER\_Contribution\_v1.doc



DS VALUE NETWORK	
Device provider	UniPR LHA PR WindTre
Network provider	WindTre
Platform provider	C2K IBM
Application provider	C2k
Service provider	C2k LHA PR AuroraDomus
Payers	LHA PR Region Emilia Romagna
Customer	Assisted Persons Formal Care Givers (Care Managers, Case Managers and Social workers) Informal Care Givers
Society	Social services providers (AuroraDomus) Home of Health (LHA's organization) Stroke patient association

Figure 3 DS Value network

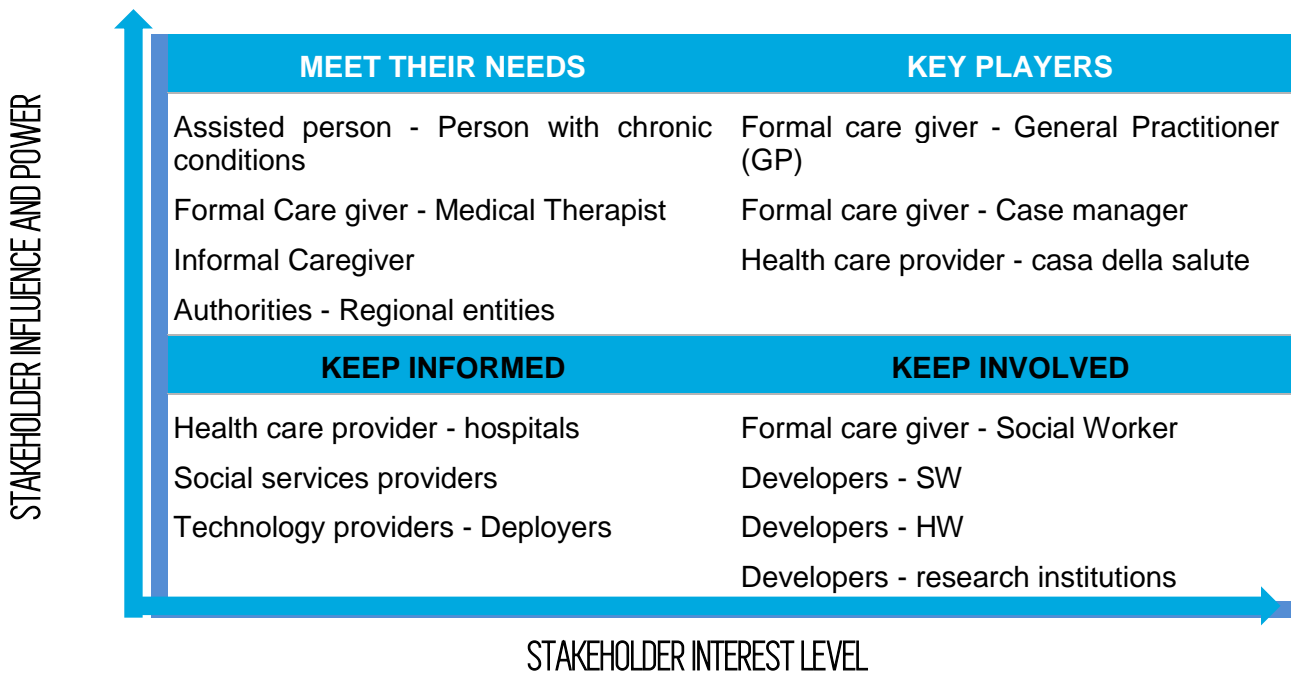


Figure 4 Stakeholder analysis map

Partners description:

**C2K** –DS RER coordinator, it is an in house-providing company of the Emilia Romagna Region, it represents both supply (ICT provider for the Region) and demand side (experience on organization and execution of the pilot). It has developed and is managing the regional eHealth infrastructure and other services related to the management of chronic pathologies.

**LHA Parma**– health authority, user recruitment and pilot execution, motivation and engagement of seniors, result analysis

**AURORA** – social cooperative providing social services to elderly and operating both at regional and national level

**CNR-ISTI** – support on the long-term monitoring of elderly

**UNI PR** – competence on smart environment and Ambient Assisted living solutions

**IBM** – a major player in the Information Technology industry support the data integration and analysis. At European Level IBM is actively involved in AIOTI (Alliance for Internet of Things Innovation) Working Groups.

**WIND** – Telecommunication company that provides internet connections and hardware for home installations.

Role as stakeholders:

	C2K	LHA Parma	AURORA	CNR-ISTI	UNI PR	IBM	WIND
Formal care giver - General Practitioner (GP)	x						
Formal care giver - Case manager	x						
Health care provider - casa della salute	x						
Assisted person - Person with chronic conditions							
Formal Care giver - Medical Therapist	x						
Informal Caregiver							
Authorities - Regional entities							
Formal care giver - Social Worker		x					
Developers - SW	x		x	x	x		
Developers - HW	x			x		x	
Developers - research institutions			x	x	x		
Health care provider - hospitals		x					
Social services providers		x	x				
Technology providers - Deployers	x			x			

Figure 5 DS RER partners stakeholder roles

## 2 Selected UCs

### 2.1 Local UCs description and targeted cohorts

1	NAME	DSRER_LUC01 Use of toilet
2	MAPPING TO ACTIVAGE UCs	AUC 1 - Daily activity monitoring
3	CONTEXT OF USE	<p>Toilet usage is an expressive indicator of many health-related conditions, with particular reference to older adults. A proximity sensor is deployed in the bathroom, suitable for discriminating actual toilet usage from bathroom visit due to different reasons (personal hygiene, for instance).</p> <p>No actual interaction is required to the end-user, and only basic maintenance (battery replacement, upon system notification) is required to the caregiver. The device reading range can be calibrated, to account for different bathroom sizes and arrangements.</p> <p>Usage data are transmitted to the cloud, and feed analytics modules, to extract meaningful information (statistics, trends, anomalies). To this purpose, machine-learning techniques are exploited, with training being carried out on actual specific users to enable personalized assessment.</p> <p>Besides triggering the attention of the caregiver and of the case manager in case of gross anomalies, toilet usage data contribute to the fusion strategy, aiming at extracting synthetic and intuitive indicators (e.g., “traffic light” encoding) about needs of attention from caregivers of the end-user.</p> <p>On given situations, the end-user himself may receive notifications about analytics outcomes, casted in the form of feedbacks and suggestions for improving his lifestyle.</p>
4	STORY LINE	<p>Carlo is 70 years old, and is recovering from a stroke he suffered of a couple of years ago. He lives in his own home, with his wife Maria, who takes care of housekeeping and looks after Carlo’s daily therapies. Carlo also suffers from prostatic hypertrophy, which occasionally fosters infections of the urinary tract. Such condition, in turn, result in marked alteration of the toilet usage pattern. Even though Carlo and Maria share the same bathroom, the system is trained upon family usage: all anomalous patterns detected, are visible by the case manager at the Casa della Salute accessing into the system. To avoid false alarms (for instance due to a guest visiting the couple for a few days), the case manager or the caregiver then check the situation with the family and validate the information. The GP in charge of Carlo’s cure may then promptly prescribe appropriate therapy adjustments.</p> <p>Through this strategy, infections are possibly detected at an earlier stage, preventing further complications and reducing Carlo’s discomfort.</p>

1	NAME	DSRER_LUC01 Use of toilet
5	INVOLVED USERS / TARGETED COHORTS	<p>Assisted person: +65yo, with CFS level between 3 and 6, recovering from stroke episodes and living at home.</p> <p>Caregiver: either formal or informal, is in charge of elementary device maintenance and receive notifications from the system in case of anomalies. He also connects with the Case Manager at the Casa della Salute, supporting him with home insights and information.</p> <p>Case Manager: located at the Casa della Salute, he is in charge of validating system notifications and to enact related actions, connecting with end-user, caregiver, GP, and specialist doctor.</p> <p>GP: in charge of the general cure of the elderly person, receive notifications from the case manager when general cure provision is needed. Also, forward relevant information to the specialist doctor.</p> <p>Medical therapist: in charge of specific cure of elderly person main pathologies, gets notified from the Case Manager or the GP whenever information relevant to the specific cure strategy come out.</p> <p>HW and SW developers: Analytics service provider, in charge of continuous analysis of the data stream and of the inference of relevant information. Health-management service provider, in charge of bringing behavioural information into medical records management and visualization systems</p> <p>Technology provider: Provision, deployment and technical maintenance of the sensing equipment (IoT devices). Cloud-based infrastructure manager, watching over data acquisition, storage, and sorting.</p>
6	GOALS TO BE ACHIEVED	<p>Assisted person: Safety, comfort, prevention.</p> <p>Caregiver: Awareness, early notification, peace of mind</p> <p>Case Manager: prompt information, objective reporting of anomalies</p> <p>GP: pre-screening of patient notification, reducing unnecessary access</p> <p>Medical therapist: enhanced insight of the assisted person cure needs</p> <p>Technology providers: increase of customer networks</p> <p>Developers: increase of knowledge base</p>
7	SYSTEM CAPABILITIES	<p>Smart IoT device, encompassing both sensing (toilet proximity) and network communication (Wi-Fi, no base station required) capabilities.</p> <p>Standard Wi-Fi WLAN equipment: modem-router, phonline or 4G connection.</p> <p>Analytics module, working out trend and anomalies information.</p> <p>Cloud architecture, dealing with data management and storage.</p> <p>User interfaces toward different stakeholders, integrated/compatible with pre-existing software tools (e.g. medical health record management systems in use by local healthcare provider).</p>

1	NAME	DSRER_LUC01 Use of toilet
8	PRELIMINARY LIST OF SCENARIOS	<p>SC_DSRER.1.2 Deployment and configuration</p> <p>SC_DSRER.1.3 Analytics (toilet usage) and data fusion</p> <p>SC_DSRER.1.4 Feedback and user interfaces</p>

1	NAME	DSRER_LUC02 Sleep quality
2	MAPPING TO ACTIVAGE UCs	AUC 1 - Daily activity monitoring
3	CONTEXT OF USE	<p>Sleep disturbances are frequently associated to unfit conditions or health issues. A pressure pad is placed under the assisted person bed mattress, and provide information about bed occupancy.</p> <p>No actual interaction is required to the end-user, and only basic maintenance (battery replacement, upon system notification) is required to the caregiver. Under mattress placement provides better comfort and hygiene.</p> <p>Usage data are transmitted to the cloud, and feed analytics modules, to extract meaningful information (statistics, trends, anomalies). To this purpose, machine-learning techniques are exploited, with training being carried out on actual specific users to enable personalized assessment.</p> <p>Besides triggering the attention of the caregiver and of the case manager in case of gross anomalies, sleep information (nightly and daily total time spent in bed, number of awakenings, etc., trends, anomalies) contribute to the fusion strategy, aiming at extracting synthetic and intuitive indicators (e.g., “traffic light” encoding) about needs of attention from caregivers of the end-user.</p> <p>The end-user himself may access visual reporting about quantitative and qualitative sleep assessment.</p>
4	STORY LINE	<p>Carlo is 70 years old, and is recovering from a stroke he suffered of a couple of years ago. He lives in his own home, with his wife Maria with whom he shares the bed.</p> <p>Carlo's sleep is characterized by frequent awakening and motor activity that leads him to restlessness. The functional motor limitation due to stroke creates difficulties for movements in the bed and therefore for changes of position, relegating to a forced position, usually in the back, and also to the difficulty of getting up to the toilet.</p> <p>The quality of sleep is therefore determined by these limitations and it is difficult to reach the deep phases of sleep and therefore with the difficulty to realize the dream phase. When the patient awakens, therefore, the patient presents himself with a more marked fatigue that further limits his functionality</p>

1	NAME	DSRER_LUC02 Sleep quality
		<p>The detection of the amount of sleep (how many hours' sleep) and the quality expressed as motor activity, awakening and uplifting is an important element of Charles's state.</p> <p>The system detects that Carlo has a higher than average amount of sleep and that movements are reduced during sleep.</p> <p>Once this behaviour has been reported to the GP, he will ask for confirmation by questioning Maria and will examine the causes that may have determined it, and consequently intervene on the causes.</p>
5	INVOLVED USERS / TARGETED COHORTS	<p>Assisted person: +65yo, with CFS level between 4 and 6, recovering from stroke episodes and living at home.</p> <p>Caregiver: either formal or informal, is in charge of elementary device maintenance and receive notifications from the system in case of anomalies. He also connects with the Case Manager at the Casa della Salute, supporting him with home insights and information.</p> <p>Case Manager: located at the Casa della Salute, he is in charge of validating system notifications and to enact related actions, connecting with end-user, caregiver, GP, and specialist doctor.</p> <p>GP: in charge of the general cure of the elderly person, receive notifications from the case manager when general cure provision is needed. Also, forward relevant information to the specialist doctor.</p> <p>Medical therapist: in charge of specific cure of elderly person main pathologies, gets notified from the Case Manager or the GP whenever information relevant to the specific cure strategy come out.</p> <p>HW and SW developers: Analytics service provider, in charge of continuous analysis of the data stream and of the inference of relevant information. Health-management service provider, in charge of bringing behavioural information into medical records management and visualization systems</p> <p>Technology provider: Provision, deployment and technical maintenance of the sensing equipment (IoT devices). Cloud-based infrastructure manager, watching over data acquisition, storage, and sorting.</p>
6	GOALS TO BE ACHIEVED	<p>Assisted person: Safety, comfort, prevention.</p> <p>Caregiver: Awareness, early notification, peace of mind</p> <p>Case Manager: prompt information, objective reporting of anomalies</p> <p>GP: pre-screening of patient notification, reducing unnecessary access</p> <p>Medical therapist: enhanced insight of the assisted person cure needs</p> <p>Technology providers: increase of customer networks</p> <p>Developers: increase of knowledge base</p>

1	<b>NAME</b>	<b>DSRER_LUC02 Sleep quality</b>
7	<b>SYSTEM CAPABILITIES</b>	<p>Smart IoT device, encompassing both sensing (under-mattress pressure pad) and network communication (Wi-Fi, no base station required) capabilities.</p> <p>Standard Wi-Fi WLAN equipment: modem-router, phoneline or 4G connection.</p> <p>Analytics module, working out trend and anomalies information.</p> <p>Cloud architecture, dealing with data management and storage.</p> <p>User interfaces toward different stakeholders, integrated/compatible with pre-existing software tools (e.g., medical health record management systems in use by local healthcare provider).</p>
8	<b>PRELIMINARY LIST OF SCENARIOS</b>	<p>SC_DSRER.2.2 Deployment and configuration</p> <p>SC_DSRER.2.3 Analytics (sleep quality) and data fusion</p> <p>SC_DSRER.2.4 Feedback and user interfaces</p>

1	<b>NAME</b>	<b>DSRER_LUC03 Mobility</b>
2	<b>MAPPING TO ACTIVAGE UCs</b>	AUC 1 - Daily activity monitoring
3	<b>CONTEXT OF USE</b>	<p>Evaluating physical activity is relevant to the assessment of the health status and of many medical conditions. Physical activity is inferred either indirectly, through traces coming from environmental sensors (room presence sensors, door opening, bed and chair sensors) and directly, through a wearable device (when applicable). In the former case, no interaction is required to the end-user, and only basic maintenance (battery replacement, upon system notification) is required to the caregiver. Reconstruction of mobility patterns is obtained through analytics, based on traces distribution in time. However, environmental devices are not suitable for discriminating among different persons living in the same environment (even though relative changes in the overall patterns can be observed anyway, this requiring additional interpretation to the caregivers). Thus, in selected cases, a wearable sensor will be introduced, to be worn (typically at belt) by the assisted person. The device features inertial sensors, and provide the system with a more accurate, inherently personalized view of physical activity. This come at an additional (light) user burden, who is requested to wear daily the device and to deal with battery recharge. To keep the device as small and light as possible, in fact, the rechargeable battery features limited capacity, and nightly recharge is needed (similar to mobile phones).</p> <p>The wearable device provides indicators such as the number of steps, the estimated energy expenditure (related to walking speed), by processing accelerometric data stream on board. Further features can be extracted</p>



1	NAME	DSRER_LUC03 Mobility
		<p>through cloud analytics. The device also features a programmable button, which can trigger user-requested action (e.g., request for assistance).</p> <p>Usage data are transmitted to the cloud, and feed analytics modules, to extract meaningful information (statistics, trends, anomalies). To this purpose, machine-learning techniques are exploited, with training being carried out on actual specific users to enable personalized assessment.</p> <p>Besides triggering the attention of the caregiver and of the case manager in case of gross anomalies, mobility information contributes to the fusion strategy, aiming at extracting synthetic and intuitive indicators (e.g., “traffic light” encoding) about needs of attention from caregivers of the end-user.</p> <p>The end-user himself may access visual reporting about quantitative and qualitative assessment of his physical activity</p>
4	STORY LINE	<p>Maurizio of 72 years suffered a stroke with consequent sinister hemiparesis and therefore there is a residual lack of strength both at the lower and upper left limbs. At the lower limb, the recovery was partial but such as to allow walking, albeit with support (three-foot). To climb and descend the stairs or to overcome an obstacle requires the help of Letizia, his wife. At upper limb, instead, the recovery has been minor and the use of the hand is very limited. Maurizio moves with difficulty at home and it is particularly difficult for him to get up from the armchair or chair and in daily life activities or in personal hygiene and nutrition; he spends an average of at least 4 hours per day sitting in an armchair. The system detects that Mauritiuis uses the chair daily for more than 8 hours for several days. The significant change in habit creates a signal that the case manager verifies it with the caregiver to validate the information, investigating the causes. Once informed, the GP of Maurizio will be able to evaluate the possibility of activating diagnostic-therapeutic interventions.</p>
5	INVOLVED USERS / TARGETED COHORTS	<p>Assisted person: +65yo, with CFS level between 3 and 6, recovering from stroke episodes and living at home.</p> <p>Caregiver: either formal or informal, is in charge of elementary device maintenance and receive notifications from the system in case of anomalies. He also connects with the Case Manager at the Casa della Salute, supporting him with home insights and information.</p> <p>Case Manager: located at the Casa della Salute, he is in charge of validating system notifications and to enact related actions, connecting with end-user, caregiver, GP, specialist doctor.</p> <p>GP: in charge of the general cure of the elderly person, receive notifications from the case manager when general cure provision is needed. Also, forward relevant information to the specialist doctor.</p> <p>Medical therapist: in charge of specific cure of elderly person main pathologies, gets notified from the Case Manager or the GP whenever information relevant to the specific cure strategy come out.</p> <p>HW and SW developers: Analytics service provider, in charge of continuous analysis of the data stream and of the inference of relevant information.</p>

1	NAME	<b>DSRER_LUC03 Mobility</b>
		<p>Health-management service provider, in charge of bringing behavioural information into medical records management and visualization systems</p> <p>Technology provider: Provision, deployment and technical maintenance of the sensing equipment (IoT devices). Cloud-based infrastructure manager, watching over data acquisition, storage, and sorting.</p>
6	GOALS TO BE ACHIEVED	<p>Assisted person: Safety, comfort, prevention.</p> <p>Caregiver: Awareness, early notification, peace of mind</p> <p>Case Manager: prompt information, objective reporting of anomalies</p> <p>GP: pre-screening of patient notification, reducing unnecessary access</p> <p>Medical therapist: enhanced insight of the assisted person cure needs</p> <p>Technology providers: increase of customer networks</p> <p>Developers: increase of knowledge base</p>
7	SYSTEM CAPABILITIES	<p>Smart IoT device, encompassing both sensing and network communication (Wi-Fi, no base station required) capabilities. Both environmental (presence, bed and chair occupation, door opening) and wearable sensors contribute to the use case.</p> <p>Standard Wi-Fi WLAN equipment: modem-router, phonenumber or 4G connection.</p> <p>Analytics module, working out trend and anomalies information.</p> <p>Cloud architecture, dealing with data management and storage.</p> <p>User interfaces toward different stakeholders, integrated/compatible with pre-existing software tools (e.g. medical health record management systems in use by local healthcare provider).</p>
8	PRELIMINARY LIST OF SCENARIOS	<p>SC_DSRER.3.2 Deployment and configuration</p> <p>SC_DSRER.3.3 Analytics mobility and data fusion</p> <p>SC_DSRER.3.4 Feedback and user interfaces</p>

1	NAME	<b>DSRER_LUC04 Monitor drug consumption</b>
2	MAPPING TO ACTIVAGE UCs	AUC 2 – Integrated care
3	CONTEXT OF USE	Compliance with prescriptions is of the utmost importance in the treatment of medical conditions. A wide range of technologies can be exploited to support compliance: here a low-tech, low-intrusiveness approach is adopted, to be integrated with caregiver support and possibly with pill-reminding apps

1	NAME	<b>DSRER_LUC04 Monitor drug consumption</b>
		<p>or similar tools. All pills are stored in a sensorized box, which is periodically restocked by the caregiver. The consumption schedule is known to the system, and each opening of the pill-box is tracked. This, of course, provides no certainty about the actual pill consumption, but allows to detect failures in doing so, with little or no intrusiveness in assisted person's habits.</p> <p>Data are transmitted to the cloud: missed consumption can be notified to caregiver and care manager, at the same time feeding analytics modules. Frequency and distribution of failures also provide behavioural hints and contribute to the fusion strategy, aiming at extracting synthetic and intuitive indicators (e.g., "traffic light" encoding) about needs of attention from caregivers of the end-user.</p>
4	STORY LINE	<p>Not meaningful.</p> <p>Gennaro is a 67 yo male that is recovering from a stroke he suffered of a couple of years ago. His GP prescribed a drug treatment that includes three different types of pills every day with different frequencies. Gennaro is not as diligent as required in the consumption of the pills, and he is not even able to report correctly if he was compliant with the prescribed treatment. His son visits him every Sunday, and put the pills in the corresponding boxes for the whole week. The boxes can sense if Gennaro is taking the pills from the box. The GP or the case manager can therefore monitor the compliance of Gennaro to the treatment and react accordingly.</p>
5	INVOLVED USERS / TARGETED COHORTS	<p>Assisted person: +65yo, with CFS level between 3 and 6, recovering from stroke episodes and living at home.</p> <p>Caregiver: either formal or informal, is in charge of elementary device maintenance and receive notifications from the system in case of anomalies. He also connects with the Case Manager at the Casa della Salute, supporting him with home insights and information.</p> <p>Case Manager: located at the Casa della Salute, he is in charge of validating system notifications and to enact related actions, connecting with end-user, caregiver, GP, and specialist doctor.</p> <p>GP: in charge of the general cure of the elderly person, receive notifications from the case manager when general cure provision is needed. Also, forward relevant information to the specialist doctor.</p> <p>Medical therapist: in charge of specific cure of elderly person main pathologies, gets notified from the Case Manager or the GP whenever information relevant to the specific cure strategy come out.</p> <p>HW and SW developers: Analytics service provider, in charge of continuous analysis of the data stream and of the inference of relevant information. Health-management service provider, in charge of bringing behavioural information into medical records management and visualization systems</p> <p>Technology provider: Provision, deployment and technical maintenance of the sensing equipment (IoT devices). Cloud-based infrastructure manager, watching over data acquisition, storage, and sorting.</p>

1	NAME	DSRER_LUC04 Monitor drug consumption
6	GOALS TO BE ACHIEVED	<p>Assisted person: Safety, care improvement and prevention.</p> <p>Caregiver: Awareness, early notification, peace of mind</p> <p>Case Manager: prompt information, objective reporting of anomalies</p> <p>GP: pre-screening of patient notification, reducing unnecessary access</p> <p>Medical therapist: enhanced insight of the assisted person cure needs</p> <p>Technology providers: increase of customer networks</p> <p>Developers: increase of knowledge base</p>
7	SYSTEM CAPABILITIES	<p>Smart IoT device, encompassing both sensing (pill-box opening) and network communication (Wi-Fi, no base station required) capabilities.</p> <p>Standard Wi-Fi WLAN equipment: modem-router, phonenumber or 4G connection.</p> <p>Analytics module, checking for compliance failure and working out trend and frequency information.</p> <p>Cloud architecture, dealing with data management and storage.</p> <p>User interfaces toward different stakeholders, integrated/compatible with pre-existing software tools (e.g., medical health record management systems in use by local healthcare provider).</p>
8	PRELIMINARY LIST OF SCENARIOS	<p>SC_DSRER.4.2 Deployment and configuration</p> <p>SC_DSRER.4.3 Analytics and data fusion</p> <p>SC_DSRER.4.4 Feedback and user interfaces</p>

1	NAME	DSRER_LUC05 Bodyweight monitoring
2	MAPPING TO ACTIVAGE UCs	AUC 2 – Integrated care
3	CONTEXT OF USE	<p>Bodyweight need to be checked on a regular basis. Weight changes (either slow or abrupt) may provide clues about many medical conditions. A Wi-Fi enabled bodyweight scale is exploited. The assisted person uses the scale as usual, with each measurement being automatically forwarded to the cloud. Abrupt changes (possibly indicating water retention, kidney insufficiency, heart failure risks) are promptly detected by streaming analytics, whereas weight tracking enters the behavioural picture as well, contributing to the fusion strategy, aiming at extracting synthetic and intuitive indicators (e.g., “traffic light” encoding) about needs of attention from caregivers of the end-user.</p> <p>The end-user himself may access visual reporting about bodyweight tracking and trends.</p>

1	NAME	DSRER_LUC05 Bodyweight monitoring
4	STORY LINE	<p>Elisa is a 72 yo lady, married with Antonio 76 yo. Elisa suffered from a stroke 3 years ago. She take care of her shape and measures each day her weight. With the help of their son Alfredo, she can check the trend of her weight on her, and confirm or disprove her perception on her weight. Meanwhile care and case manager, with the possible help of data analysis, can be aware of any significant change in Elisa's weight and, possibly, react accordingly</p>
5	INVOLVED USERS / TARGETED COHORTS	<p>Assisted person: +65yo, with CFS level between 3 and 6, recovering from stroke episodes and living at home.</p> <p>Caregiver: either formal or informal, is in charge of elementary device maintenance and receive notifications from the system in case of anomalies. He also connects with the Case Manager at the Casa della Salute, supporting him with home insights and information.</p> <p>Case Manager: located at the Casa della Salute, he is in charge of validating system notifications and to enact related actions, connecting with end-user, caregiver, GP, and specialist doctor.</p> <p>GP: in charge of the general cure of the elderly person, receive notifications from the case manager when general cure provision is needed. Also, forward relevant information to the specialist doctor.</p> <p>Medical therapist: in charge of specific cure of elderly person main pathologies, gets notified from the Case Manager or the GP whenever information relevant to the specific cure strategy come out.</p> <p>HW and SW developers: Analytics service provider, in charge of continuous analysis of the data stream and of the inference of relevant information. Health-management service provider, in charge of bringing behavioural information into medical records management and visualization systems</p> <p>Technology provider: Provision, deployment and technical maintenance of the sensing equipment (IoT devices). Cloud-based infrastructure manager, watching over data acquisition, storage, and sorting.</p>
6	GOALS TO BE ACHIEVED	<p>Assisted person: Safety, care improvement and prevention.</p> <p>Caregiver: Awareness, early notification, peace of mind</p> <p>Case Manager: prompt information, objective reporting of anomalies</p> <p>GP: pre-screening of patient notification, reducing unnecessary access</p> <p>Medical therapist: enhanced insight of the assisted person cure needs</p> <p>Technology providers: increase of customer networks</p> <p>Developers: increase of knowledge base</p>
7	SYSTEM CAPABILITIES	<p>Smart IoT device, encompassing both bodyweight sensing and network communication (Wi-Fi, no base station required) capabilities.</p>

1	NAME	<b>DSRER_LUC05 Bodyweight monitoring</b>
		<p>Standard Wi-Fi WLAN equipment: modem-router, phoneline or 4G connection.</p> <p>Analytics module, checking for abrupt changes and working out trend and frequency information.</p> <p>Cloud architecture, dealing with data management and storage.</p> <p>User interfaces toward different stakeholders, integrated/compatible with pre-existing software tools (e.g., medical health record management systems in use by local healthcare provider).</p>
8	PRELIMINARY LIST OF SCENARIOS	<p>SC_DSRER.5.2 Deployment and configuration</p> <p>SC_DSRER.5.3 Analytics and data fusion</p> <p>SC_DSRER.5.4 Feedback and user interfaces</p>

1	NAME	<b>DSRER_LUC06 Notify suspicious contingency situations</b>
2	MAPPING TO ACTIVAGE UCs	AUC 2 – Integrated care
3	CONTEXT OF USE	<p>Based on first-level analytics (i.e., trend and anomalies evaluated on different sensor sources), fusion is exploited to detect multidimensional patterns or specific events combinations requiring caregiver attention.</p> <p>Only information produced in other LUCs are used and therefore no specific hardware device is involved; thus, no user interaction is foreseen. The analytics back-end periodically checks for a set of features. Exploiting knowledge coming from caregivers, the analytics sensitivity to meaningful patterns can be enhanced (through improvement of the system training).</p> <p>Notification strategy can follow a programmable schedule, defining number and order or dependency of notified persons (caregivers, family members, case manager).</p>
4	STORY LINE	<p>Besides stroke after-effects, Nicola (80 y.o., living alone) suffers of congestive heart failure episodes, during which he feels more tired, tends to rest longer on the couch, while finding it more difficult to sleep in his bed, due to difficult breathing (caused by pulmonary oedema). Excess liquids accumulate in his body, resulting in an abrupt weight increase. All of the above symptoms can be assessed by sensing and analytics, so that Nicola's caregivers can get early notification when potentially unstable conditions occur. The case manager, upon checking with Nicola, alerts the GP, who may adjust diuretics and anticoagulant therapies.</p>
5	INVOLVED USERS / TARGETED COHORTS	Assisted person: +65yo, with CFS level between 3 and 6, recovering from stroke episodes and living at home.

1	NAME	DSRER_LUC06 Notify suspicious contingency situations
		<p>Caregiver: either formal or informal, is in charge of elementary device maintenance and receive notifications from the system in case of anomalies. He also connects with the Case Manager at the Casa della Salute, supporting him with home insights and information.</p> <p>Case Manager: located at the Casa della Salute, he is in charge of validating system notifications and to enact related actions, connecting with end-user, caregiver, GP, and specialist doctor.</p> <p>GP: in charge of the general cure of the elderly person, receive notifications from the case manager when general cure provision is needed. Also, forward relevant information to the specialist doctor.</p> <p>Medical therapist: in charge of specific cure of elderly person main pathologies, gets notified from the Case Manager or the GP whenever information relevant to the specific cure strategy come out.</p> <p>HW and SW developers: Analytics service provider, in charge of continuous analysis of the data stream and of the inference of relevant information. Health-management service provider, in charge of bringing behavioural information into medical records management and visualization systems</p> <p>Technology provider: Provision, deployment and technical maintenance of the sensing equipment (IoT devices). Cloud-based infrastructure manager, watching over data acquisition, storage, and sorting.</p>
6	GOALS TO BE ACHIEVED	<p>Assisted person: Safety, care improvement and prevention.</p> <p>Caregiver: Awareness, early notification, peace of mind</p> <p>Case Manager: prompt information, objective reporting of anomalies</p> <p>GP: pre-screening of patient notification, reducing unnecessary access</p> <p>Medical therapist: enhanced insight of the assisted person cure needs</p> <p>Technology providers: increase of customer networks</p> <p>Developers: increase of knowledge base</p>
7	SYSTEM CAPABILITIES	<p>Analytics module, implementing data fusion and checking for specific patterns, possibly indicating needs of caregiving.</p> <p>Cloud architecture, dealing with data management and storage.</p> <p>User interfaces toward different stakeholders, integrated/compatible with pre-existing software tools (e.g. medical health record management systems in use by local healthcare provider).</p>
8	PRELIMINARY LIST OF SCENARIOS	<p>SC_DSRER.6.1 Service specification design</p> <p>SC_DSRER.6.2 Deployment and configuration</p> <p>SC_DSRER.6.3 Analytics and data fusion</p> <p>SC_DSRER.6.4 Feedback and user interfaces</p>

1	NAME	DSRER_LUC07 Video visit
2	MAPPING TO ACTIVAGE UCs	AUC5 Exercise promotion
3	CONTEXT OF USE	<p>Rehabilitation protocols require frequent checks from different specialists. In particular, periodic visits from a physiotherapist are required, to assess evolution and to adjust physiotherapy prescriptions. Frequency of such visits is often limited (well below the optimal cadence) by the physiotherapist availability, who needs to visit many persons, possibly living on a very sparse territory.</p> <p>In order to improve care effectiveness, a “remote visit” procedure is defined, availing ourselves of video-communication facilities and of the collaboration of formal caregivers.</p> <p>The formal caregiver visits much more frequently the assisted person’s home, and can provide bridging toward the physiotherapist, either on a schedule basis or when needed due to unexpected events.</p> <p>The caregiver exploits a tablet/laptop, connected to the internet through the home Wi-Fi network. The tablet/laptop runs a video communication application, exploited to connect with the physiotherapist headquarter. Once connected, the physiotherapist may ask questions to the assisted person, propose specific tasks and observe reactions. Based on such outcomes, the physiotherapist may decide to plan a visit in person, or prescribe the assisted person adjustments of his physiotherapy routines, and instruct the caregiver on how supporting the assisted person in dealing with it.</p> <p>Of course, video session does not replace conventional physiotherapist session, but it is exploited to make the interaction with physiotherapist more frequent and immediate when needed. On the other hand, the physiotherapist may preliminarily evaluate situations with no need of moving to the patient home: this may help in optimizing the visits schedule and priorities, improving effectiveness of his action.</p>
4	STORY LINE	<p>Diego is a 73 yo senior with a stroke event in his recent past. The event has as a consequence a sinister hemiparesis. Diego is intended to recover the mobility of his arm as much as possible. When Maria, the social operator is visiting him, Diego asks has some question on the mobility of his arms. Maria already planned to connect with the physiotherapist via video and proposes to Diego to do some exercise in video call and solve his doubts directly with the specialist.</p>
5	INVOLVED USERS / TARGETED COHORTS	<p>Assisted person: +65yo, with CFS level between 3 and 6, recovering from stroke episodes and living at home.</p> <p>Caregiver: either formal or informal, is in charge of elementary device maintenance and receive notifications from the system in case of anomalies. He also connects with the Case Manager at the Casa della Salute, supporting him with home insights and information.</p>



1	NAME	DSRER_LUC07 Video visit
		<p>Case Manager: located at the Casa della Salute, he is in charge of validating system notifications and to enact related actions, connecting with end-user, caregiver, GP, and specialist doctor.</p> <p>GP: in charge of the general cure of the elderly person, receive notifications from the case manager when general cure provision is needed. Also, forward relevant information to the specialist doctor.</p> <p>Medical therapist, or physiotherapist in the LUC at hand. In charge of specific cure of elderly person main pathologies, gets notified from the Case Manager or the GP whenever information relevant to the specific cure strategy come out.</p> <p>HW and SW developers: Analytics service provider, in charge of continuous analysis of the data stream and of the inference of relevant information. Health-management service provider, in charge of bringing behavioural information into medical records management and visualization systems</p> <p>Technology provider: Provision, deployment and technical maintenance of the sensing equipment (IoT devices). Cloud-based infrastructure manager, watching over data acquisition, storage, and sorting.</p>
6	GOALS TO BE ACHIEVED	<p>Assisted person: Safety, care improvement and prevention.</p> <p>Caregiver: Awareness, early notification, peace of mind</p> <p>Case Manager: prompt information, objective reporting of anomalies</p> <p>GP: pre-screening of patient notification, reducing unnecessary access</p> <p>Medical therapist: enhanced insight of the assisted person cure needs, improve effectiveness and better planning.</p> <p>Technology providers: increase of customer networks</p> <p>Developers: increase of knowledge in the real time video communication</p>
7	SYSTEM CAPABILITIES	<p>Peer to peer audio/video streaming communication system, optimized for slow data connections.</p> <p>Working on Windows operating system.</p> <p>Central server needed to collect user connection data and dynamic addresses.</p> <p>User friendly and natural graphical user interface.</p>
8	PRELIMINARY LIST OF SCENARIOS	<p>SC_DSRER.7.1 Service specification design</p> <p>SC_DSRER.7.2 Deployment and configuration</p> <p>SC_DSRER.7.3 User interfaces</p>

1	<b>NAME</b>	<b>DSRER_LUC08 Monitors daily social habits</b>
2	<b>MAPPING TO ACTIVAGE UCs</b>	AUC7 Prevention of social isolation
3	<b>CONTEXT OF USE</b>	<p>Based on first-level analytics (i.e., trend and anomalies evaluated on different sensor sources), fusion is exploited to infer possible information about social activity and assisted person's mood.</p> <p>Only information produced in other LUCs are used and therefore no hardware device is involved; thus, no direct user interaction is foreseen. The analytics back-end checks for reduced activity pattern: most relevant data comes from motion sensors and home door sensors. Exploiting feedback coming from caregivers, the analytics sensitivity to assisted person's mood can be enhanced (through improvement of the system training).</p> <p>Should a social activity reduction be inferred, the care and case manager is notified, and reacts accordingly, by warning family members and caregivers.</p>
4	<b>STORY LINE</b>	<p>Mario had a stroke 2 years ago at age of 65. Since then he had to reduce the interaction with his friends. He managed to maintain relationship with few old friends that come visiting him to play cards every Thursday. The information elaborated from the door sensor data can make care and case manager aware of any possible change in this behaviour. Case manager could then contact the informal care giver to trigger action to improve sociality of Mario and avoid his isolation.</p>
5	<b>INVOLVED USERS / TARGETED COHORTS</b>	<p>Assisted person: +65yo, with CFS level between 3 and 6, recovering from stroke episodes and living at home.</p> <p>Caregiver: either formal or informal, is in charge of elementary device maintenance and receive notifications from the system in case of anomalies. He also connects with the Case Manager at the Casa della Salute, supporting him with home insights and information.</p> <p>Case Manager: located at the Casa della Salute, he is in charge of validating system notifications and to enact related actions, connecting with end-user, caregiver, GP, and specialist doctor.</p> <p>HW and SW developers: Analytics service provider, in charge of continuous analysis of the data stream and of the inference of relevant information. Health-management service provider, in charge of bringing behavioural information into medical records management and visualization systems</p> <p>Technology provider: Provision, deployment and technical maintenance of the sensing equipment (IoT devices). Cloud-based infrastructure manager, watching over data acquisition, storage, and sorting.</p>
6	<b>GOALS TO BE ACHIEVED</b>	<p>Assisted person: prevention of social isolation.</p> <p>Caregiver: Awareness, peace of mind</p> <p>Case Manager: holistic vision of assisted person's wellbeing.</p> <p>Technology providers: increase of customer networks</p>

1	NAME	DSRER_LUC08 Monitors daily social habits
		Developers: increase of knowledge base
7	SYSTEM CAPABILITIES	<p>Analytics module, implementing data fusion and checking for reduced social activity, possibly indicating needs of caregiving.</p> <p>Cloud architecture, dealing with data management and storage.</p> <p>User interfaces toward different stakeholders.</p>
8	PRELIMINARY LIST OF SCENARIOS	<p>SC_DSRER.8.1 Service specification design</p> <p>SC_DSRER.8.2 Deployment and configuration</p> <p>SC_DSRER.8.3 Analytics and data fusion</p> <p>SC_DSRER.8.4 Feedback and user interfaces</p>

## 2.2 Definition of local KPIs and targeted cohorts

### **Primary Endpoint**

- Reduction in relapses and hospitalization and physical resource utilization through surveys of essential daily activities for the attainment of the primary objectives.

In Emilia Romagna, there are 7380 new stroke adverse event each year.

Even considering the mortality (30 days and 6 months), about 5.000 persons who had a stroke adverse event each year survive and need care assistance. Obviously, the above number is related to just one year thus the percentage of the total population who had a stroke is higher and in sole Province of Parma (where the pilot is located) is near to 10.000 persons.

Direct cost for a person admitted in a stroke unit is about 5.250 euro, followed by the rehabilitation protocol (at least 30 days) which costs about 8.370 Euro each person. Thus, each year direct cost for managing stroke adverse event in a stroke unit are about 39 Million, while rehabilitation using the usual protocol costs about 54 Million each year.

15% of reduced hospital admission would save about 8 million Euro each year.

The data related from Parma's province in the year 2016 record a number of hospitalisation for stroke equal to 692 and of rehospitalisation following the first one, equal to 231. In the evaluation of the type of rehospitalisation the raw rate calculated as the number of hospitalisation following the first one / number assisted with first hospitalisation is equal to 33,38%: the objective of the project is the reduction of the 15% of the rate of rehospitalisation.

### **Secondary Endpoint**

Survey of the essential actions to the maintenance of a life of relationship and such communication to be allowed the life in family and in the social context, using the protocols and the rating scale of evaluation as express in the choice used in the criteria of inclusion.

Intends therefore:

- to reach a more active share of the process of assistance from the users in a rate of 25% valuate in comparison to the basal data.
- to reach an increase of the ability of relationship in a rate of 40% in comparison to the basal values.

Evidence on the benefit of the proposed solutions for active and independent living and quality of life and for cost saving in public expenditures, they will be measured according to the following KPIs:

Indicator (KPI)	Measurement tool	Target
<b>Impact on QoL</b>		
<b>Reducing adverse events related to comorbidities</b>	Data comparison through SOLE network and EHR (Emilia Romagna eHealth infrastructure)	35% reduction
<b>More active participation in the care process</b>	Social Interaction (Kane Scale)	25% increase
<b>Improved interaction paradigms</b>	User Experience Questionnaire; SPMSQ	>40%
<b>Improved physical well-being</b>	Barthel Scale, Activity of Daily Living Questionnaire (ADL); Instrumental Activities of Daily Living Scale (IADL)	15%
<b>Sustainability</b>		
<b>Reduction of hospital admission and days spent in hospital</b>	Administrative Data: Hospital Discharge Data (SDO)	15%
<b>Reducing frequent visits to the Emergency Department</b>	Administrative Data: Emergency Admission Data (PS)	30,00%
<b>Reduction of re-hospitalisation rate</b>	Administrative Data: Hospital Discharge Data (SDO), Home Care (ADI), Severe Acquired Disability (GRADA)	15,00%
<b>Users' relatives: decrease in days off work</b>	CarerQoL-7D Informal Care Questionnaire (still under discussion)	after +2 years: 25% 2 days per months

Monitoring and reducing consumption of assistive devices for post-stroke patients (observation from the beginning of the pilot)	Administrative Data: Assistive Device	
<b>Innovation and Growth</b>		
Number of Open Source components made available	Count publications on open source platforms like GitHub etc.	at least 5
Creation of a market place for apps addressing ageing well need and older people requirements	Record date of market place creation / count number of apps available	target date / target number of apps
Enable new services linked to IoT and increase the number of services provided by social assistance cooperatives	User Experience Questionnaire	Up to 30%
Increasing the size of the spin-off ICUBO: 50% new employees	Verify new employee contracts	

## 2.3 Technical Solution

### 2.3.1 Architecture of proposed solution

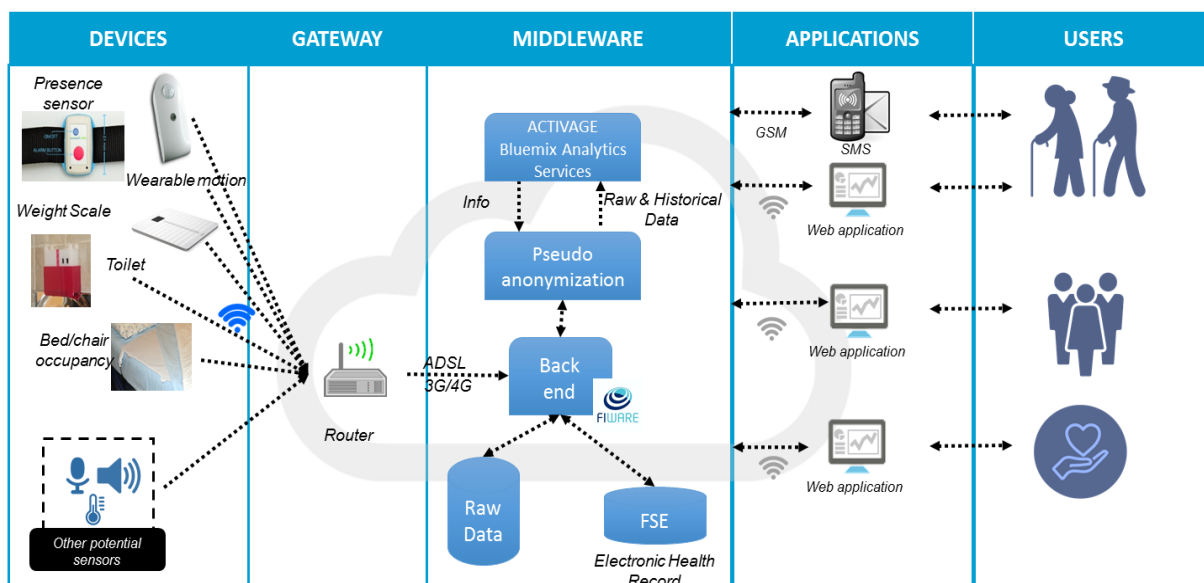


Figure 6 DS RER architecture

IoT Devices are all Wi-Fi connected and send directly through the router data to middleware, hosted at c2k premises in a protected environment regional node of Sole network; the cloud platform is enhanced with the analytics modules managed by IBM, Bluemix, that receives and manages pseudo-anonymised data. Users access information on WebUIs. The system can also send SMS to informal care givers

## 2.3.2 IoT infrastructure

The ACTIVAGE Home sensor kit features a heterogeneous network of many Wi-Fi-enabled devices. All sensors are battery operated: this choice was made to allow for an easier and less constrained pilot installation phase. In fact, sensor placement will not be constrained by the availability of a nearby power socket, nor will it require any cumbersome or anaesthetic cabling. At the same time, running pilot maintenance is supposed to be limited to battery replacement whenever the system detects that the sensor is running with a low battery level. This operation is simple and does not require the work of any qualified technician.

Overall, the complete sensor portfolio is composed as follows:

- Passive InfraRed (PIR) sensors for motion detection. Such sensors are useful to trace room occupancy habits of the users
- Magnetic contact sensors, useful for monitoring open/close states of different objects, including, for example, doors, drawers, medical cabinet.
- Bed occupancy sensor, to trace sleeping patterns
- Chair occupancy sensor, to gather information on how much time and when a user sits
- Toilet presence sensor, specifically developed to trace toilet use information
- Wearable sensor, useful for extracting information on user's activities (e.g. steps, activity levels, time spent sitting/lying etc.)

It is worth remarking that not all sensors are necessarily installed in each home, possibly just a subset, based on the monitoring needs of each user. Also, adoption of the wearable sensor may start at a later time with respect to the other "environment" sensors.

All the home sensors will connect to the home Wi-Fi router via WPS authentication, when plugged in for the first time. After the setup, sensors will rely on the MQTT protocol to transfer data to the cloud facilities. Each sensor is configured to transmit data both on an event basis (change in status detected) and as periodic reports (i.e. if no change is detected after  $n$  minutes, the status of the sensor is re-transmitted to the cloud).

Data are encoded as JSON strings, generally organized into two main fields:

- Status. This field details the status of the sensor. Regarding the above-mentioned sensor list, we report the associated status values:
  - Toilet: {1: presence detected; 0: absence}
  - Bed/chair: {1: presence detected, cable connected; 0: absence, cable connected, -1: cable disconnected, unknown presence}
  - Magnetic contact: {1: closed; 0: open}
  - PIR: {1: presence detected; 0: absence}
  - Wearable: { - to be defined - }
- Battery: a field for reporting battery voltage. It will be up to the cloud-based services to implement battery management services. I.e., when a low voltage is detected, the

system should return an alert to the designated users' user interface, prompting to replace batteries as soon as possible.

### 2.3.3 Scenarios specification

- AUC 1 - Daily activity monitoring
  - DSRER\_LUC01 Use of toilet
    - SC\_DSRER.1.2 Deployment and configuration
    - SC\_DSRER.1.3 Analytics (toilet usage) and data fusion
    - SC\_DSRER.1.4 Feedback and user interfaces
  - DSRER\_LUC02 Sleep quality
    - SC\_DSRER.2.2 Deployment and configuration
    - SC\_DSRER.2.3 Analytics (sleep quality) and data fusion
    - SC\_DSRER.2.4 Feedback and user interfaces
  - DSRER\_LUC03 Mobility
    - SC\_DSRER.3.2 Deployment and configuration
    - SC\_DSRER.3.3 Analytics mobility and data fusion
    - SC\_DSRER.3.4 Feedback and user interfaces
- AUC 2 – Integrated care
  - DSRER\_LUC04 Monitor drug consumption
    - SC\_DSRER.4.2 Deployment and configuration
    - SC\_DSRER.4.3 Analytics and data fusion
    - SC\_DSRER.4.4 Feedback and user interfaces
  - DSRER\_LUC05 Bodyweight monitoring
    - SC\_DSRER.5.2 Deployment and configuration
    - SC\_DSRER.5.3 Analytics and data fusion
    - SC\_DSRER.5.4 Feedback and user interfaces
  - DSRER\_LUC06 Notify suspicious contingency situations
    - SC\_DSRER.6.1 Service specification design
    - SC\_DSRER.6.2 Deployment and configuration
    - SC\_DSRER.6.3 Analytics and data fusion
    - SC\_DSRER.6.4 Feedback and user interfaces
- AUC5 Exercise promotion
  - DSRER\_LUC07 Video visit
    - SC\_DSRER.7.1 Service specification design
    - SC\_DSRER.7.2 Deployment and configuration
    - SC\_DSRER.7.3 User interfaces
- AUC7 Prevention of social isolation

- DSRER\_LUC08 Monitors daily social habits
  - SC\_DSRER.8.1 Service specification design
  - SC\_DSRER.8.2 Deployment and configuration
  - SC\_DSRER.8.3 Analytics and data fusion
  - SC\_DSRER.8.4 Feedback and user interfaces

Any LUC is described by similar scenarios that can be specified for the peculiarity of the LUC.

Service ID	Stakeholders involved	Description
<b>SC_DSRER.x.1 Service specification design</b>	Formal care giver - General Practitioner (GP) Formal care giver - Social Worker Formal Care giver - Medical Therapist Developers - SW ¶	Involved and responsible actor need to specify the terms the specific service need to be used.
<b>SC_DSRER.x.2 Deployment and configuration</b>	Formal care giver - General Practitioner (GP) Formal care giver - Case manager Developers - SW Technology providers - Deployers ¶	The solution is installed and configured in the system. Depending on the available configuration tools and the item to be configured, the activity is performed by different actors.
<b>SC_DSRER.x.3 Analytics and data fusion</b>	Developers - research institutions¶	The system allows to configure needed analytics.
<b>SC_DSRER.x.4 Feedback and user interfaces</b>	Formal care giver - General Practitioner (GP) Formal care giver - Social Worker Formal care giver - Case manager Formal Care giver - Medical Therapist Informal Caregiver¶	Information will be accessible by formal care giver on request. Informal care giver and assisted person can visualize a set of information. Some information will be notified to informal care giver (SMS)

Table 5 Services description



## 2.3.4 Data model and Information model

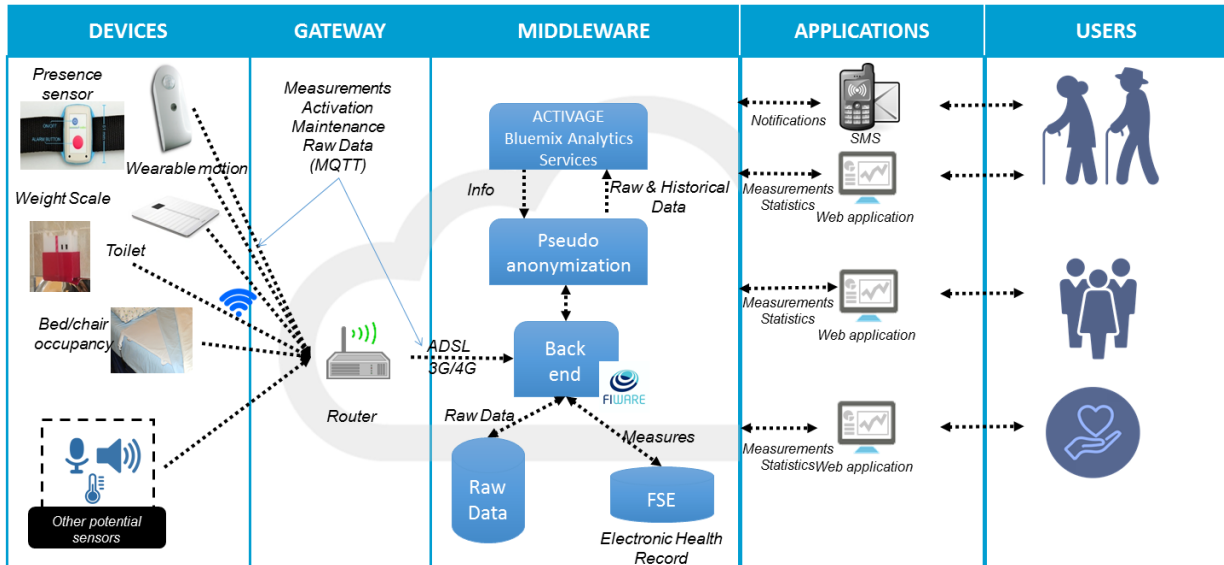


Figure 7: Information flow model of DS RER

ROLES	STAKEHOLDER
PRODUCER	Sensors with or without interaction of the assisted persons
CONTROLLER	LHA Parma
PROCESSOR	Cup 2000; IBM; CNR; Uni PR; LHA PR
CONSUMER	Developers - research institutions: IBM; CNR; Uni PR; Health care provider - Casa della Salute; Health care provider – hospitals: LHA PR Assisted person - Person with chronic conditions Formal care giver - General Practitioner (GP) Formal care giver - Case manager Informal Caregiver
SUPERVISOR	LHA PR

Table 6 Data stakeholders and roles

### List of Datasets

- DSRER.01.rawSensorsData
- DSRER.02.MeasurementsData
- DSRER.03.DataForAnalysis
- DSRER.04.AnalysisResults

Dataset name	DSRER.01.rawSensorsData
--------------	-------------------------

Data identification	
Data set description	<p>Data coming from the home environment through IoT sensors listed in Section 2.3.2.</p> <p>Monitored quantities include:</p> <ul style="list-style-type: none"> <li>room occupancy</li> <li>open/close states of doors, drawers, medical cabinet.</li> <li>Bed occupancy</li> <li>Chair occupancy</li> <li>Toilet presence</li> <li>Wearable sensor button (other wearable sensor outcomes to be defined)</li> <li>Battery status of each sensor</li> <li>Fault information (if any) from each sensor</li> </ul>
Source (i.e. which device?)	Data come from wireless sensors deployed in the home environment. Sensors are directly connected to the Internet through the Wi-Fi network. Data are collected on the cloud side through a MQTT broker.
Partners responsibilities	
Owner of the device	Devices will be given, on free loan, from UNIPR to the Assisted person - Person with chronic conditions
Partner in charge of data collection (if different)	UNIPR
Partner in charge of data analysis (if different)	IBM, UNIPR, CNR, C2K
Partner in charge of data storage (if different)	C2K
Standards and metadata	
Info about metadata (Production and storage dates, places) and documentation?	Not defined yet
Standards, Format, Estimated volume of data	Sensor data will exploit a JSON format over MQTT protocol. Finer details are still to be defined.
Data exploitation and sharing	
Data exploitation (purpose/use of the data analysis)	Raw data will feed (once anonymized) data analytics section, to extract behavioural indicators (trends, anomalies, group similarities) related to health.

Data access policy / Dissemination level (Confidential, only for members of the Consortium and the Commission Services) / Public	Access to raw data will be strictly limited to partners managing devices and communication (UNIPR and C2K). Once anonymized, data will be available to selected partners (IBM, C2K, CNR, UNIPR) for analytics purpose. Statistically aggregated data might be exploited for dissemination activities.
Data sharing, re-use and distribution (How?)	Not decided yet
Embargo periods (if any)	None
<b>Archiving and preservation (including storage and backup)</b>	
Data storage (including backup): where? For how long?	Not decided yet

Table 7 Dataset DSRER.01.rawSensorsData

<b>Dataset name</b>	<b>DSRER.02.MeasurementsData</b>
<b>Data identification</b>	
Data set description	The smart weight scale, installed at the user's home, provides the weight of the assisted person.
Source (i.e. which device?)	Data come from a wireless weight scale directly connected to Internet through the Wi-Fi network. The way in which data will be stored will be defined soon.
<b>Partners responsibilities</b>	
Owner of the device	Devices will be given, from LHA_PR to the Assisted person - Person with chronic conditions
Partner in charge of data collection (if different)	LHA_PR
Partner in charge of data analysis (if different)	IBM, UNIPR, CNR, C2K
Partner in charge of data storage (if different)	C2K
<b>Standards and metadata</b>	
Info about metadata (Production and storage dates, places) and documentation?	Not defined yet

Standards, Format, Estimated volume of data	Not defined yet
<b>Data exploitation and sharing</b>	
Data exploitation (purpose/use of the data analysis)	Measurement data will feed (once anonymized) data analytics section, to extract trends and anomalies related to the weight of the Assisted person.
Data access policy / Dissemination level (Confidential, only for members of the Consortium and the Commission Services) / Public	Access to measurement data will be strictly limited to partners managing devices and communication (LHA_PR and C2K). Once anonymized, data will be available to selected partners (IBM, C2K, CNR, UNIPR) for analytics purpose. Statistically aggregated data might be exploited for dissemination activities.
Data sharing, re-use and distribution (How?)	Not decided yet
Embargo periods (if any)	None
<b>Archiving and preservation (including storage and backup)</b>	
Data storage (including backup): where? For how long?	Not decided yet

Table 8 Dataset DSRER.02.MeasurementsData

<b>Dataset name</b>	<b>DSRER.03.DataForAnalysis</b>
<b>Data identification</b>	
Data set description	The set of Data for Analysis is composed by: Raw Data and Measurement Data, appropriately anonymized, filtered and pre-processed. Automatic analysis processes exploit this data set to produce the final results. Also, previous analysis results (time series) might be fed back to the analytics section (this becoming input data themselves).
Source (i.e. which device?)	Data for Analysis are produced starting from Raw Sensor Data, Measurement Data, previous analytics results.
<b>Partners responsibilities</b>	
Owner of the device	C2K
Partner in charge of data collection (if different)	C2K

Partner in charge of data analysis (if different)	IBM, UNIPR, CNR, C2K
Partner in charge of data storage (if different)	IBM/C2K (details under evaluation)
<b>Standards and metadata</b>	
Info about metadata (Production and storage dates, places) and documentation?	Not decided yet
Standards, Format, Estimated volume of data	Not decided yet
<b>Data exploitation and sharing</b>	
Data exploitation (purpose/use of the data analysis)	Indicators related to the condition of the well-being and health of the assisted person will be produced. These may include: trends, anomalies and predictions about future behavior.
Data access policy / Dissemination level (Confidential, only for members of the Consortium and the Commission Services) / Public	Data will be available to selected partners (IBM, C2K, CNR, UNIPR) for analytics purpose. Statistically aggregated data might be exploited for dissemination activities.
Data sharing, re-use and distribution (How?)	Not decided yet.
Embargo periods (if any)	None
<b>Archiving and preservation (including storage and backup)</b>	
Data storage (including backup): where? For how long?	Not decided yet.

Table 9 DSRER.03.DataForAnalysis

<b>Dataset name</b>	<b>DSRER.04.AnalysisResults</b>
<b>Data identification</b>	
Data set description	This Data Set is composed by the results of analysis and includes high-level information such as: behavioural trends and anomalies, probability estimation of meaningful events, averages and statistic reports, ...

Source (i.e. which device?)	Results are obtained by processing the Data for Analysis
<b>Partners responsibilities</b>	
Owner of the device	Analytics platform will be hosted by IBM. Specific analytics services may be owned by IBM, C2K, UNIPR, CNR
Partner in charge of data collection (if different)	IBM
Partner in charge of data analysis (if different)	IBM, UNIPR, CNR, C2K
Partner in charge of data storage (if different)	C2K
<b>Standards and metadata</b>	
Info about metadata (Production and storage dates, places) and documentation?	Not decided yet.
Standards, Format, Estimated volume of data	Not decided yet.
<b>Data exploitation and sharing</b>	
Data exploitation (purpose/use of the data analysis)	The final purpose of this data is to provide insights on the state of health of the user (assisted person) to: <ul style="list-style-type: none"> <li>- the Assisted person himself</li> <li>- Formal and informal caregivers</li> <li>- Health care provider (case manager at LHA_PR)</li> </ul>
Data access policy / Dissemination level (Confidential, only for members of the Consortium and the Commission Services) / Public	Results of analysis can be accessed by entity interested in the evaluation of the state of well-being of the final user, namely: <ul style="list-style-type: none"> <li>- the Assisted person himself (who owns data and authorize others)</li> <li>- Formal and informal caregivers</li> <li>- Health care provider (like, casa della salute; LHA_PR)</li> </ul>
Data sharing, re-use and distribution (How?)	Not decided yet
Embargo periods (if any)	None
<b>Archiving and preservation (including storage and backup)</b>	

Data storage (including backup): where? For how long?	Not decided yet
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Table 10 Dataset DSRER.04.AnalysisResults

## 3 Procedures

### 3.1 Legal and ethical assessment

The DS-4 RER study protocol was presented to the Ethics Committee for Parma according to the attached check list. The Ethics Committee is an entity that has the task of evaluating the ethical and legal aspects of a study protocol.

#### CHECKLIST DOCUMENTATION TO BE SUBMITTED FOR EXPERIMENTAL CLINICAL STUDIES WITHOUT PHARMACY

- Extended Protocol (Italian or English)
- Protocol synopses (in Italian),
- Curriculum Vitae of the Local Principal Investigator, dated and signed and which reports the certification of attendance at GCP courses or other topics related to clinical research
- Form of assumption of responsibility and absence of conflict of interest by the Principal Investigator and the Director of the Operational Unit involved for STUDY NO-PROFIT
- Information sheet and written informed consent form with version number and date (at the foot of each page)
- Permission to process personal data as per Privacy Guidelines 24/07/2008, with version number and date (at the foot of each page)θ
- Letter to be sent to a physician to inform you that your patient has been enrolled in a particular study (example: Annex D) with version number and date (at the foot of each page)
- Full insurance certificate and full insurance policy (if available) for cover of civil liability related to the trial
- Letter of Intent Insurance Cover Letter from the Local Principal Investigator (NO-PROFIT STUDIES)
- Material to be delivered to subjects (diaries, questionnaires, etc.)
- Declaration of the Promoter of Disclosure on Disclosure of Data in the case of Studies NO PROFIT WITHOUT PHARMACY
- Grant Agreement, Consortium Agreement, Proposal-SEP-210350610
- Formal adhesion of the study associates, who do not work at the Experimental Center but at another Operational Unit.

Ethical committee plan to evaluate the study protocol in October.

### 3.2 User recruitment and consent procedures

Screening will affect more patients (approximately 300) to avoid subsequent abandonment and will double randomized into two groups: 100 in the Experimental Group and 100 in the Control Group.

GPs, particularly afferents to the Nucleuses of Primary Cares of the involved Houses of the Health, make a pre-screening, identifying the patients that satisfy the criteria of pre-inclusion

Pre-inclusion criteria by general practitioners

The general practitioners are in charge of the identification of people potentially recruited, doing a preselection according to the following criteria:

- patients who have had a stroke
- greater than or equal to 65 years old



- be able to walk even though with help of assistive devices (cane, Walker, tripod, etc)
- Absence of serious cognitive impairment (allowed patients with mild cognitive impairment or mild-medium).
- presence at least one Caregiver;
- knowledge and availability to the use of IT technologies means to evaluate return data on electronic health dossier (FSE)

*Such patients will meet, together with the GP, the principal investigator at House of the Health premises. The Principal Investigator (PI) will evaluate the select criteria using scales and questionnaires. If the person accepts to participate, the PI illustrates the objectives of the protocol and collect the signed informed consent.*

#### **Inclusion criteria**

- Age  $\geq$  65 years
- Diagnosis of Stroke, independently from the onset
- State of disability according to the above proposal for a disability scale upper-middle type (score from 4 to 6) using:
  - The Barthel scale sec. Shaa with values between 48 and 74 (moderate dependency) with values between 18 and 32 motor activity part
  - Activity of Daily Living Questionnaire (ADL) with resulting values equal to or greater than 4 on 6, normalcy is 6 items on 6.
  - Instrumental Activities of Daily Living Scale (IADL) with resulting values equal to or greater than 5 on 8, , normalcy is 8 items on 8.
  - Performance status of cognitive-psychological with use of the scale value corresponding to 5 max SPMSQ (Short Portable Mental Status Questionnaire) mild or medium to slight deterioration
  - observational type scale for activities and social relationships(KANE)
  - User experience questionnaire
  - Carer QoL-7D
- presence of Comorbidities and drug therapies in place
- presence of at least one Caregiver
- knowledge and willingness to use computer tools to evaluate return data on the electronic health file (FSE)
- informed consent signed by user and care-giver

#### **Exclusion criteria**

- Disability greater than 6 but less than 4 in the scale above
- the absence of care-giver
- Barthel scale sec. Shaa with inferior values to 48 and superior to 74, with values motor departs inferior to 18
- -It respectively files ADL and IADL with inferior values to 3 on 6 and 4 on 8 presence of cognitive disorder with score in the SPMSQ staircase greater than 5;
- negative evaluation to the staircases KANE, User experience questionnaire, Carer QoL-7D
- not availability to the use IT systems, means to not be able to appraise the back data on the electronic sanitary issue (FSE)
- Not-acceptance of the informed consent of the user and the care-giver

*The process will detect 200 users with the characteristics that satisfy the requisite of admission and that can, with or without the help of the informal care giver, handle the digital tools, in particular the FSE (Fascicolo Sanitario Elettronico), the regional eHR.*

*The 200 users will be randomized in casual rate in two groups (100 in the group of experimentation and 100 in the group of control) and will be given them information of the inclusion besides to the caregivers and the care managers (general practitioner)*

## 3.3 Procurement

Procurement procedures will follow the standards of the public administration and of the entities to which they belong.

Laptop for video visit and Smart weight scale shall be procured by LHA PR.

Environmental sensor is produced by UniPR.

Pill dispenser is under evaluation. It could either be produced by UniPR or procured by LHA PR.

WindTre provides smartphone and routers.

## 3.4 Installation procedures

The deployment process starts as soon as the assisted person is enrolled.

WindTre plans the installation of the network (ADSL or UMTS) and routers at assisted person premise and communicate to C2k and UniPR the planning and the successful installation.

The assisted person is then visited by a technician that installs the sensor kit, provides the user with documentation and an initial small introduction.

The persons that act as installer will change along the project. The first installations will involve either C2k and UniPR, and possibly LHA PR.

The aim is to train a C2k installer that will follow a specific procedure. This procedure will be specified after the first installations, by M10/12.

The base procedure is the following:

LHA enrolls the patient (see 3.2 User recruitment and consent procedures)

LHA provide WindTre with apartment to be connected

WindTre plans the activation of the connection (ADSL or temporary 3/4G)

If a mobile connection is used, it could be activated by the installer directly

The deployment team plans the installations contacting the assisted person or their informal care giver

UniPR prepares the sensors kit.

The configuration of the sensor in the system can be done prior or during the activity at the assisted person premises. And depending from the availability of an online tools of configuration

- Offline in advance by UniPR, followed by a back-office configuration by installer or c2k developers
- Online in advance by deployment team or UniPR
- Online during the installation activity by the installer

The installer places the devices

The installer makes connection test for each device

The installer instructs the assisted person and the informal care giver on what has been installed and hands out manuals and service overview material.

The installer must collect and deliver to deployment team the following information:

- List of installed material (signed)
- Installation checklist completed
- Technical information, when available:
  - o IP
  - o Gateway
  - o Serial numbers
  - o Type of devices
  - o Location of the devices
  - o Any other relevant information

## 3.5 User training and support

End users that need training are:

- 1- Installers
- 2- Care manager
- 3- Case manager
- 4- Assisted person
- 5- Informal care giver
- 6- OOss (Operatori Sanitari, Social worker and Nurse)
- 7- Physiotherapist

Each type of user will receive training according to their level of involvement in the project and their skills.

Training will focus on three level of information:

- Overview of the project and of the specific role in the project
- Detailed training
  - o Classroom
  - o Online
  - o 1to1
- Reference material
  - o online/printed
  - o manuals, video, presentation, leaflets
- Support (see section below)

	Overview	Detailed	Reference
<b>Installers</b>	By Deployment team	Classroom	Online
<b>Care manager</b>	At enrolment by LHA PR	Classroom 1to1 if needed	Online Manual
<b>Case manager</b>	At enrolment by LHA PR	1to1 if needed	Online Manual
<b>Assisted person</b>	At enrolment by Care Manager (GP)	1to1 if needed	Online Video/presentation/leaflet

<b>Informal care giver</b>	At enrolment by Care Manager (GP)	1to1 if needed	Online Video/presentation/leaflet
<b>OOss (Social worker and Nurse)</b>	At enrolment by LHA PR	Classroom 1to1 if needed	Online Manual
<b>Physiotherapist</b>	At enrolment by LHA PR	He is participating in the definition of the project	Online Manual

Table 11 Training sessions details

## SUPPORT

First line of support will be done via call centre held by AuroraDomus

The request can be then forwarded to C2k Helpdesk for technical issues or to the case manager for organizational questions.

## 3.6 Operation procedures

At the domicile of the 100 users of the Experimental Group, daily activities will be monitored with IoT smart-sensors; the activities of the patients will be evaluated using the scales described in the criteria of inclusion by the Care assistant / Case manager assistant with the same formalities with which the group of control is examined.

The IoT device constantly produces with the minimum impact on person's normal behaviours, mainly in a transparent way, a flow of data that will be sent to cloud hosted at cup2000 premises. All data is then analysed in order to detect contingent situation that need be notified to informal care giver (e.g. the bed has been occupied for more than N hours; the door has been opened for 1 hour) and significant changes in normal behaviours of the assisted person. Information extracted from raw data (f.i. the quality of sleep) of directly coming from devices (f.i. the weight scale) is collected in patient's eHR and therefore accessible also by informal care giver.

Case manager and Care manager access the information on regular basis and possibly take action if changes in normal behaviour indicate a possible decline in person wellbeing.

The 100 users, members of Control Group, will not use technological systems for the activities of daily life. They will be treated under the conditions of normal assistance and evaluated according to the same scales, questionnaires and diaries or with a purely papery survey. Operators will use forms online to collect data, that will therefore be accessible by web, accessible in reasonable time by GPs via eHR or their mHR sw.

The users of both the groups will receive an average of 18 domiciliary visits from the Care assistant / Case manager.

## 3.7 Termination procedures



Figure 8 workplan Activage lifecycle

*From month 01 to month 09 (January 2017 - September 2017): elaboration and layout of the protocol of study and its organization.*

*From month 10 to month 15 (October 2017 - March 2018): collection of cases and randomization.*

*From month 16 to month 40 (April 2017 - April 2020): execution of the study.*

*From month 40 to month 42 (April 2020 - Jun 2020): Evaluation of the data, discussion and conclusions.*

The study ends at 40th month. Throughout the study run, the data captured by CK2000 and IBM is constantly monitored through the GP SOLE clinical SW and the Electronic Health Record, as well as from the user's own and caregiver's, from the care manager and case manager. After the fortieth forty-two months, the data will be processed by IBM via BlueMix via C2k according to the statistical data specified in section 3.8.

At the end of the project rather than at the drop out, for any reason, of a user, the data collected will be anonymized and used only for scientific and research purposes. It is still to be decided the procedure of dismissing the technology in possession of the users.

## 3.8 KPIs evaluation procedures

At the end of the project, after the two years of observation of the behaviours, the results will be examined according to the select endpoints described in the description of the protocol of study. We will evaluate how many cases have had a rehospitalisation, to respect the primary principal objectives and the level of own motor functionality inside domicile. Score will be appraised for reaching an equivalence or an improvement in comparison to the base scores. Subsequently will be proceeded to evaluate what IoT device has best performances in representing the function to explore.

In addition, the significance of a procedure for which technological systems have effectively made it possible to assess clinical conditions according to the primary and secondary objectives underlying the study protocol should be examined.

The statistical study will allow to analyse later whether the detection path, home-IoT - router--CUP2000 and IBM, allows to transfer the data in a statistically significant way.

Another point to be evaluated will be whether the best solution to know the situation of users and to evaluate the validity of the methodology of a more complete and appropriate detection of the clinical picture of the person with stroke is through the eHR and/or the the GP's eMR (electronic medical record), so called Cartella Clinica SOLE.

For the valuation of primary end point we will use the following indicators:

**As of the determination of the rehospitalisation rate**, considered 30 percentage of re-hospitalization in the population with stroke in the province of Parma in 2016 \*, goal to reach is significant redaction.

Therefore with 100 patients for experimental group it has a power of 0.72 for a  $p < 0.05$  to observe a reduction from 30% < at 15% of the primary end point.

For the valuation of secondary end point it will use the following indicators:

**As for the Barthel ADL and IADL** statistical values will be measured on percentage of users who will maintain the numeric values chosen the inclusion.

**Statistical values for KANE and SPMSQ** will be considered a statistical point lower compared with baseline values.

The statistic method is used to measure is Kaplan-Meier.

Questionnaire will be submitted to assisted persons along with the domiciliary visits. Results are stored online and available for elaboration of KPIs.

## 3.9 Data management procedures

### Data collection and management for the first group (experimental group).

#### Assumptions

- IBM consider the data source for all sensor and patient-related data to be C2k.
- IBM consider that we only get pseudonymized data without identification attributes from C2k.
- All transactions are assumed to happen over a secured network link.
- The used IBM Bluemix instance will be in the European Union.
- Data is only transferred and stored on IBM Bluemix if it is required for the analytics.
- Data Exchange (C2k ↔ IBM Bluemix)

IBM consider different ways for exchanging data between C2k and IBM Bluemix:

- Message Brokers, such as Bluemix Message Hub (via Apache Kafka, MQ Light or REST API) or MQTT
- Direct HTTP-based calls, e.g. REST, SOAP
- Direct database connections, e.g. via JDBC
- Data Storage (in IBM Bluemix)

Data within IBM Bluemix will be stored using the appropriate IBM Bluemix services, depending on the type of data and the intended analytics to be run on top of it. The following ways are currently considered:

- Relational database (e.g. dashDB)
- NoSQL Database (e.g. Cloudant)
- Graph Database (e.g. IBM Graph)
- Object Store (e.g. Cloud Object Storage)
- Time Series Database (TBD)

The data storage services are hosted and managed within IBM Bluemix and details can be found in the Bluemix services catalogue .

#### Objective

The analysis of the observed sensor data should help to better understand how different actions, internal factors and external factors are influencing the defined KPIs. Exploiting these

insights can then then lead to improvements of the quality of life of the patients. Methods that we currently consider are from the areas statistical analysis and machine learning.

The results of Bluemix's Services Analytics, will be available for questioning by queries in electronic health Dossier (Fascicolo Sanitario Elettronico); logs and data needed for subsequent evaluations will be kept in the repositories of CUP 2000 and the FSE will make access the patient data relevant for him, through the use of special interfaces.

### **Data collection and management for the control group**

During the execution of ACTIVAGE project, the users of the experimental group that will use the proposed technologies and the users of control group will be submitted a series of questionnaires:

- The Barthel scale sec. Shaa with values between 48 and 74 (moderate dependency) with values between 18 and 32 motor activity part
- Activity of Daily Living Questionnaire (ADL); Instrumental Activities of Daily Living Scale (IADL)
- Performance status of cognitive-psychological with use of the scale value corresponding to 5 max SPMSQ (Short Portable Mental Status Questionnaire) mild or medium to slight deterioration
- observational type scale for activities and social relationships(KANE)
- User experience questionnaire
- Carer QoL-7D

The operators will use online forms. Privacy and security will be granted.

The individualized systems are: The team site of the ACTIVAGE project, hosted on Sharepoint 2013 facilities of CUP 2000, or a dedicated web app and, after a verification of technical feasibility, will be also activated the GP's eMR (electronic medical record).

The GP's eMR is a web application of the region Emilia Romagna, currently in distribution, whose data are hosted in the servers of the Data Center of CUP 2000.

Data could be elaborated in the IBM cloud, under circumstances that guarantee the privacy.

If data is collected on the GPs' eMR, each GP is the controller of the data related to his patient.

In this case, GP can appoint certain operator to manage data.

The data remains accessible by patient's referring physician (GP) and could be used for research purposes, after anonymization and specific communication to the patient

# 4 Detailed planning

## 4.1 Definition phase

The activity done by all DS RER partner during the first months (until the end of May 17) has been described in D2.1 section *2UCD application* and following resumed:

Described in D2.1									
M1	M2	M3	M4	M5	M6	M7	M8	M9	
Definition of Parma Working Groups (PWG)									
	PWG - UC Group								
				Assisted persons and informal care giver interviews					
					PWG - Ethical Committee				
					Data scientists				→
		PWG – Communication							
								Digital Festival @Modena	
								Press Release	
		PWG – collaboration with LHA clinical engineering							
								Assisted person enrolment	→

As shown in the figure above, the activity is going on to define all aspect of the kick of the experimentation.

The activity of the PWG – communication has been described in *D8.5 Dissemination Plan and Reports* section *9.4 DS REGIONE EMILIA ROMAGNA*.

Resulting in the preparation of a press release initially planned for M6 and postponed to M9, and the participation at *After - Futuri digitali Modena Smart Life 2017* (<https://www.afterfestival.it/>)

The enrolment of the first set of assisted persons and their informal caregiver is planned at M9. A first set of 2-4 users will be enrolled. They will not participate in the clinical investigation as the set of 200 post stroke elderlies need to be randomly distributed between study and control groups.

This first set of users are the living lab of the solution.

In parallel the technical partners (C2k, UniPR, CNR and IBM) refined iteratively the platform architecture whose first version was discussed before the starting of the project and the design of the solution. The activity has been carried out with virtual or physical meetings, between two or more partners, depending on the aim of the discussion.

Same partners were involved in the Data Analysis discussions. Starting from M5 a set of focused conference call and 1to1 calls delineated three fields of analysis as starting point:

- Sleep
- Use of toilette



- Mobility

Data scientists (IBM, CNR and UniPR) will continue evolving capability of the solution in the analysis of this habits. Along with the evolution of the project new analytics will be explored following the evolving needs of stakeholders.

## 4.2 Implementation phase

The partner involved in the implementation of the solution from the technical point of view are C2k, UniPR, CNR and IBM. As described in previous section has been iteratively refined in specific conference call, physical meetings and a workshop.

Each partner implements a specific portion of the solution that could be implemented in parallel:

- C2k: platform, UIs, analysis algorithms
- IBM: data analysis platform (Bluemix)
- UniPR: Sensors, analysis algorithms
- CNR supervision and support, videoconferencing, analysis algorithms

The platform is based on FiWare and previous experience of FISTAR project, but it has been decided to modify the set of generic enabler and specific enabler to be used, considering their availability and robustness.

UniPR enhanced the set of sensors toward Wi-Fi and MQTT protocol, for increased performances.

The video conferencing tool was conceived by CNR and is evolving to meet user requirement and technical constraint.

Bluemix platform, used for data analysis, is used by data scientists to implement the algorithm that will meet requirement of the stakeholders, and will evolve along the project

Currently we are working of the point of contact of these modules:

- messages sensors  $\leftrightarrow$  platform
- exchange of information platform  $\leftrightarrow$  Bluemix

The first 2-4 users will be chosen as Living Lab Testing users, as described in following section.

## 4.3 Living lab testing

In the framework of ACTIVAGE project, approximately 100 pilot experimentations are planned for the DS\_RER. Each pilot consists of the installation of a home-based IoT sensors system for monitoring the end-users' behaviour and habits.

By some preliminary consideration, LHA of Parma, that has the task of the end-users' recruitment, estimates that about 300 "potential users" will be contacted: 100 will be actual users participating in the trial, 100 will be the control group, and 100 will be backup user in case some participants decide to withdraw from the experimentation.

Among this set of potential users, a sample of 2-4 users will be chosen as Living Lab Testing users.

The Living Lab installations will precede, and then proceed in parallel, those of the actual trial experimentation.

The purpose of these firsts experimentation is to implement a preliminary test installation of the IoT system, in realistic work conditions.

Living Lab Testing activities aimed to pursue the following goals:

- Testing the installation procedure - it must be simple and not invasive for the user
- Check the stability of the home Wi-Fi network and the continuity of the Internet connection
- Ensure that IoT sensors work properly in a realistic environment (the user's home)
- Estimate the battery life of IoT sensors
- Test if the battery replacement procedure is an activity that can be carried out by the end user (or his/her caregiver)
- Verify that the data produced by the system is sent and stored in the CUP2000-database, making sure they are correct and consistent

From a scientific point of view, it is important to note that users identified for the Living Lab Testing will not participate in the clinical investigation. The data produced by the Living Lab Testing installations will not be used in order to produce statistical surveys or medical results.

## 4.4 Deployment and operation

LHA PR enrolls 2-4 users during M9, as Living Lab Testing users, as described in previous section.

The ramp up of the deployment is planned for April 2018, after 200 potential assisted persons have been selected and randomly distributed between study and control group, the first receiving the technology. It will be planned tightly, considering the field experience gained during the first months of the Demonstrate phase.

The platform (FiWare generic enablers, UIs, communication module, other private cloud modules) and Bluemix are under deployment along with the implementation.

At beginning of M10 the first user will be visited and all environmental sensors will be installed in the apartment and locally tested.

Pill dispenser and weight scale devices are still under evaluation and will be installed in a later moment, planned at M11.

The technology for *DSRER\_LUC07 Video visit* is planned for M11. It is not dependant from the rest of platform.

During this first 6 months (M10 – M16) all procedures (deployment, installation, training, operation, support) will be improved and optimized to ramp up to 100 users in the less time frame as possible.