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eCare

Digital solutions for frailty prevention in old adults

Pre-Commercial Procurement (PCP)

Tender Document 2 (TD2)

Challenge Brief

Deadline to submit an offer:

15th September 2021, at 12:00 midday (CET)

Important notice: This Request for Tenders is composed by a set of documents listed hereafter:

- TD1 – Request for Tenders
- TD2 – Challenge Brief
- TD3 – Tender forms
- TD4 – Framework agreement
- TD5 – Specific contract template for phase 1
- TD6 – Annexes

All documents available on *https://ecare-pcp.eu/* website.

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Acronyms list

AgID: Agenzia per l'Italia Digitale
AI: Artificial Intelligence
ASL BN: Azienda Sanitaria Locale Benevento
BP: Blood Pressure
bpm: beats per minute
CDAr2: Clinical Document Architecture. Release 2
CERT: Computer Emergency Response Team
CH: Challenge
CR: Commercialization requirements
CSI: Consorci Sanitari Integral
DCCT: Diabetes Control and Complications Trial
EHR: Electronic Health Records
EQ-5D: Standardized instrument for measuring generic health status
EU: European Union
GDP: Gross Domestic Product
GPDR: General Data Protection Regulation
HDL: High-density lipoprotein
HL7: Health Level Seven
HTTPS: Hypertext Transfer Protocol Secure
ID: Identification
IFCC: International Federation of Clinical Chemistry
IHE: Integrating the Healthcare Enterprise
JAG: Jaggaer
LDL: Low-density lipoprotein
LRR: Legal and Regulatory Requirement
NFR: Non Functional Requirement
NGO: Non-Government Organization
OSR: Organizational and staff
PCP: Pre-Commercial Procurement
PMR: Parameters and unit's measurements
RIS-PACS: Radiology Information System – Picture Archiving and Communication System
SCMA: Santa Casa da Misericordia da Amadora
SDR: Santander City Council
SILO: Science and Innovation Link
TBM: Ticbiomed

UAAG: User Agent Accessibility Guidelines
UC: Use Case
UI: User Interface
UKA: Universitätsklinikum Aachen
UX: User Experience
VPN: Virtual Private Network
WCAG: Web Content Accessibility Guidelines
XML: eXtensible Markup Language

1 Introduction

1.1 eCare project

1.1.1 Context and main objective

Longevity is one of the biggest achievements of modern societies. In fact, children born after 2011 have a one in three chances of reaching their 100th birthday. By 2020, a quarter of Europeans will be over 60 years of age. Combined with low birth rates, this will bring about significant changes to the structure of European society.

In this regard, population ageing has profound implications for the planning and delivery of health and social care. EU spending on medical care is currently growing faster than GDP. According to the 2015 Ageing Report, the total ageing costs in the euro area are projected to increase by 1.5 percentage points of GDP, from 26.8% in 2013 to 28.3% in 2060.

eCare is a European project aiming to deliver disruptive digital solutions for the prevention and comprehensive management of frailty to encourage independent living, wellbeing and to relieve health and care services budget pressure, throughout the implementation of a Pre-Commercial Procurement (PCP) scheme.

The main objective of eCare is to launch a PCP call for tender to deliver disruptive digital solutions for the prevention and comprehensive management of frailty to encourage independent living, wellbeing and to relieve health and care services budget pressure. Solutions sought should improve outcomes for frailty in old adults entailing the physical and the psychosocial factors. The target groups are the pre-frail/frail old adults with emphasis on those that feel lonely and/or isolated.

The project will procure the development, testing and implementation of digital tools/services and communication concepts to facilitate the transition to integrated care models across health and social services.

1.1.2 Description of the consortium

The consortium carrying out eCare project activities is formed by eight European organizations belonging to Italy, Germany, Portugal, and Spain and committed to digital transformation in healthcare. Four of them are the procurers for the PCP and the remaining four are healthcare specialists with strong research capabilities, has coordination, technical and communication support roles.

Procurers are public institutions being a group formed by:

- **Azienda Sanitaria Locale Benevento** (ASL BN), one of the 7 Local Health Agency of the Campania Region. It is a public entity with managerial, technical and financial autonomy. It carries out the tasks of the national health system in the geographical area of the province of Benevento. ASL BN is organized in 5 districts including hospitals and three multifunctional health centers, including prevention and mental health departments. ASL BN is the lead procurer and therefore it is the beneficiary appointed by the buyers' group to coordinate and lead the joint procurement, as member of the procurers group. The lead procurer awards the R&D service contracts in the name and on behalf of the buyers group. The lead procurer and the public procurers in the buyers group are contracting entities as defined in the EU public procurement Directives. The Consortia will have all selected tenderers paid by the lead procurer (centralized payment modality). (http://www.aslbenevento1.it/)

- **Universitätsklinikum Aachen** (UKA), The University Hospital Aachen is a supramaximal care provider that combines patient-oriented medicine and care, teaching and research at an international level. With 34 specialized clinics, 25 institutes and five interdisciplinary units, the university hospital covers the entire medical spectrum. Development of innovative, telemedical solutions is part of the mid to long-term strategy of UKA (https://www.ukaachen.de/)

- **Consorci Sanitari Integral** (CSI), a public organization which manages 14 centres in the Barcelona and Baix Llobregat areas of Catalonia, in Spain. The distribution of centers includes: - specialized care, primary care, sociohealth care and social area (assessment service for the degree of disability, dependency assessment service). (https://www.csi.cat/)

- **Santander City Council** (SDR), local government of Santander city of the Cantabria region in Spain, well-known for having setup a unique living lab for technologies, applications, and services experimentation. The city of Santander is the capital of the Cantabria region in the north of Spain and has a current population of approximately 173,000 inhabitants. (http://santander.es/)

Consultant experts are formed by these entities:

- **SILO Science and Innovation Link** (SILO), a consulting company specialized in the field of R & D & i and business development in technological sectors. The public-private experience at the highest level of the management team allows the design, implementation, management and evaluation of tailor-made solutions for all agents of the innovation ecosystem. SILO has a unique knowledge of the health and biotechnology sector that allows the company to work with hospitals, administrations and innovative companies in the biotechnology, pharmaceutical and health technology sectors.

  SILO Company is divided into six business units: Life Sciences, Research, Digital, Public Sector, Funding and Ventures. Two of them, Public Sector and Funding, will be directly involved in the project.

  The Public Sector Unit address all facets of public procurement in all sectors and organizations, accompanying them throughout the process of generating the contracting, bidding and awarding file until the end of the project. The support to clients is given either with specific actions in specific tenders or through comprehensive support to the contracting area with technical public procurement offices. Due to the nature of SILO and due to the particularity and complexity inherent to R & D & i, a large part of the work focuses on innovation public procurement processes.

  The Funding Unit offers a comprehensive support in the framework of regional, national and European projects from the definition of the project idea, through the execution of the activities or requests for financing to be developed, the follow-up and the financial and technical justification.

- **Jaggaer** (JAG), the brand name of BravoSolution España SAU, a leading international provider of Supply Management Excellence, delivered through software, professional services and category expertise, with a mission to generate value by supporting its clients in the improvement of procurement processes. It works with supply management to address each business's unique processes, stakeholders and goals to deliver tailored solutions across the entire supply management cycle. With over 60,000 procurement professionals in 60 different countries using its technology and services, offers leading software, practice innovation and expertise to ensure that supply management is aligned with the company's strategic objectives to drive business growth. It has participated as a

former coordinator of the project and currently is the responsible partner of the design and management of the eTendering platform for the preparation and submission of the tenders.

- **Santa Casa da Misericordia da Amadora** (SCMA), an NGO founded in 1987, oriented to Human dignity in a sustainable and organized way, it has the mission to provide, create and develop appropriate social services according to Amadora Community needs, promoting solidarity, quality of life and human dignity. Its objectives are empowering individuals/families in a disadvantage position; Deliver Social Responses to the Community, suitable to the diagnosis of needs, on Educational, Elderly, Health and Social Areas; Develop Integrated &Proximity Services; Work in Partnership with the 3 Sectors of Economy; Maximize Internal/External Social Accountability; Transference of Knowledge and Good Practices. Nowadays, the Organisation has a work force of 470 employees and delivers daily support to 5300 Beneficiaries, in Amadora Council. (https://www.misericordia-amadora.pt/)

- **Ticbiomed** (TBM), a cooperative cluster of ICT companies, Universities, Healthcare providers, and Public Institutions that work together to promote eHealth innovation in the Region of Murcia (Spain). It is legally a non-profit business association, founded under the auspices of the Universities, Enterprises and Research regional Ministry. It counts currently more than 50 members at national level gathering Healthcare, ICT organizations and other stakeholders. In 2010 the association was awarded with the ´Excellence label´ for its strategic plan and since, joined the national database of excellent Innovative Enterprise Associations. It also holds a ´Gold label´ from the European cluster management excellence programme awarded in 2016. As part of its core expertise, the association has specialized in the identification of unmet needs and challenges in Health that can be solved with the use of ICT in order to spot areas of opportunity for the development of profitable eHealth innovation, following a methodological approach when interacting with potential customers and end-users (healthcare managers, professionals, patients, etc.). TBM also makes a strong emphasis on Business Modelling, to realistically address market opportunities in the eHealth space. The association has a track record of business mentoring and support to entrepreneurs and SMEs, which can be also applied to the development of project-specific exploitation plans. (https://ticbiomed.org/en/)

1.1.3 eCare project in a nutshell

- Starting date: 1st September 2019
- Duration: 54 months
- Global Project Budget: 5,040,000 €
- PCP Budget: 3,920,000 € (VAT included)
- Webpage: https://ecare-pcp.eu/
- Funding: European Union's Horizons 2020 under grant agreement No 856960

1.2 Introduction to the PCP

1.2.1 Strategic foundation and progress expected

The strategic vision for the eCare project was founded in the following findings and considerations that emerged from the current state-of-the-art:

- Longevity is one of the biggest achievements of modern societies. In the last 20 years, people all over the world have, on average, gained 6 years of life expectancy. Europeans are living longer than ever before, and this pattern is expected to continue due to unprecedented medical advances and improved standards of living.

- Combined with low birth rates, longevity will bring about significant changes to the structure of European society, which will impact on our economy, social security, and health care systems.
- Population ageing has profound implications in the planning and delivering of health and social care.
- Despite the life expectancy rise, the quality of life in these latest years may be poorer due to frailty and long-term conditions.
- The most problematic expression of population ageing is the clinical condition of frailty. Frailty develops because of age-related decline in multiple physiological systems, which collectively result in an increased vulnerability to sudden health status changes triggered by relatively minor stressor events.
- Frailty does not occur in silos, it usually comes along associated with another risk factor, loneliness. Older people who experience important levels of loneliness are at increased risk of becoming physically frail.
- Ageing, frailty, and loneliness constitute overlapping conditions submitted to multiple health and care interventions. This combination demands a high specialization of hospital and domiciliary care and a constant struggle to improve efficiency and quality of healthcare provision.
- Integrated care offers perhaps the greatest opportunity for preserving function in late aging; however, health and care systems are currently not organized to deliver integrated care, but rather to identify and treat acute illness.
- Whereas the earlier conceptualizations of frailty were dominated by a medical paradigm focusing on a biological syndrome, the evidence of a bidirectional relationship between frailty and loneliness has led recently to the adoption of a broader multi-dimensional approach to acknowledge psychological elements like quality of life, as well as social elements such as lack of social contacts, situational factors and wellbeing.

Having the above context in consideration, eCare aims to pursue the following progress on the development of the state of the art on ageing, frailty, and integration of care:

- Creating holistic programs and innovative partnerships to address needs, from physical conditions to mental health, and psychosocial risk factors.
- Creating and delivering a better methodology for the screening and identification of pre-frail status in older adults that may be progressively adopted by health and care delivery services across EU.
- Procuring the development, testing and implementation of digital tools/services and communication concepts to facilitate the transition to integrated care models across health and social services and country specific cross-institutional set-ups, including decentralized procurement environments and collaboration across institutions.
- Enabling the procurers, health, and care services providers to share knowledge, test results and needs to better coordinate the primary and community care towards more local responsibility for care services, monitoring and rehabilitation.
- Identifying innovative solutions encompassing a stronger focus on early diagnosis.

- Shifting from reactive disease management to screening, triage, anticipatory care and prevention on functional decline and frailty through innovative, coordinated, and comprehensive prevention, assessment, and integrated solutions for frailty management.

1.2.2 Frailty definition in eCare project

In order to identify the frailty definition that best served the purpose of the eCare project a literature review was done allowing to identify the chosen definition to be used throughout the project. The one proposed by Apostolo, et al. in *Effectiveness of interventions to prevent pre-frailty and frailty progression in older adults: a systematic* review (2018) was nominated:

> Frailty is an age-related state of decreased physiological reserves characterized by a weakened response to stressors and an increased risk of poor clinical outcome. Frailty predisposes falls and fractures, disability, dependency, hospitalization, and institutional placement, and ultimately leads to death. It can be preceded by, but also occurs in the absence of, chronic disease. According to some authors, this clinical condition results from decrease in reserves across multiple physiological systems that are normally responsible for healthy adaptation to stress. Alternatively, it is considered that frailty is due to critical accumulation of dysregulation in important signalling pathways and subsequent depletion of homeostatic reserve and resilience. Other authors describe this state of increased vulnerability as being associated with the reduced capacity to compensate ageing-related molecular and cellular damage. Independently of pathophysiological conceptualization, it is assumed that frailty is a dynamic process that leads to a spiral of decline in various functional domains and that exacerbates risk of geriatric syndromes.

This definition revealed to be comprehensive enough for the purpose of the Project, acknowledging frailty as a dynamic process that leads to a spiral of decline in various functional domains, outlining that frailty has no single dependence on chronic diseases and that the poor clinical outcomes are related to a depletion of homeostatic reserves and resilience that reduce the capacity to compensate ageing-related molecular and cellular damage.

1.2.3 Common terminology definition in eCare project

A common terminology definition to be used in eCare project has been elaborated and agreed by the members of the consortium. This terminology is aimed to be used throughout the project, both for helping the proposers to understand the nature of the requirements and for further communications among procurers and awarded proposals.

This terminology is summarized in the following table that holds the equivalence between each common term and its definition within eCare:

Table I. eCare project terminology definition

Common term	Definition within eCare project
Old adults	Target and end users
IT managers	Procurer's IT staff
Pilot site manager/facilitator	Procurer's staff in charge of eCare project
Old adults' family	Old adults' family (considered also as end users)
Informal caregivers	Caregivers in charge of old adult daily care (with non-economic rewarding)
Social care professionals	Procurer's social care and externalized services staff professionals
Health care professionals	Procurer's health care and externalized services staff professionals
Social care volunteers	Social care volunteers
Caregivers	Professional in charge of old adults' daily care

1.2.4 Preparatory activities for the PCP

- **Methodology**

The eCare project has had the vision of introducing collaborative models focused on co-creation and co-design methodologies and solutions as well as on person centeredness approaches. This led to the decision of implementing a collaborative methodology both in what regards to its conceptual and processual framework.

The conceptual approach was based on a collaborative strategy to gather the active involvement of both Procurers/Partners and reference stakeholders in the different steps of the development of the outputs. Co-creation and co-design methodologies were applied both at the Consortium level as well at as the stakeholder's level (potential end users, social/healthcare professionals and IT internal staff), involving, all the time, the key stakeholders, gathering their feedback and introducing the proposals and suggestions into the design of the outputs.

- **Stakeholders' consultation**

The identification of the strategic demand-side stakeholders was done both at the Consortium level so that each procurer could conduct their focus groups, and co-creation workshops with the users inside their organisations, and at an external level to validate the needs with organisations outside the Consortium that are relevant for the topic in question. For internal stakeholders 3 different profiles were selected: end users, social and healthcare professionals and IT staff.

External stakeholders are considered in the Project the key players/Organisations from the demand side, with know-how and track record in the field of ageing, social and/or healthcare, frailty management at a European level, both making part of the networking of the project´s partners, as well as some reference clusters operating in the field of eCare. The analysis carried out resulted in 86 external Organisations and individuals identified by the consortium. The list comprehends Organization's Directors, CEO's, Presidents, and representatives; Heads of innovation; R&D managers and consultants; Project Coordinators; Associate Professors and Researchers. The distribution of type of organizations to which these stakeholders belonged is summarized in the following table.

Table II. Classification of types of external stakeholders' organizations

Type	TOTAL
Social care	12
Healthcare	14
Social and healthcare	10
Patients-related	14
Other (Academia, clusters, consortia, and decision makers)	36

- **Demand-side stakeholders' questionnaire**

A questionnaire was prepared in order to get an understanding of older adults' needs as well as social and healthcare professionals' for recognising needs and delivering care in the management of frailty and loneliness; to gain a comprehensive understanding of the barriers that hinder the exploitation of the technology and to understand to what extent the situation changes in different European countries. The questionnaire was developed to be shared with external demand-side stakeholders as well as with any other interested stakeholder acting on the demand side, through the eCare project website.[1]

- **Focus groups**

Focus group sessions were created and facilitated in each of the 4 Procurers' sites – Campania (Italy), Barcelona (Spain), Santander (Spain) and Wroclaw (Poland) as a way to achieve a deep understanding of the actual unmet needs, correlating them with the ones defined at the proposal phase from a biopsychosocial perspective, as well as to identify potential strategies to overcome those needs. A total of 122 participants were invited and engaged by the procurers according to a pre-defined profile and level of expertise. Each procurer organized 3 sessions held between December 2019 and January 2020.

Table III. Focus groups participants summary

Profile	Barcelona	Santander	Campania	Wroclaw	TOTAL
End users	9	18	15	20	**62**
Social and healthcare professionals	12	9	11	5	**27**
IT staff	12	2	4	5	**23**

- **Prior Information Notice (PIN) publication**

PIN publication was made on 5th August 2020 in the Ted (Tenders electronic daily) supplement to the Official Journal of the EU. It can be reached through the link: https://ted.europa.eu/udl?uri=TED:NOTICE:367803-2020:TEXT:EN:HTML .

- **Open Market Consultation (OMC)**

In preparation of the PCP call for tender, an OMC with potential tenderers and end-users was held to broach the views of the market about our scope. The purpose of the OMC was to canvass wide stakeholder opinion on the suitability of eCare PCP. With the market consultation, the consortium

[1] https://ecare-pcp.eu/omc/ , https://ec.europa.eu/eusurvey/runner/eCare-demand

got insight into the market, the state of the art and future developments in order to tune the procurement with the right and feasible scope.

The OMC related activities have been a series of participative webinars and questionnaires.

4 iterative webinars to present the eCare challenge and open a dialogue with the market about the procurement scope: one conducted in English and the others in the procurers' languages (Polish, Spanish and Italian).

Table IV. Summary of eCare webinars

Date	Procurer	Language
21st October 2020	Wroclaw (A. Falkiewicz Specialist Hospital) [Poland]	Polish
22nd October 2020	Santander (Ayto. Santander) + Barcelona (Consorci Sanitari Integral) [Spain]	Spanish
29th October 2020	Campania (Azienda Sanitaria Locale Benevento) [Italy]	Italian
3rd November 2020	International webinar (all procurers)	English

To complement the analysis, an online survey (**supply-side OMC questionnaire**) has been prepared and published with the purpose to get knowledge about the already existing technologies[2].

All the proceedings of the OMC have been published in https://ecare-pcp.eu/omc/ and are consequently available to all OMC participants and other interested stakeholders. The webinars were recorded and are available in the same webpage.

It was made clear to all participants that participation in the OMC events was not a prerequisite for submitting a tender for this call.

- **Matchmaking platform**

Companies that cannot cover the whole eCare PCP solution area encouraged to team up with other companies. Especially for SMEs it may not be easy to cover the whole bandwidth. Furthermore, having to deploy field solutions in 3 different countries can be also a barrier even for bigger ones.

In order to ease contacts among national and international companies that are aware about the project and interested in participating or simply offer useful services for others, a matchmaking platform has been established during the OMC. This platform is intended to be alive and active until the closure of the Call for Tenders.

The matchmaking platform is also maintained in the eCare website. More details are provided in https://ecare-pcp.eu/matchmaking/

[2] https://ecare-pcp.eu/omc/ , https://ec.europa.eu/eusurvey/runner/eCare-supply

- **Frequently Asked Questions (FAQ)**

During the OMC and before the closing of the call for procurement, suppliers can submit questions relating to the eCare procurement by sending an e-mail to hello@ecare-pcp-eu . Answers are elaborated jointly by the eCare procurers and made available on a FAQs webpage to assure transparency and fair competence among suppliers. The FAQs link is https://ecare-pcp.eu/faqs/ .

1.2.5 OMC insight

The key insights obtained in the OMC activities are summarised in this section.

- **Interest from the market and level of participation**

Figures from the OMC reveal a high interest from the market in the PCP. The webinars were attended by more than 180 participants from +10 different countries, especially from Spain (48%) and Italy (24%). Similarly, a good response was achieved in the other activities: 45 answers were received in the supply questionnaire and 22 answers in the demand questionnaire. Besides, at the time of writing this document 42 organisations have already signed up for partner search in the matchmaking tool and 64 FAQs have been published on the website.

SMEs seemed to be an important part of the market. 48% of the webinars participants were SMEs. Besides, big players and well-established companies in the sector were also interested in the eCare PCP (16% of the webinars participants).

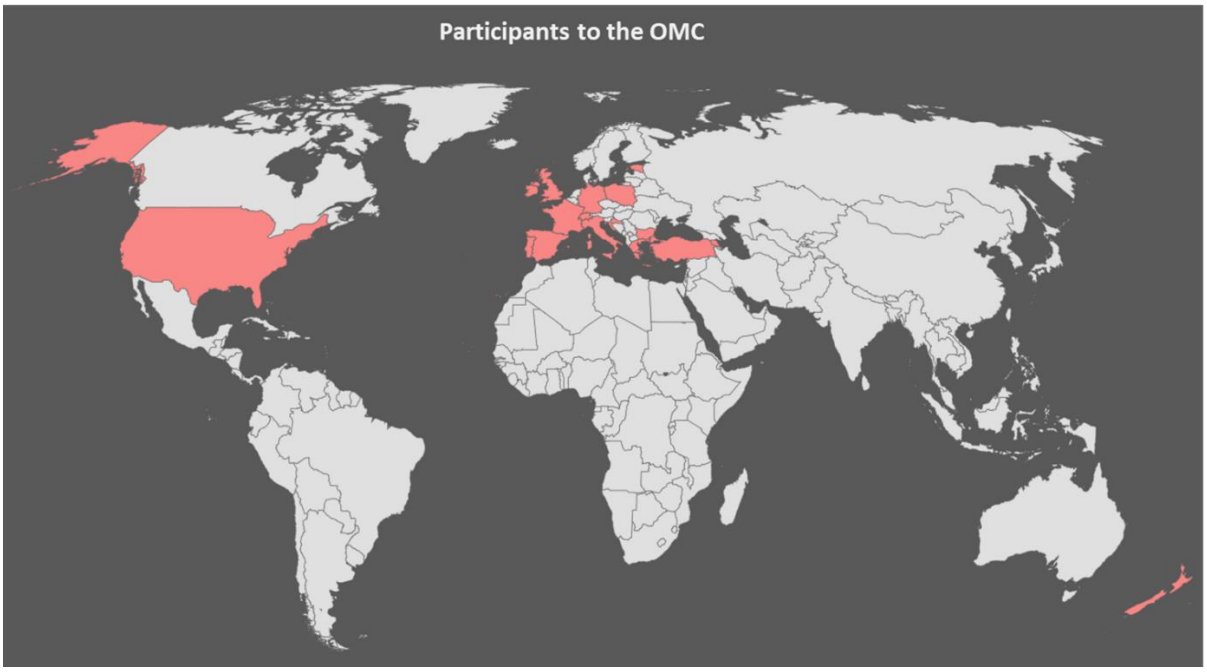

Figure 1. Headquarters' countries of the OMC participants

- **The eCare challenge and expected solutions**

OMC participants agreed that the eCare challenge was innovative, clear and feasible. On this regard, its relevance for society was claimed by the participants, who had previous experience in the seniors and Active and Healthy Ageing market as well as in integrated care. Technological solutions with different Technology Readiness Levels (TRLs) seem to exist for some of the eCare dimensions, however, the market agreed that the innovation lies in their combination in a holistic solution and to design a new care service supported by the technology.

According to the participants' experience, all the dimensions foreseen in eCare are very relevant to meet the proposed challenge.

Nonetheless, participants also commented several aspects that should be improved on the eCare challenge before the official tender launch. These aspects and how the eCare Consortium has addressed them are included in the table below:

Table V. Feedback from the OMC to improve the eCare challenge

Topic	Description	How eCare has addressed the issue
Frailty and pre-frailty detection	The scale of frailty to be used was generating some uncertainty, as numerous factors may have an impact on frailty and the scale adopted for its assessment would condition the solution.	Procurers have clarified that it is expected to test different approaches to assess and detect frailty. Besides, other information for each site has been provided, such as current service portfolio being provided to old adults; and data that will be available for the pilot.
Social and healthcare systems integration	This topic was seen by the participants as potentially challenging, not only because of the usual fragmentation of health and social systems but also because it was not clear whether both social and health stakeholders would participate in each procurer site.	Procurers have made available information on the number and type of users as well as other actors that will participate per site (health/social professionals, IT experts, caregivers, etc) to reduce the perceived uncertainty by suppliers and manage expectations.
Data Management and Interoperability	Interoperability was mentioned as challenging due to different health and/or social systems in four organizations with different technologies and legal and regulatory contexts.	In the tender documents, the existing local systems have been described. In addition, other relevant information such as the legal and regulatory environment in each site are detailed.
Use cases	Some OMC participants claimed that the use cases were not sufficiently clear and that they should be made more outcome oriented.	Procurers have refined the use cases based on the feedback provided. Procurers have also elaborated the requirements in an outcome-oriented approach.
Profiles of the target end-users	Several questions were raised in terms of how to better frame the profile of the users.	The profiles of the target end-users and their specific unmet needs have been described via user personas.

- **The PCP tender process and phases implementation**

The budget and timeframe proposed for addressing the challenge seemed to be adequate for most of the participants (+80%). The distribution of time among the phases was also considered adequate overall.

As for the implementation of the phases, OMC participants expressed the need to co-create with end users for designing the best possible solution. On this regard, procurers will facilitate the mechanisms among suppliers and end-users so that they can co-create.

In terms of exploitation, the market manifested its readiness to keep the Intellectual Property Rights and exploit the solutions beyond the PCP. Besides, OMC participants expressed their willingness to offer preferential conditions to procurers in exchange, such as licenses of use or a reduced tender price.

2 eCare PCP challenge

The eCare Project has taken the challenges outlined during the proposal phase and they have been reviewed according to the actual unmet needs identified by each of the four procurers during the focus groups and validated by all the partners employing the data framework analysis and elicitation processes that followed.

The main challenge of this PCP initiative is to deliver digital solutions supporting continuum of care for frailty prevention in old adults / deliver disruptive digital solutions for the prevention and comprehensive management of frailty to encourage independent living, wellbeing and to relieve health and care services budget pressure. Table VI contains the detailed descriptions of the challenges to be addressed in a deeper and more elaborated way.

Table VI. eCare challenges detailed description

No.	Title	Icon
CH1	Reliable, efficient, holistic, and responsive technology solutions for frailty **detection**…*to prevent disability, avoiding adverse health events and hospital admissions.*	CH1 DETECTION
CH2	Better understanding of the psychosocial **factors**, gender dimension and its correlations affecting frailty progression…*to form a solid knowledgebase that allows moving frailty understanding and health and care provision one step forward.*	CH2 FACTORS
CH3	More towards **holistic** solutions to address frailty prevention, form physical condition to psychosocial risk factors…*to mitigate the feelings of loneliness and isolation, avoid social exclusion, and support mental health and independent living, while promoting healthy lifestyles and safe habits.*	CH3 HOLISTIC
CH4	Co-development to ensure clinical supervision and experimental **validation** in the field testing…*to gain deeper insight into the complex mechanisms of frailty and aid the development and evaluation of interventions to improve outcomes.*	CH4 VALIDATION
CH5	Establishment of monitoring and performance **evaluation** systems to improve the user experience…*supporting the paradigm shift in the provision of health and care of frail older people towards a more appropriate goal-directed service.*	CH5 EVALUATION
CH6	**User-centered** care interventions tailored to the individual needs …*that are more efficient (and sometimes less costly) to slow the impact of frailty (on cognition, mental health, autonomy, quality of life) than a usual intervention program.*	CH6 USER-CENTERED
CH7	Ensure stakeholder's **engagement** and technology acceptance…*and adherence by the target user for the solution to commercially succeed, namely older adults that might be pre-frail, feeling lonely and/or isolated.*	CH7 ENGAGEMENT
CH8	Enable user **empowerment** to self-manage their condition by means of education and training…*to feel more secure about dealing with their health status, which will improve the psychological side of their condition.*	CH9 EMPOWERMENT
CH9	Education/**training** of the workforce, including informal caregivers…*to deliver the holistic, anticipative, and based-on function type of care that frail older adults require.*	CH10 TRAINING

CH10	Collect data for **research** purposes: basic methodological and standardized research on different aspects of frailty*…to connect the learnings into an evidence-based roadmap for different use-case scenarios that are data-driven.*	CH11 RESEARCH
CH11	Pursue the cost-effectiveness, sustainability, and **affordability** of the solution*…in terms of both of purchasing prices and maintenance of running costs, providing evidence how technology may positively impact on frailty prevention.*	CH12 AFFORDABILITY
CH12	Facilitate effective **continuum care** across a range of health and care services*...to build and communicate meaningful information across service boundaries in order to facilitate the staff organization and provision of service.*	CH13 CONTINUUM CARE

Procurers participating in this PCP project are looking for a general improvement linked to the PCP challenge in terms of quality and efficiency in providing services to the citizenship. Considering the leap forward the PCP concept establishes, it is difficult to give quantitative figures about the expected improvement. This may be caused by the absence of a systematic and well assessed approach to the problem. Additionally, the broad range of aspects to the solution to be provided is expected to address, cross-cutting effects and synergies seems to add complexity to the scenario. In fact, some benefits the solution may provide is a progress on the ability to assess how services are delivered and the degree of impact in the society.

In addition to the above, it should be borne in mind that the entities that make up the set of procurers are heterogeneous in nature. Although they have in common that they provide health and/or social care services, each of the entities may provide one or both services, with different approaches and with different degrees of integration between the two services. Therefore, a specific description for each of the entities is provided below.

Azienda Sanitaria Locale Benevento (ASL BN) is one of the 7 Local Health Agencies of the Campania Region. It is a public entity with managerial, technical and financial autonomy.

This kind of public entities have been created by the Italian Public Administration so as to manage the health issues at regional level. Indeed, ASL BN carries out the tasks of the national health system in the geographical area of the province of Benevento.

ASL BN is characterized by:- an area of 2071 sq km; - a population of 287,874 inhabitants (with 139,682 males and 148,192 females); 78 municipalities.

ASL BN is organized in:

- n.5 Healthcare Districts
- n.3 multifunctional Health Centers, including Prevention and Mental Health Departments.
- Emergency Medical Service of Benevento Province (*Operational Center of Regional Emergency Health Service*)
- about 1500 workers (health, administrative, technical)

The objective of ASL BN is to improve the quality of life of the patients, preventing diseases and frailty with a multidimensional approach by providing users with a reliable, acceptable and sustainable service.

Through the eCare project, ASL BN aims to:

- provide its patients with innovative digital solutions for the prevention and complete management of therapeutic diagnostic path, aimed at encouraging independent living, well-being and supporting the transition to integrated care.
- improve and manage a smart and integrated healthcare management system.
- develop preventive medicine models, which increase the effectiveness and efficiency of health services, reducing social and economic costs.

With reference to **CSI**, the entity is a social and healthcare organisation with different services distributed over the metropolitan area of Barcelona, in the city of Hospitalet de Llobregat, the second largest city of Catalonia by number of inhabitants. Services include primary care, acute hospital and intermediate care.

District II (Collblanc and La Torrassa), which is one of CSI main areas of influence, is the most populated one with 52,884 people.

Out of the 98.107 households that exist in this city (according to 2017 data), 11.586 are inhabited by people aged 65+ living alone, and the percentage of inhabitants living alone increases as the age range gets higher: 15,4% (65 -74); 24,6% (75-84); 39,6% (84 onwards), being women most of the people who live alone at home.

The City Council has adhered to the project of Friendly Cities promoted by the World Health Organization (WHO), to promote active development policies that address the development and different generations, among the elderly people.

The OMS indicates that the cities must adapt their environment and the serious service because the elder people should live safety, maintaining their health and participation in the life of the city.

We hope that the e-Care project will help elder people to be able to live with a higher quality of life, in a friendlier environment, with better and greater accessibility to public services and potentially generate relationships between equals. It can also facilitate the caring system (social and healthcare) to provide support, monitor and accompany the needs of care.

With regard to **UKA**, the IZDM of the University Hospital RWTH Aachen has carried out and is carrying out various telemedical projects in the field of intensive care medicine. IZDM has made the experience that it is better to determine critical parameters of patients at an early stage and to be able to intervene actively than to react to symptoms of an illness.

For example, a project, called Optimal@NRW, which represents a new intersectoral approach to acute care for geriatric patients in need of care, is currently underway. This approach includes the implementation of early warning systems, equipment with teleconsultation systems and cross-sector digital treatment documentation in 25 nursing homes. The project takes up the currently planned changes in emergency care in Germany and extends them by a so-called "virtual digital counter", which is operated around the clock by the University Hospital RWTH Aachen together with the KV Nordrhein. In concrete terms, this means that if a medical issue arises in one of the participating nursing homes, a teleconsultation can be carried out with the virtual counter via the physician call center after an initial medical assessment, or other assistance can be organized. Here, too, it becomes clear how important it is to act at an early stage.

The IZDM is convinced that by continuously providing and evaluating various vital signs of elderly frail people, signs of critical processes can be detected earlier and thus intervene and treat earlier and better.

Regarding **SDR**, Santander city has a population (25%) older than the regional average (close to 22%) which is among the highest ones in the country (national average ca. 20% according to 2019 data). Clearly, this scenario is expected to accentuate in the following years and will produce a stressing demand on the municipality services as proportional increase of resources seems not to be feasible. Several measures have been taken for the short- and mid-term.

Among them, with the Smart City concept approach in mind, a platform for collecting and storing data that will produce insights for municipality services responsibles is being developed. This platform will be fed by the information coming from all municipality services including the social

service which oversees the area in which eCare project is contextualized. However, the definition of the Key Performance Index (KPI) of the service provided and any other element that helps to improve efficiency, quality and impact benefit in the society lays in the specific area.

To give an example of what SDR is looking specifically for, at present, the municipality social service is working with ca. 3,000 citizens. Santander City Council is being carried out a specific care program for those old adults who are living alone and with more risk of isolation in order to extend as much as possible the time they are living at home and environment. 150 of them has been included in this program under the criterion of not having close relatives. This aspect is being recognized as one of the factors of frailty and a more holistic approach is expected to improve the criteria. Also, a stratified approach for services providing in a more systematic and data educated decision-making is sought.

The degree of progress on the baseline situation that the proposed solution is expected to provide is, among others, the definition of indicators to facilitate better service management, with improved efficiency in resource use and social impact, be able to measure the degree of impairment and needs of older people in order to be able to target actions and resources in a systematic and data-driven manner.

Finally, to facilitate the design and the development of the solutions it has been defined two Persona models which are described in Table VII and in Table VIII.

Table VII. Persona model #1 (frail)

Maria Attribution: Vecteezy.com	María is an **85-year-old widow** that lives alone in a 2nd floor old apartment in the **city downtown** that needs refurbishment, however, she cannot afford it because she has a low retirement pension. In her block of apartments, there are some neighbour that can assist her in case of emergency, but it does not exist a close relation. She suffers from **diabetes type II** and also has **hypertension**. She knows, owing to the diabetes, she has to go for a walk every day and be careful with her food. However **currently she only monitors her glycaemia values**, and she is **very rigorous taking her pills**. She feels that her health and phycological condition may worsen after she had to quit going to the **painting course** she used to attend at the facilities of a **widow's association** because it is now closed owing to the pandemic restrictions. At this association she had also the opportunity to learn **how to work with the computer**, but she still does **not feel comfortable** using them without support. Fortunately, her **granddaughter used to visit her** very frequently but after her pregnancy **she is only able to call her by telephone** and the frequency of face-to-face contact has decreased. She regrets not having taught her grandmother how to use a **smartphone** because she thinks it **would bring more proximity**, now even more important during the COVID-19 pandemic.

Table VIII. Persona model #2 (at risk of frailty)

Anna Attribution: Vecteezy.com	Anna is **75-years-old woman** that takes care of her older husband that suffer from multiple health conditions and mobility difficulties and **lives in a small country house in a village**. Her house is quite isolated, and it is **quite distant from the hospital**. The **couple has a pension** which is enough for covering the basic costs of caring, but some **additional costs** like adapting the house for easing the mobility of her husband **are not easy for them**. She **recovered from a breast cancer 2 years ago** and she has to go for regular appointments to make a follow-up. She has **not much time to think and take care about her own health and leisure activities** that she used to do, i.e., painting courses organized in her municipality or by the church. Both institutions have setup some **remote interesting courses**, but she has **not skills and confidence in using a tablet or a computer**. She may have **access to Internet connection**, but she still **prefers traditional telephone line** for her communication necessities. It would also be nice for her to use technology in order to communicate by i.e., a videocall, with her **large family** and mainly with her 9 grandchildren. Although **some of them visit the couple sometimes** owing to their daily duties they have **not as many opportunities as she would like**.

3 Unmet needs

To improve the outcomes for frailty in older adults affected by loneliness and/or isolation, one must tackle the barriers that hinder active and healthy ageing by changing the way the user experiences the services/systems and/or the processes in which is involved/affected by. In line with this, the eCare challenge is focused on addressing categories or dimensions of unmet needs that act as layers to be tackled, aggregating a cluster of unmet needs addressing a common topic/field (e. g. the clinical condition management category arose from the Needs for symptom management and how these can be met section of the script).

The dimensions (D) of unmet needs are the following:

- **Frailty and pre-frailty detection (D1)**. Providing reliable, efficient, holistic, and responsive technology solutions for frailty detection, to prevent disability, avoiding adverse health events and hospital admissions.

- **Capacity/autonomy to manage critical events and emergencies (D2)**. Alerting in order to prevent and better manage critical events, such as falls or acute episodes, to accelerate the emergency handling response while promoting older adults' sense of safeness at home despite functional limitations due to Health conditions.

- **Psychological and emotional support (D3)**. Moving towards holistic solutions to address frailty prevention, from physical condition to psychosocial risk factors, namely loneliness and isolation. Mitigating psychological and emotional distress, thus avoiding social exclusion, supporting mental health and independent living, while promoting healthy lifestyles and safe habits.

- **Access to social and healthcare services (D4)**. Establishment of monitoring and performance evaluation systems to improve the user experience, thus supporting the paradigm shift in the provision of health and care of frail older people towards a more appropriate goal-directed service.

- **Cognitive and functional decline support (D5)**. Developing and implementing sustainable multimodal and multidimensional interventions for the prevention and comprehensive management of functional decline, frailty, and isolation and/or the perception of loneliness and isolation, enabling a sense of safeness at home.

- **Clinical condition management (D6)**. Conveying the shift to User-centered interventions tailored to the individual needs, through the adoption of integrated pathways of care that are more efficient (and sometimes less costly) to slow the impact of frailty (on cognition, mental health, autonomy, quality of life) than a usual intervention program.

- **End-users' education and empowerment (D7)**. Enabling user empowerment to self-manage their condition by means of education and training, promoting a sense of secureness about dealing with their health status, which will improve the psychological side of their condition.

- **Social and healthcare systems integration (D8)**. Facilitating effective continuum care across a range of health and care service to build and communicate meaningful information across service boundaries in order to facilitate the staff organization and provision of service.

- **IT adoption (D9)**. Ensuring engagement and technology acceptance by the target user for the solution to commercially succeed, namely older adults that might be pre-frail, feeling lonely and/or isolated, that usually have a low level of proficiency on digital skills.

- **Data management and interoperability (D10)**. Enhancing interoperability, flexibility and scalability to overcome technology silos. Pursuing higher automation levels, exploiting data in an efficient and cost-effective way.

Table IX. eCare challenges, dimensions, and unmet needs classification

eCare Challenges	Categories or Dimensions	Unmet needs
CH1 DETECTION	Frailty and pre-frailty detection (D1)	• Difficulties in the identification and management of frailty (e.g., understand causes)
CH5 EVALUATION CH6 USER-CENTERED CH9 EMPOWERMENT	Capacity/autonomy to manage critical events/emergencies (D2)	• Difficulties in the management of falls and acute episodes (hyperglycaemia, severe respiratory symptoms, anxiety, and panic attacks. • Slow responses on emergencies handling.
CH2 FACTORS CH3 HOLISTIC CH6 USER-CENTERED	Psychological and emotional support (D3)	• Feeling psychological distress (phobias, anxiety, depression, sleep disorders) • Feeling emotional distress (fear of being a burden, fear of cognitive and functional decline, fear, and shame of being identified as frail and lonely, difficulties in accepting and coping with frailty's condition, low self-esteem) • Feeling isolated
CH1 DETECTION CH7 ENGAGEMENT CH9 EMPOWERMENT CH12 AFFORDABILITY CH13 CONTINUUM CARE	Access to social and healthcare services (D4)	• High costs of services • Difficulties in mobility/accessibility • Complexity and bureaucracy of the assessment processes • Follow Up (continuum care of multiple physical, clinical, and psychosocial dimensions) • Difficulties on the screening of older adults in need of social assistance

CH5 EVALUATION CH3 HOLISTIC CH6 USER-CENTERED	Cognitive and functional decline support (D5)	• Difficulties to prevent/halt/delay deterioration of functional and cognitive health. • Difficulties in feeling secure at home.
CH4 VALIDATION CH8 INTEROPERABILITY CH13 CONTINUUM CARE	Clinical condition management (D6)	• Lack of communication in between social and healthcare services at local/regional and national level • Lack of communication in between care professionals • Lack of comprehensive data (updated and multidimensional) to support follow-up by clinical staff
CH6 USER-CENTERED CH7 ENGAGEMENT CH9 EMPOWERMENT CH13 CONTINUUM CARE	End-users' education and empowerment (D7)	• Insufficient communication and collaboration between patients, professional and relatives • Lack of self-management support and tools • Lack of motivation to adhere to therapies and prescriptions. • Lack of health literacy and digital skills • Low investment of peers' support
CH8 INTEROPERABILITY CH11 RESEARCH	Social and healthcare systems integration (D8)	• Insufficient communication and collaboration in between social/health care departments and IT departments • Lack of IT systems on a social level
CH7 ENGAGEMENT CH10 TRAINING	IT adoption (D9)	• Low level of proficiency on digital skills • Lack of IT support services when dealing with IT difficulties. • Low security/security breaches on end-user level (fraud risk)

CH5 EVALUATION CH8 INTEROPERABILITY CH11 RESEARCH	Data management and interoperability (D10)	• Lack of ICT resources for data exploiting in an efficient and cost-effective way. • Vulnerability of data storage, management, and transfer • Uncertainty about privacy and legal risks

4 Use cases

4.1 Introduction

PCP projects pose the main objective of finding a comprehensive approach on how to structure the vision of the procurers in a way that will be understood by the suppliers. Thus, a complete set of use cases that defines all behavior required by the system, bounding its scope needs to be defined. The use cases aim to provide a clear response to the validated unmet needs of the Project.

As part of this Challenge Brief document that supports the call for tender, the Consortium presents identified requirements, use cases and service process models. In order to ensure that the system is correctly designed and developed, the requirements must be captured from the user's point of view with a focus on the "what" and not the "how" so the use cases can clearly describe what steps will be taken by the user through the system to accomplish a particular goal that will address one or more of the identified unmet needs.

In this sense, the eCare solution presents itself as user centric system that encompasses concomitantly **4 main drivers**:

- Frailty screening, related to Use Case 1 (UC1)
- Frailty management and prevention, related to Use Case 4 (UC4)
- Develop integrated pathways, related to Use Case 2 (UC2) and Use Case 3g (UC3)
- Knowledge sharing related to Use Case 5 (UC5)

and **3 main building blocks** focused on:

- care assessment (Use cases UC1, UC2 and UC3)
- care delivery (Use cases UC4, UC4.1, UC4.2, UC4.3, UC4.4 and UC5)
- on the providence of an effective integrated system (Use cases UC6, UC6.1 and UC0)

Knowing that use cases should start off simple and at the highest view possible, and only then can be refined and detailed further, the consortium defined the use case set list and organized in a sequential way the set of interactions in between the use cases.

Table X. eCare Use Case set list

UC0	Registering users into eCare
UC1	Detecting frailty and pre-frailty in Older adults
UC2	Matching older adults' needs, preferences, and limits with existing care pathways
UC3	Shared care planning
UC4	Comprehensive management of frailty
UC4.1	Providing psychological and emotional support
UC4.2	Managing functional decline
UC4.3	Managing critical events/emergencies
UC4.4	Supporting self-management
UC5	Increasing the skills of Older adults, their Caregivers and Care professionals
UC6	Enabling information exchange and improving communication
UC6.1	Integrating data and ensuring interoperability

Following the perspective of the actor, it starts off with his/her registering into the system (UC0) ➔ passing through a frailty screening (UC1) ➔ and a matching of his/her needs, limits and preferences with existing procurers' care pathways (UC2) ➔ to develop a shared care plan (UC3) ➔ able to inform, both users and care professionals, what and how the comprehensive management interventions should be implemented (UC4 and their children) + what and how skill trainings should be developed (UC5)✓ The shared care plan (UC3) is continuously updated in accordance to older adults' physical and psychosocial status changes, as well as to any therapeutic prescribed by the Care Professionals, resulting from the comprehensive management (UC4) that comprises 4 typologies of intervention: psychological and emotional support (UC4.1)✓; functional decline management (UC4.2) ✓; critical events/ emergencies management (UC4.3) ✓; self-management support (UC4.4) ✓.

Last, but not least, for the system to work properly it is necessary to enable an effective information exchange and to improve communication between actors (UC6)☑ supported by data integration and ensuring interoperability (UC6.1)☑.

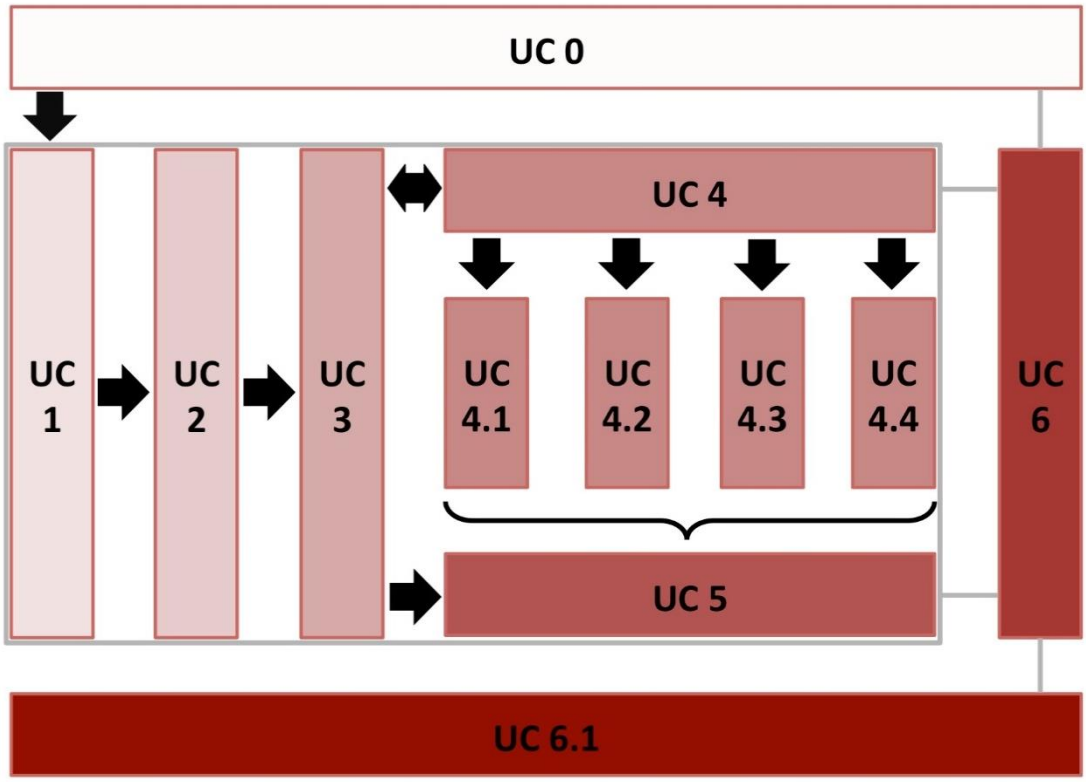

Figure 2. Set of interactions in between use cases in the eCare system

4.2 Use cases template

To further develop the use cases, the consortium adopted the following use case template, here presented filled with an explanation of each of the use case elements, as well as a typification of the actors.

Table XI. Use cases description template

ID	Each use case has an ID number to allow for easy referencing.
Title	Each use case should have a unique title suggesting its purpose. The name should express what happens when the use case is performed. Usually, a combination of a verb and a noun is chosen which is occasionally extended by adjectives or adverbs
Summary	Gives an overview over the purpose of the use case and provides the ideal outcome (result) of the use case.

Actors	An actor specifies a role played by a user or any other system that interacts with the subject. It may represent roles played by human users, external hardware, or other subjects. The actors involved in the eCare solution are: - Older Adult (one over the age of 65 who is diagnosed with frailty or at risk) - Caregiver (or informal caregiver, is usually a relative without formal training who helps with the activities of daily living) - Formal carers (one who is paid to provide professional care to an individual or group of individuals) - Healthcare Professional (one who provides health care treatment and advice based on formal training and experience) - Social Worker (one who aim to improve people's lives by helping with social and interpersonal difficulties, based on formal training and experience) - Emergency Services (organization that respond to and deal with emergencies when they occur) System Administrator (one who is responsible for the upkeep, configuration, and reliable operation of the ICT systems - System (ICT system is the set-up consisting of hardware, software, and data inputted by the users)
Parent	Use cases can have sub-use cases, in which case the former are "parents" of the latter.
Children	Use cases can have sub-use cases or "children", which are listed in this field.
Preconditions	Preconditions In some cases, certain conditions and factors need to be present for the use case to be applied. They are described in this field.
Base flow	Describe the main aspects of the envisioned system, implying steps that the actors and the system go through to accomplish the goal of the use case.
Post conditions	Clearly describes the end state or outcome of the use case
Triggers	Describes the entry criteria for the use case. This becomes especially important in semi-automatic or automatic processes which apply to services.
Frequency	How often a use case is executed.
Exception paths Frequency	Exceptions of the standard case
Open issues/Notes	Free text to report issues and make comments is also available for each use case. Exceptions of the standard case

4.3 Use cases definition

4.3.1 UC0 – Registering users into eCare

ID	UC0
Title	Registering users into eCare
Summary	The eCare solution shall be able to differentiate user types and include new users in the system – older adults, their caregivers, formal carers, healthcare professionals and social workers. Each Procurer will have an overall administrator who can create new healthcare professional and/or social worker profiles. Healthcare professional and/or social worker register new older adult and their caregiver into eCare. The system shall re-use existing information (e.g. EHR) as much as possible and local authentication techniques and/or biometric signature so these will be used throughout the eCare service, including access to the Shared Care Plan. The eCare solution should be user friendly and provide accessibility options like screen reading capacity or screen magnification tool available as a part of interface and voice control.
Actors	Older Adult; Caregiver; Formal carer; Healthcare Professional; Social Worker; System Administrator; System
Parent	-
Children	-
Preconditions	The eCare solution developer provides an administrator role for each local Procurer. The administrator can register new users.

Base flow	**1. Register healthcare professionals and/or social workers** Administrators can generate and reset credentials for healthcare professionals and social workers. They can select from a list of healthcare professionals and social workers that work at the care facility, which will be possible because eCare must be developed in a way to be interoperable with the local systems. The generated credentials are based on the existing local authorization mechanisms (e.g. existing username, email, ID) and/or by biometric signature, so it can be used later for local authentication. The user will be prompted to change the password when logging in for the first time. The administrator can view, edit, and remove healthcare professionals and/or social workers from the eCare service. **2. Register older adults** Typically done when the older adult's needs are assessed by either healthcare professional or a social worker during a visit. The healthcare professional or the social worker chooses from a list of his/her managed cases, possible because the eCare solution must be developed in a way to be interoperable with the local systems. The credentials are generated using existing information such as the older adults' email address or their biometric signature, so it can be used later for local authentication. In addition, the older adult may wish that his/her caregiver is registered, in which case another set of credentials are generated by the care professional. Caregivers' access to the system is equivalent to the role of observers – they cannot, for example, adjust the different goals for the older adult but they have access to information (e.g., latest physiological parameter readings) that helps them to assist the older adult as best as possible, providing guidance and support. **3. Register formal carers, new healthcare professionals and/or social workers** Healthcare professionals and/or social workers can also register formal carers and other healthcare professionals and/or social workers (e.g. Specialist, Nurse, Psychologist, Dietician, Physiotherapist; Occupational therapist) to take part in the older adult's shared care plan. The healthcare professionals and/or social workers can select from a list of formal carers, healthcare professionals and social workers that work in the care facility
Post conditions	Upon registering, users have immediate access to the eCare service process model.
Triggers	Healthcare professional or social worker has been selected to participate in eCare. Older adult has been selected to participate in eCare. (Optional) Older adult has requested that their caregiver(s) is/are provided access to eCare. (Optional) Healthcare professional or social worker provides access to eCare to older adult's formal carers or other healthcare professionals or social workers.
Frequency	Every time a new older adult, caregiver, formal carer, healthcare professional or social worker needs to be registered into eCare system.
Exception paths	Older adult decides to withdraw from the eCare trial
Open issues/Notes	The ethical and legal implications to ensure safety measures of the processes and systems to be implemented. The solution should comply with the dispositions of the GDPR: 1. Authentication and authorization; 2. Pseudonymization and Encryption; 3. Backups and Business Continuity; 4. Infrastructure security (physical protection); 5. Applications security. Older adults and their caregivers should receive basic training once registered into the eCare service considering both health literacy and digital literacy, with respect to their needs, limits and preferences.

4.3.2 UC1 – Detecting frailty and pre-frailty in older adults

ID	UC1
Title	Detecting frailty and pre-frailty in older adults
Summary	The eCare solution shall be leveraged by an online system that provide an module that embed available existing data (EHR) and data from other sources (e.g. weather), screening older adults and identifying those who might have frailty or pre-frailty. Predictors of frailty and pre-frailty are from both physical and psychosocial spheres (parameters are yet to be decided. The identified older adults will be flagged, and a report provided to the healthcare professional and social worker in charge of their care to refine the shared care plan. Being an online solution, the assessment can be done either at the older adult's home, at a care center or at a nursing home.
Actors	Older Adult; Healthcare Professional; Social Worker; System
Parent	-
Children	-
Preconditions	Improved understanding of the factors affecting frailty and the feelings of loneliness and isolation, and how they do correlate (e.g.: gender dimension, social context, etc.) in order to choose or develop a frailty algorithm that takes both physical and psychosocial measures to identify frailty and pre-frailty stages.
Base flow	1. **Older adults' physical and psychosocial data feeding** eCare system should allow for an automatic and semi-automatic data input, collecting data relevant to the older adults' risk of developing frailty. This includes: - EHRs and other databases. - Questionnaires based on knowledge/international guidelines and validated instruments. - Data from wearable devices and Medical Devices that detect specific parameters (to be defined)- Data from sensors (e.g. eWare) and/or robots installed at home. **2. Identifying older adults with frailty or pre-frailty** The older adults' inputted data is reviewed by the system thorough a risk stratification algorithm allowing the identification of those with frailty or pre-frailty. Innovative systems should be implemented, for example that use predictive methods based on artificial intelligence, monitoring trends in the parameters. **3. Communicating results to healthcare professionals and/or social workers in charge of the older adults' care.** The system provides a report on older adults' assessed risk within the profile of the Care professional assigned to the case that will be available through the shared care plan. The EHR should provide an alert, flagging the older person as fragile.
Post conditions	Healthcare professionals and social workers are alerted of identified frail and pre-frail older adults and can refine their shared care plan to better manage frailty and encourage independent living
Triggers	After every physical and/or psychosocial user data update, the system automatically runs a screening to detect any change in the frailty risk assessment.
Frequency	Access should be continuous. A systematic routine screening should be promoted

Exception paths	-
Open issues/Notes	Since there are several frailty algorithms, the parameters to be used by the eCare system are to be decided by the Contractor. As much as this element is elaborated better would be the solution performance. The developed solution should improve utilization of care and health outcomes collecting data for research using a standard and reusable format in the case of a data set (Pre-defined standard data model). eCare system should provide evidence of cost effectiveness and demonstrative how technology positively impact on frailty prevention, simultaneously relieving health, and care services budget.

4.3.3 UC2 – Matching older adults' needs, preferences, and limits with existing care pathways

ID	UC2
Title	Matching older adults' needs, preferences, and limits with existing care pathways
Summary	This use case is characterized by being a bridge between UC1 and UC3. In order to develop a personalized shared care plan, an assessment of the needs, preferences and limits of the older adult should be done. The eCare solution should allow to collect this information, as well as identify older adults' knowledge, attitude and capability towards topics such as healthy habits (nutrition and physical activity), socialization, and the ones addressed in UC5, namely on ICT usage, acts of care and soft skills. By taking a standardized survey/interview older adult provide one piece of the necessary info to enable a match with existing care pathways at procurers' site.
Actors	Older adult; Healthcare Professional; Social worker; Caregiver; System
Parent	-
Children	-
Preconditions	The standardized survey/interview needs to be developed.
Base flow	**1. Comprehensive profile building** A standardized survey/interview to be addressed by Care professionals to older adults and their caregivers (optional) should allow to capture their: - Health needs, preferences and limits. - Psychosocial needs, preferences and limits. - Habits, knowledge, attitude, and capability. **2. Matching existing care pathways with older adult's profile** The captured information will enable UC3, UC4, UC5 by identifying the services and its personalization that can be delivered in a holistic, anticipative and based-on-function type of care to the older adult in order to best serve its needs, preferences and limits. The information is conveyed in the shared care plan dashboard (UC3)
Post conditions	A comprehensive understanding of the older adult needs, preferences and limits is collected enabling a more personalized share care planning
Triggers	Care professional walks older adult through the survey/interview.
Frequency	This use case is executed whenever an older adult is detected as frail. It can be repeated periodically.
Exception paths	If older adult does not want to provide such information, the shared care plan will not be as personalized as it could.
Open issues/Notes	The ethical and legal implications. The solution should comply with the dispositions of the GDPR.

4.3.4 UC3 – Shared care planning

ID	UC3
Title	Shared care planning
Summary	A shared care plan is a user-centered health record designed to facilitate communication among members of the care team, including the older adults and providers. In integrated care settings, it is vital that all members of the care team have access to the same information and can build upon the shared care plan. In this sense, the Shared Care Plan represents a structured way by which the Care professionals and the older adult can co-organize in a negotiation basis a plan for the management of frailty. The Shared Care Plan is built upon all necessary parameters that make the Shared Care Plan a comprehensive document are available in the plan itself, while some come from local systems (EHR, PHR, other), others are recorded by using other innovative functionalities of the eCare solution (UC1 and UC2). The shared care plan provides the older adult, their caregiver and the care professionals a common guidance on how to comprehensively manage frailty (UC4). A Care professional, most often the older adult's physician (GPs and/or specialist) will act as administrator of the care plan and permits access to other stakeholders, under express consent. The Shared Care Plan allows to set up and track goals, schedule events, manage alerts and notifications, medication and dosage, as well as view, generate and export reports, including one adapted to older adults with a user-friendly design to be printable and easily understandable. The Information is displayed in two different views – the older adults' and the Care professionals', and each user can be assigned with different permissions such as observer or co-creator of the care plan. All necessary parameters that make the Shared Care Plan a comprehensive document are available in the plan itself, while some come from local systems (EHR, PHR, other), others are recorded by using other innovative functionalities of the eCare solution (UC1 and UC2). The access is done through authorization mechanisms and/or by biometric signature.
Actors	Older Adult; Caregiver; Formal Carer; Healthcare Professional; Social Worker; System
Parent	-
Children	-
Preconditions	Procurers' existing IT systems, both in terms of functionalities and design of Electronic Records

Base flow	The Shared Care Plan has one view for the older adult and caregivers and another for Care Professionals. The system shall have one Shared Care Plan appointed health/social care professional administrator with full access and authorization to the system. The administrator grants access to other Care Professionals, providing different levels of access; the manager level, authorization to modify the care plan, and read-only. A both-ways option of integration of the system with the EHRs is needed, to feed Shared Care Plan and the Shared Care Plan can be stored in and be accessed from the EHR (UC6). Changes to the Shared Care Plan should generate an automatic notification to the users. The shared Care Plan will allow to: 1. **Set up and track goals/targets.** Goals/targets will be typically (but not limited) set when the care professional and older adult are together, being the different targets based on the discussions by selecting a target category (e.g. physical activity targets, nutrition targets, blood glucose targets, weight and other physiological parameter targets, emotional regulation targets, socialization targets). Adjustments in the targets are performed by the Care professionals, ensuring that they reflect the older adult's current health status. Both older adult and Care professional can view whether the older adult is on track or not, being also actively informed about whether or not targets are met using positive messages (e.g. instead of saying "You are not on target", a notification can say "If you walk for another 12 minutes today, you will be on target" or "have you talked to a friend/relative on the phone today?"). Alerts can be used for more critical targets and deviations from them, such as dangerous blood sugar levels. 2. **Upload vital signs readings and other relevant data, via Bluetooth or manually** The eCare system should allow users to upload data derived from self-assessment, will it be automatically (e.g. wearables) or through manual input: - Vital signs. - Physical activity. - Food and Nutrition. - Psychological state of mind. - Therapy adherence. - Socialization (e.g. walking with people, going to sewing class, painting workshop, dancing, shopping, volunteering, talking on the phone, etc.). 3. **Schedule and update events** The Care professional and the older adult will be able (but not limited to them, i.e. an AI can participate in the process) to set up different events for the foreseeable future (e.g. they plan together until their next meeting, which itself is planned and put into the schedule). Each event entry has a minimum of required information: name of event, due date and time, occurrence (one-time vs. recurring) and frequency (e.g. every three months), notification target (e.g. just for the older adult, for Care professional, or for both), event reminders (e.g. sending an alert 1, 3 days before event, 30 minutes before event, etc.), notes related to the event. The Older adult can enter own events (e.g. related to the UC4). Events can be updated, new times set, notes added, etc. Certain changes (such as changing the schedule of the next visit) can be valid only if both Older adult and the Care professional first approve them, and this approval mechanism should be supported by the system.

	4. **Manage alerts, notifications, and recommendations** Alerts can be issued to the older adult and/or the care professionals when there are deviations from pre-set information (e.g. agreed targets, monitored parameters). The system can send urgent alerts to the Care professional (e.g. when a measured parameter is out of the accepted range the physician has defined), the caregiver (if applicable), or even to a nearby Emergency Centre. These critical episodes will be automatically registered in the Shared Care Plan. The older adult receives personalized notifications on how to best manage his/her health and recommendations, advices, or tips (e.g. today is market day). He/she can also define personal reminders, such as family birthdays and other socialization related events. This information is accessible through the virtual carer (UC4.1). 5 **Manage medication and dosage** The Shared Care Plan shall allow the recording of the prescribed medication and for the older adult to communicate the actual medication intake actively or passively by simply confirming that the medication was taken. Subsequently, the Care professional can adjust the medication prescribed, and add new or remove old medication. For each medication the Medication name and Dosage (amount and frequency) is recorded after verifying possible drugs interaction. 6. **View, generate and export/print reports** The system is expected to be able to produce a standardized output in form of a report, that help Care professionals to adjust the therapy and to support his/her decision making. Suitable reports for older adults should also be available, using user-friendly design and understandable language and graphics. Past reports will be available for comparison of older adult's data related to the eCare services as part of a dashboard. There should be different export options available (minimum: PDF, HTML), as well as a possibility to print the results. 7. **Send/receive messages and information material** The eCare users will have access to a dedicated channel to exchange information and communicate regularly**.** The idea is that a question, which requires no more than 30 seconds to be answered, can be more effectively answered using a messaging system rather than clinical visit. The UC5 will also take advantage of this functionality.
Post conditions	The built Shared Care Plan will guide both the comprehensive frailty management and point out the skills to be developed by the Older adult and their caregiver.
Triggers	Whenever an older adult is identified as either frail or pre-frail, the process of creating a shared care plan is triggered and the healthcare professionals and/or social workers assigned to the case is alerted so Shared care plan is to be filled out by them (preferably with the older adult).
Frequency	The Shared Care Plan is continuously accessible and is updated frequently in accordance with older adults' physical and psychosocial status changes, as well as to any therapeutic prescribed by the Care Professionals
Exception paths	-
Open issues/Notes	The Shared Care Plan must have tracking of changes.

4.3.5 UC4 – Comprehensive management of frailty

ID	UC4
Title	Comprehensive management of frailty
Summary	Since frailty does not necessarily represent a point of no return, early intervention is necessary to prevent disability, avoiding adverse health events and hospital admissions. In terms of frailty comprehensive management integrated care technologies offer the greatest opportunity for preserving function in late aging in both physical and mental spheres. The eCare solution should encourage healthy aging, thorough the delivery of the sustainable multimodal interventions outlined in the Shared care plan (UC3). These interventions should be mainly proactive and not reactive as the shared care plan acts as a strategic framework ensuring that an integrated and person-centric intervention is delivered in a way capable of empowering older adults and promotion of independent living. In order to optimize resources, systems and societal costs associated with ageing, the eCare solution should include 4 interlinked modules: - Psychological and Emotional Support (UC4.1) - Functional decline management (UC4.2) - Critical events management (UC4.3) - Self-management support (UC4.4) The effective implementation of this actions that focus on behavior change correlate highly with the Increasing of skills of Older Adults, their Caregivers and Care Professionals (UC5) that focus on information provision.
Actors	Older adult; Healthcare Professional; Social worker; Formal Carer; Caregiver; System
Parent	-
Children	UC4.1 ; UC4.2 ; UC4.3 ; UC4.4
Preconditions	The shared care plan must already have been developed
Base flow	This use case aims to optimize the frailty and loneliness management in the health and social systems of the eCare procurers by 1) shortening the time of finding the optimal treatment and by 2) increasing adherence to therapeutics. eCare will approach older adults not just in terms of their frailty but also in terms of physical, cognitive and psychosocial care and support to prevent functional decline and disability. In integrated care settings, it is vital that all members of the care team have access to the same information and can build upon the shared care plan. Team members must act in coordination toward a common goal to provide quality integrated care. In this sense, the project key components to address frailty are those that define also integrated care. The eCare solution should allow the care professionals to monitor entries periodically or view summary reports (UC3) adjusting the multidimensional goal-directed interventions and providing feedback to the older adult automatically or during visits.
Post conditions	The Care is delivered in a more efficient and comprehensive way
Triggers	The care professionals and the older adult initiate the actions outlined in the shared care plan.
Frequency	Continuous
Exception paths	-
Open issues/Notes	-

4.3.6 UC4.1 – Providing psychological and emotional support

ID	UC4.1
Title	Providing Psychological and Emotional Support
Summary	According to Jazaieri et al (2014) *Emotion regulation strategies are an effective way to change emotions, feelings, desires, beliefs, and practices of the individual and giving order and meaning to daily life*. The eCare solution should provide a mobile context-aware system that predicts the user mood, cognitive and motivational state in order to deliver personalized emotional and psychological support at specific moments of the day. This is especially important because all stakeholders identified psychological distress (phobias; anxiety; depression; sleep disorders) and emotional distress (Fear of being a burden; fear of Cognitive and functional decline; fear and shame of being identified as frail and lonely; difficulties in accepting and coping with frailty's condition; low self-esteem) as key determinants of older adults' condition.
Actors	Older adult; Healthcare Professional; Social worker; Formal Carer; Caregiver; System
Parent	UC4
Children	-
Preconditions	The shared care plan must already have been developed

Base flow	**1. Assess and predict older adult's mood, cognitive and motivational state** A virtual carer should engage with older adult in such a way that they will provide a daily self-report predicting emotional/psychological status. This assessment will encompass the acknowledgement of sleep quality, stress and significant life events that could be risk factors, physical activity and quality of social interactions. The data is then analyzed through machine learning techniques and/or AI algorithms in order to provide older adults with tailored support leveraged by a better understanding of unique factors and behaviours associated with cognitive decline, loneliness, social isolation, resilience decrease, and behavioural symptoms like agitation. These algorithms complement the detection, classifying, and prediction of early pathological cognitive decline in older adults require the use of novel inputs like wearables, mobile devices and sensor signals. The trends and other critical information are recorded into the shared care plan (UC3) in order to increasing personalize self-management support (UC4.4) and training (UC5) as well as to alert (UC4.3) in case of a serious deviation from pre-set information (e.g. agreed targets, monitored parameters). **2. Provide support** Ongoing emotional/psychological care - Since frailty is simultaneously one of the causes and effects of emotional and psychological distress, support must not be limited to people with "diagnosable/classifiable" psychological disorders. Effective frailty management is largely dependent on how people care for themselves (UC4.4), therefore ongoing emotional/psychological care provided by the same virtual carer that does the emotional/psychological assessment can improve not only psychosocial outcomes but also physical outcomes. This virtual carer will act as a companion, providing for example: - The news of the day. - "knowledge pills" as way of learning new thing. - Book reading or audio books listening. - Family events remembering. - The local cultural agenda. - Talking about daily tasks. - Discussions about topics of interest. - Engaging contents (e.g. community feedback from UC4.4). - Music therapy. - Biofeedback therapy with relaxation exercises like deep breathing; progressive muscle relaxation; guided imagery; mindfulness meditation. - Overnight tools to aid sleep or to beat insomnia. Psychological first aid is about comforting someone who is in distress and helping them feel safe and calm. It provides basic emotional support and helps people to address immediate basic needs and find information, services, and psychosocial support. In case of a critical event (UC4.3) care professionals are alerted in order to address a fast response to the older adult avoiding therefore future complications resulting of emotional or psychological distress from that same critical event. This support is provided either in person or by phone/video-call that is triggered by the virtual carer.
Post conditions	The older adult has received emotional/psychological support
Triggers	The Care professionals and the Older adult initiate the actions outlined in the shared care plan.
Frequency	Continuous access, offered according to the user's needs.
Exception paths	Older adult does not want to take advantage of the module
Open issues/Notes	-

4.3.7 UC4.2 – Managing functional decline

ID	UC4.2
Title	Managing functional decline
Summary	An active social life can slow health decline and improve physical and mental fitness, even if social ludic activities are not considered to be formal exercise. To promote social or psychological wellbeing in older adults with frailty or pre-frailty, the eCare solution should encourage users to participate in social ludic activities, improving their physical and mental condition at the same time that loneliness and isolation and/or the perception of loneliness and isolation is tackled. This use case aims to deliver a serious game based therapeutic anchored on the experiences of sharing, giving and receiving.
Actors	Older adult; Healthcare Professional; Social worker; Formal Carer; Caregiver; System
Parent	UC4
Children	-
Preconditions	The shared care plan must already have been developed.
Base flow	Serious games are games that go beyond the merely playful to achieve a particular purpose, which may have to do with education, therapeutics, etc. Serious Games promote rule-based activities that involve challenges and active participation to reach goals, provide feedback on progress made towards the goals that in this case are related to sharing, giving, and receiving. If possible, this solution should be able to provide intuitive user experiences supported by wearable Human-Computer Interaction that are able to recognise cognitive impairment and trigger a referral for a formal assessment. These games for functional health could be leverage on Virtual Reality or Augmented Reality and the manipulation of physical objects. In order to obtain a serious game played by its end users, it is recommended to find a point where the intrinsic and extrinsic motivation of the players can converge, i.e. where the players can enjoy a future desirable outcome (e.g. better mobility) made virtually present in the game. Second, to avoid the development of a game which does not fulfill its objectives developers should consider the four pillars of learning: 1) Attention - promoting strategies that help to select relevant information (modeling/examples, modality/use of the audio channel for verbal explanations to guide visual search, feedback, integration of relevant information in virtual tools); 2) Active learning - promoting interactivity rather than convey the learning content via text or audio explanation. 3) Feedback - promoting the use of feedback which deals with the task completed, not with the self-esteem. 4) Consolidation - promoting the repetition of interactions with important learning content inside the game. The role of Care professionals is essential in prescribing and promoting the system in a suitable way, considering dosing intensity of training and the balance between practicing tasks using gaming systems and practicing functional tasks outside the simulated environment. Selection and progression of training should allow transfer of training from the simulated environment to the real-life environment.
Post conditions	The older adult has engaged in physical and cognitive stimulation exercises and activities.
Triggers	The Care professionals and the Older adult initiate the actions outlined in the shared care plan.
Frequency	Continuous

Exception paths	Older adult does not want or is unable of taking advantage of the module
Open issues/Notes	-

4.3.8 UC4.3 – Managing critical events/emergencies

ID	UC4.3
Title	Managing critical events/emergencies
Summary	Through the use of digital devices, the eCare solution should be able to provide two types of alerts in order to prevent and better manage critical events. It should be able to measure user's progresses as well as classify his/her behavior in order to identify possible alerts to be communicated, as well as be capable of providing automatic and semi-automatic alerts in case of falls or acute episodes to accelerate the emergency handling response. The solution should allow older adults to feel more secure at home despite functional limitations due to Health conditions.
Actors	Older adult; Healthcare Professional; Formal carer; Caregiver; Emergency services; System
Parent	UC4
Children	-
Preconditions	The information based on latest data needs to be available.
Base flow	**1. Preventive alerts** A digital device should allow an in advance home security check to reduce possible fall risks (home safety intervention). Alerts should also be issued to the older adult and his/her caregiver or formal carer (if applicable) when there are deviations from pre-set information, e.g. agreed targets, monitored parameters to better support self-management (UC.4.4). The Care professionals only receive critical alerts when there are deviations from pre-set information (e.g. agreed targets, monitored parameters) defined in the shared care plan (UC3). These critical episodes will be automatically registered in the Shared Care Plan. **2. Emergency alerts** In the case of an emergency (e.g. a fall), the system prompts to send an urgent alert to the caregiver (if applicable) and informs a nearby emergency centre, so that they can intervene. The episode is then noted on the Shared Care Plan (UC3) so psychological first aid can be triggered (UC4.1). The automatic report could be done with the support of a user-friendly IT emergency wearable device that can perform the following functions: • Continuously measure the user's vital parameters (UC.4.4). • Support emergency self-management by giving step-by-step instruction to be carried out at home or outside it in case of emergency/extraordinary situation. • Voice connecting the user to the caregiver/emergency services.
Post conditions	Alert is emitted
Triggers	A critical event occurs
Frequency	The system is continuously available, being triggered according to user's needs and/or will.
Exception paths	-
Open issues/Notes	-

4.3.9 UC4.4 – Supporting self-management

ID	UC4.4
Title	Supporting self-management
Summary	Self-management, which is also referred to as "self-control" or "self-regulation," is the ability to regulate one's emotions, thoughts, and behaviors effectively in different situations. Empowerment-based support tools aims to promote user engagement in behaviors that positively impact their health, improving health-related outcomes and decreasing the cost of care. Novel digital solutions with a self-management approach can improve the efficiency and effectiveness of the care delivery services. This use case should use nudging techniques in an ethical way, and take advantage of community feedback to engage user in Self-management in a way capable of: - Increasing adherence to therapies and prescriptions - Improving nutritional intake - Improving physical activity levels
Actors	Older adult; Healthcare Professional; Social worker; Formal Carer; Caregiver; System
Parent	UC4
Children	-
Preconditions	The shared care plan must already have been developed
Base flow	This part of the solution focuses on empowering the older adult to adhere to the treatment plan defined in the Share Care Plan (UC3). **1. Importing captured behaviors** This use case will take advantage of the information the older adult communicated to the system in UC2.1 (e.g. the challenges he/she encounters regarding food, exercise, medication intake and socialization.) **2. Nudging behaviors** Based on the imported data the system provides nudging notifications in an engaging and ethical way (e.g. showing a bottle of water with hour marks, to promote water intake) to supporting comorbidities self-management. After concluding the task the user can share their accomplishment in the system either actively or passively (e.g. the system asks whether the medication has been taken as prescribed, and the older adults can simply confirm or click to adjust the entry) Other forms of share can be used (e.g. photographing the meal). **3. Community feedback and support** The eCare solution shall allow users to mark other community members as friends. All users will have possibilities to communicate with other community members asynchronously (via chat, comments on accomplished results). The virtual carer (UC4.1) will engage with users in order to facilitate the interaction with the community, promoting emotional and psychological wellbeing by providing clear and simple information on the services available in the area, possible therapeutic paths and support during de-hospitalization. In order to improve the interaction is important that the care professional provide positive feedback to the older adult and keep track on the goals/targets.
Post conditions	Older adult develops healthier habits
Triggers	The Older adult initiate the actions outlined in the shared care plan.
Frequency	Continuous
Exception paths	Older adult is unable to take advantage of the module
Open issues/Notes	-

4.3.10 UC5 - Increasing the skills of Older adults, their Caregivers and Care professionals

ID	UC5
Title	Increasing the skills of Older Adults, their Caregivers and Care Professionals
Summary	eCare system encompasses a capacity building programme so that users can enroll in specific training modules according to their needs and will. This programme is focused on three great themes - soft skills; IT usage and acts of care - delivered in different approaches according to the user's profile (Older Adults, their Caregivers and Care Professionals). The eCare solution should collect and use certain users' characteristics related to the knowledge to suggest specific modules according to the users' profile, working on a fast learning curve enhanced by gamification techniques to promote engagement. Education may improve older adults' knowledge on frailty leading to a more positive and active role in the management of their health.
Actors	Older adult; Healthcare Professional; Social worker; Formal Carer; Caregiver; System
Parent	-
Children	-
Preconditions	Content availability and accessibility
Base flow	**1. Capturing users' knowledge, and learning preferences** The users' level of knowledge and learning preferences should be determined via a standardized set of questions, according to users profile, that need to be developed as part of this use case (e.g. resilience building to avoid burnout) **2. Training content** The training content is selected by the users from a list of available modules divided in three main topics: 1) Soft Skills - Training emotion regulation strategies; Effective communication and active listening; Empathy, negotiation, and conflict resolution; Resilience and self-motivation; Loss&Grief; etc. 2) IT usage - Training on new technologies usage to leverage the potential of the eCare system it-self, as well as to empower Older adults and Care professionals. 3) Acts of Care - Training self-care; health promotion; care techniques; etc. 4) The modules should have a high degree of ICT and multi-media (tutorials, videos, interviews, games, etc.) use and interaction, with a special attention to include demonstrations (e.g. how to use medical devices). The different modules are dynamic, and content is suggested depending on the user's knowledge and capabilities, as well as their accomplishments during the training. Moreover, the system should provide continuous positive feedback to the users and tracks their goals in the shared care plan. The content is to be provided by the eCare suppliers, based on users' unmet needs identified by the procurers. The contents should be translated into the procurers' language.
Post conditions	Older Adults, their Caregivers and Care Professionals have developed their skills. The results (modules completed) are automatically recorded to provide even more personalization, and for older adults the accomplishment is marked in the shared care plan.
Triggers	Older Adults, their Caregivers or Care Professionals decide to engage in a specific training module.
Frequency	The contents are continuously available and can be accessed multiple times according to user's needs and will.
Exception paths	The possibility of Older Adults, their Caregivers or Care Professionals do not want to be engaged in any training module.

Open issues/Notes	A user community can be developed so that users registered in the eCare solution (including its caregivers) can have access to a dedicated online community that offers the environment necessary to exchange information, identify and engage with peers, and communicate regularly.

4.3.11 UC6 – Enabling information exchange and improving communication

ID	UC6
Title	Enabling information exchange and Improving communication
Summary	The eCare system should be able to provide systematic access to social and medical services, and improving communication in between systems at local/regional and national level, enabling the different actors in the eCare environment to be able to exchange information. The eCare system should pay a special attention to accessibility in order to untie the knot of complexity and/or bureaucracy of the assessment processes, making the articulation/ cooperation between healthcare professionals and social workers more efficient by preventing the overlapping of interventions/prescriptions. The eCare solution must thereby use data aggregation and provide the resources for data exploitation to make care system more efficient and cost effective through the delivery of comprehensive decision support to Care professionals.
Actors	Older adult; Healthcare Professional; Social worker; System
Parent	-
Children	UC6.1
Preconditions	Procurers' existing IT systems, both in terms of functionalities and design of Electronic Records
Base flow	A dashboard should be implemented to simplify the access as a screen that displays individual's aggregated data and allows monitoring his/her progress on the most important clinical and social parameters in real time. The dashboard should make available the following aggregated data: - Agile Reporting of group of users by imputed variables. - Statistical analysis and graphical reporting of users. - Shared care plans. - Critical alerts. The dashboard should also be able to ensure integration and provide a single access to social and healthcare services, as well as to ensure real time connection between users and carers and report any problems that must be managed and routed to the appropriate professional. Through the use of artificial intelligence, the solution must be able to provide support for Care professionals' decisions (UC3), based on users' clinical and laboratory results, data derived from self-assessment (wearables and self-report), accomplished activities, etc. The delivery of information will improve with time as regards to what information is desired by providing a feedback loop.
Post conditions	The information based on latest data is available.
Triggers	The Care professional access the dashboard.
Frequency	Information is continuously accessible.
Exception paths	Network access is interrupted.
Open issues/Notes	The ethical and legal implications. The solution should comply with the dispositions of the GDPR.

4.3.12 UC6.1 – Integrating data and ensuring interoperability.

ID	UC6.1
Title	Integrating data and ensuring interoperability
Summary	A key requirement for the eCare solution is that is supported by a platform that integrates data and ensures interoperability with existing systems and with other devices that are necessary to capture certain clinical parameters. The selection of parameters depends on the characteristics of the proposed solution and the data it requires for its algorithms. The system should be able to integrate/refer to other databases where the older adult is enrolled at the hospital/center premises (e.g. existing EHR, administrative databases, order entries of the hospital). EHR systems, clinical decision support systems and analytic tools need to compute on coherent psychosocial and health data in order to support a more efficient and cost-effective care system.
Actors	Older adult; Healthcare Professional; Social worker; System
Parent	UC6
Children	-
Preconditions	Procurers' existing IT systems, both in terms of functionalities and design of Electronic Records
Base flow	1. The eCare solution will have to make use of different data, as all the data is not available in one place. Therefore, integrating data from different sources and using it innovatively in order to deliver personalized support is seen as a key factor for a good solution. There should be a strategy of clearly define what data is necessary for the solution to work, where this data will come from (collected autonomously by the user or from a determined system), and how to ensure interoperability in order to integrate and use the data. Data may come from: - The existing systems of the procurers, that can provide basic or detailed patient data (age, weight, height, BP, lab results, etc.). - devices such as smartphones, wearables. - older adults themselves, by providing information to the system, such as the tests in UC1 and UC2. - the Care professionals (e.g. prescribed medication). - non clinic data sources (e.g. cultural agenda, weather, local news, from an Open Data Portal, such as Santander Datos Abiertos) - other databases or platform present at the premises 2. Automatic data upload will be the preferred choice for any data that the older adult must handle (e.g. Blood Pressure). Depending on the proposed solution, developers will have to define a profile through an analysis of the existing laws, rules, work processes, and actors involved in the use of the systems in relation with the data they need to ensure that it is included in the system. 3. There should be a focus on the operability of the solution and its universal access for all parties involved in the project, therefore the platform should incorporate the use of open data formats for exchange and processing of data with particular attention paid to formats such as CSV, JSON, XML, etc. It must also be possible for the data (in standard formats) to be consumed by other internal applications from the procurers, with the required security. For this purpose, the necessary APIs (Application Programming Interfaces) must be developed.
Post conditions	All data required for the envisaged eCare system to run is available.
Triggers	-
Frequency	Integration of new data is a continuous process.
Exception paths	-

Open issues/Notes	The ethical and legal implications. The solution should comply with the dispositions of the GDPR. Data should be available through bulk downloads in open data formats.

5 Requirements

The identification and validation of the actual unmet needs aligned with the eCare challenges enabled the co-design of the corresponding specific key areas/functionalities of a user centric and integrated solution for the screening, management, and prevention of frailty, in the form of a list of requirements.

The requirements documented here represent the best attempt of the eCare procurers to define features of future solution which, individually and in total, represent significant innovation beyond the state of the art in the management of frailty.

5.1 Functional requirements

The eCare solution presents itself as user centric system that simultaneously encompasses 4 main drivers linked with some of the previously described Use Cases and related to the functional requirements. This has been described in section 4.1.

In the following sections a set of tables specifying eCare functional requirements are shown.

5.1.1 Requirements related to frailty screening.

Table XII. List of functional requirements related to frailty screening

No.	Description
FR1	*Bio-psycho-social risks identification*: eCare solution shall allow to identify older adults' bio (i.e., mobility impairments), psycho (i.e., loneliness), social risks (i.e., isolation)
FR2	*Pre-frailty and frailty assessment*: The solution shall allow evidence-based pre-frailty and frailty assessment in older adults. It should be possible to carry out the assessment at the older adult's home, in a care facility or in a nursing home (refer to section 5.3 for more information about validated frailty measurement scales)
FR3	Risk assessment report: The system shall allow to provide results (i.e., clinical frailty scale[3]) to healthcare professionals and/or social workers in charge of the older adults' care.

5.1.2 Requirements related to care frailty management and prevention

Table XIII. List of functional requirements related to frailty management and prevention

No.	Description
FR4	*Activity and health status monitoring*: eCare solution shall provide the least invasive activity and health status monitoring of older adults to support professional's decision making.
FR5	Emotional and psychosocial support: eCare solution shall provide Emotional and Psychosocial recommendations and activities according to the user's needs.
FR6	*End-user psychological state prediction provision*: eCare solution shall provide a system that predicts the user mood, cognitive and motivational state.
FR7	*End-user functional decline management*: eCare solution shall encourage users to participate in social ludic activities, improving their physical and mental condition while preventing loneliness and isolation.

[3] https://www.dal.ca/sites/gmr/our-tools/clinical-frailty-scale.html

FR8	*Ludic and educational contents provision*: The system shall deliver specific ludic and educational contents for cognitive training and adapted physical activity.
FR9	*End-user profile-based contents adaptation*: The solution shall provide user profile-based training and ludic contents.
FR10	*Community connection*: The solution shall promote a sense of living and belonging to the community by connecting older adults with family, neighbours, friends, and peers.
FR11	*Preventive alerts*: The system shall issue preventive alerts based on significant health status changes and atypical behaviours will be received by both older adults and caregivers.
FR12	*Emergency alerts*: eCare solution shall provide automatic and semi-automatic emergency alerts in case of falls or acute episodes to accelerate the emergency handling response, always with an accurate approach to neither saturate emergency services nor lose trustiness.
FR13	*Self-management engagement*: The system should promote older adults' engagement in self-management to increase adherence to therapies and prescriptions, improving nutritional intake and improving physical activity level.
FR14	*Self-management support*: eCare solution shall take advantage of community feedback and support, promoting engagement of users in self-management.

5.1.3 Requirements related to develop integrated pathways

Table XIV. List of functional requirements related to develop integrated pathways

No.	Description
FR15	*Standardized data collection*: eCare solution shall allow to gather the needs, preferences and limits data through standardized surveys/interviews to be addressed by care professionals to older adults and their caregivers.
FR16	*Comprehensive profile*: The data collected shall allow to build a comprehensive older adult profile (refer to section 5.2.5 for more information about data to be collected for the profile).
FR17	*Pathway-profile matching*: eCare solution shall allow to match organizations existing care pathways with older adult profile and care needs.
FR18	*Shared care plan definition*: eCare solution shall allow to create a *Shared Care Plan,* that is a user-centered health record designed to facilitate communication among members of the care team, including the older adults and providers. The Shared Care Plan represents a structured common guidance by which the care professionals and the older adult can co-organize in a negotiation basis a plan for the management of frailty.
FR19	*Target and goals tracking*: The Shared Care Plan shall allow to set up and track goals and targets. Targets are set together by the care professional and older adult based on the discussions by selecting among different target categories (e.g. physical activity, nutrition, health parameters like blood glucose or blood pressure , emotional balance and socialization).
FR20	*Automatic data input*: eCare system shall allow the collection of older adult's relevant data through automatic solutions such as wearables and domotics.
FR21	*Manual data input*: eCare system shall allow users (health and care professionals, caregivers and old adults) to upload relevant data to the Shared Care Plan.
FR22	*Events management*: The Shared Care Plan shall allow health and care professionals to schedule and update events (i.e., appointments, training sessions).

FR23	*Deviation management*: The Shared Care Plan shall highlight patterns from data parameters history to support better decision making of health and care professionals.
FR24	*Medication and dosage management*: The Shared Care Plan shall allow to register prescribed medication and dosage as well as their compliance.
FR25	*Reporting*: The Shared Care Plan shall allow to view, generate, and export reports, including one adapted to older adults with a user-friendly design to be printable and easily understandable.
FR26	*Messaging system*: The Shared Care Plan shall promote internal communication through a messaging system among health and care professionals, older adults and their caregivers.

5.1.4 Requirements related to develop knowledge sharing.

Table XV. List of functional requirements related to knowledge sharing

No.	Description
FR27	*User tailored training*: The system shall build a training program based on user's profile.
FR28	*Skills increasement*: eCare system shall promote the development of older adults, and their caregivers' skills (ICT usage, acts of care and soft skills).
FR29	*Capacity building program*: eCare system should encompass a capacity building program so users can enroll in specific training modules according to their needs.
FR30	*Training content*: the system should provide widely accepted by healthcare community training content on: Soft Skills (training emotion regulation strategies; effective communication and active listening; empathy, negotiation, and conflict resolution); Resilience and self-motivation *IT* Usage (Training on new technologies usage to leverage the potential of the eCare system it-self, as well as to empower older adults and care professionals) and Acts of Care (Training self-care; health promotion; care techniques; etc.).

5.2 Non-functional requirements

In the following sections a set of tables specifying eCare non-functional requirements are shown.

5.2.1 Methodology

Table XVI. List of methodology non-functional requirements

No.	Description
NFR1	*Methodology declaration*: The proposer shall select, declare in its proposal, and apply during the development of its activities a modern methodology, adapted to the technology used and chosen from those commonly used in similar projects. When applicable, the use of the ISO/IEC 12207:2008 is compulsory. In that way, the supplier must indicate which processes have been adopted from that standard.
NFR2	*Methodology application*: The proposal shall demonstrate how the chosen methodology will be applied, describing the planning, procedures, and other elements of the methodology. In addition, evidence of application of the methodology should be described and provided during project development as part of the development or final reports.
NFR3	*Pre-production environment*: The proposed shall develop, when applicable a pre-production environment able to perform tests (e.g., performance) and validation processes (e.g., security) and production environment.
NFR4	*Methodology compliance*: The methodology used must guarantee the interoperability of technologies and their methods of use, to ensure the exchange of data and the contexts of interaction and integration between public procurers, citizens and businesses. The methodology used must be compliance interoperability principles of European public services.

5.2.2 Compatibility, interoperability and adaptation to local context

Table XVII. List of compatibility, interoperability and adaptation to local context non-functional requirements

No.	Description
NFR5	*Procurers' context adaptation*: The solution shall be able to exchange information with other systems, devices and services. The proposal shall identify and address the main ones currently working in each procurer context. Considering that context may change in the future or even during the project development, mechanisms developed for this aim shall be general and as much as flexible as robust as possible.
NFR6	*Information exchange*: The exchange information formats, protocols, procedures and mechanisms shall have features adapted to the communication needs between the solution and other systems, devices, and services. They shall have the required performance i.e., when real-time is needed to work this specific feature must be addressed. The proposal shall describe these elements and the standards they are based.
NFR7	*Browser frontend*: Browser frontend is preferred instead of installed program in computer. If the second approach is offered a clear justification must be provided.
NFR8	*Browser's compatibility*: When browser frontend is used by the solution it will support correct visualization for 90% of the user's most used browser version & operating system combinations in general and all browsers used by each procurer. (i.e., see https://gs.statcounter.com/browser-market-share)

NFR9	*Installed programs compatibility*: When installed programs in procurers' computers are provided, they must be compatible with their operating systems versions and have good performance working in the computers used by procurers' staff.
NFR10	*Solution Apps*: The Apps of the solution, if applicable, shall be functional in most used mobile operating systems i.e., iOS and Android, and at least in their current and previous versions covering at least the 90% of the devices currently in use in the European market.
NFR11	*Interoperability standards*: The interoperability of the solution shall accomplish the standards stated in https://ec.europa.eu/eip/ageing/standards/healthcare/e-health_en . It is compulsory that the supplier enumerates which standards from that URL are adopted in the solution.
NFR12	*Interoperability with ASL BN*: The solution shall interoperate with ASL BN context existing system. See additional information below this table.
NFR13	*Interoperability with UKA*: The solution shall interoperate with UKA context existing system. See additional information below this table.
NFR14	*Interoperability with CSI*: The solution shall interoperate with CSI context existing system. See additional information below this table.
NFR15	*Interoperability with SDR*: The solution shall interoperate with SDR context existing system. See additional information below this table.
NFR16	*EU public services interoperability services*: The proposed solution should be compliance with interoperability principles of European public services. See Figure 3 below this table.
NFR17	*Open-source preference*: The use of open-source software technologies and products shall be preferred to save development cost, avoid a vendor lock-in effect, and allow fast adaptation to specific procurers' needs.
NFR18	*Open and non-proprietary standards*: The solution shall use primarily open and non-proprietary standards. Only will be allowed to use proprietary standards when it is mandatory for communication with an external existing system working in a procurer's context and there is no possible alternative.
NFR19	*Semantic interoperability*: The proposed solution should ensure structural and semantic interoperability that the precise format and meaning of exchanged data and information is preserved and understood throughout exchanges among different entities profiles (health and social care) and third sector agents (i.e., NGOs), in other words 'what is sent is what is understood'.
NFR20	*Technical interoperability*: The proposed solution should ensure technical interoperability including interface specifications, interconnection services, data integration services, data presentation and exchange, and secure communication protocols. The intent is to have an open-source platform that carries out communications between its systems and external systems using international standards, according to the methodologies and indications contained in the IHE Technical Framework[4].
NFR21	*Services accessibility:* The eCare system should pay a special attention to accessibility in order to mitigate complexity and bureaucracy of the assessment processes, making the cooperation between healthcare professionals and social workers more efficient by preventing the overlapping of interventions.

[4] https://www.ihe.net/resources/technical_frameworks/

ASL BN Local Context

The ASL of Benevento is equipping itself with an open-source integration platform based on communications through standards such as HL7 and XML, in compliance with the "Guideline on the technical interoperability of Public Administrations" of 04/06/2020 issued by AgID. The services and interfaces allow the exchange of data and documents, in the dual form of documents structured according to the HL7 / CDAr2 standard and textual reports. The two types of documents contain both the clinical-health descriptive attributes of the episode or macro-event (metadata), and the content of the structured or unstructured document.

As for the integration profiles, the use of IHE "profiles" is required, with reference to the Technical Framework of reference, in a design vision that provides for future integration with any other IHE compliant system.

These additions must be provided for the sending of clinical documents to stakeholders in CDAr2 format to FSE (Electronic Health Record).

The proposed solution must interface with the integration platform and allow identification through current national tools such as SpID, Electronic Identity Card (CID) and Health Card (TS).

In addition, it will be necessary to ensure the integration of the proposed solution with corporate and regional systems. Specifically, the solution will have to allow integration to the information systems described in the following mapping which is to be considered only indicative:

Table XVIII. ASL Benevento systems integration mapping

Scope of	Information system – description	Commercial software solution	Management level and fruition
Administrative – City services	Public System Identità Digital (SPID)	SPID	NATIONAL
	Digital Identity Card (CID)	CID	NATIONAL
	Assisted Registry Health Card (SOGEI)	SOGEI	NATIONAL
	Web Portal and Citizen Portal	under development	CORPORATE
	Assisted Regional Registry (ARA) – Healthcare Facilities Registry (ASS) – Healthcare Operators Registry	SYMPHONY Registry office	REGIONAL
	Vaccinal Registry	SYMPHONY Registry Vaccine	REGIONAL
Sanitary	Electronic Health Record (FSE)	National FSE	NATIONAL / REGIONAL
	Territorial Clinical Record	under development	CORPORATE
	General Booking System	SYMPHONY CUP Unique Regional	REGIONAL
	E-Prescription – Dematerialized recipe	E-Prescription (ENG spa) / SINFONIA	CORPORATE / REGIONAL
	system RIS-PACS	Suitestensa (EBIT)	CORPORATE
	Clinical Analysis Laboratory (LIS)	DIAMOND and INTEGRATED LABORATORIES MANAGEMENT	CORPORATE / REGIONAL

UKA local context

UKA is working with standard EHR systems like FallAkte+ and ELFI. We are using established health IT standards – via HL7/FHIR and/or a communication server: We support the FHIR (Fast Healthcare Interoperability resources) data format created by the Health Level Seven International (HL7) which has become one of the most popular standards for the exchange of electronic health records. FHIR

uses modern web-based technologies including a RESTful protocol and a JSON or XML data representation.

CSI local context

The EHR of CSI is based on a single system (SAP ISH/Med). It collects all the clinical information of the patient.

The systems are linked to the EHR with live data feeds by integration of the departmental systems with SAP is online, while for medical devices is based on broadcast messaging.

The messaging interface standard to which EHR adhere are HL7 2.5 and web services.

The authentication model is Single sign-on and LDAP.

The EHR is made available to staff at the hospital through the SAP customer (sap-gui).

SDR local context

For the delivering of the services portfolio that the City Council is providing, 3 of them are currently externalized to 3 private companies specialized in each type of service: teleassistance, home assistance service and food at home. Each company has their own IT systems and there are no special requirements in for them regarding IT.

The information between private companies and the City Council is exchanged using spreadsheet files and PDF documents. These files contain a list of individual services provided each month and social services department generates the receipts as payment confirmation. This information is managed by the corresponding municipality service for issuing the payments.

Internally, Social Services department make use of the municipal census application and a custom developed application for social services management. This application is developed using C# by an external software company (https://www.cic.es/) and data is stored in an Oracle 12 database. Currently, it is being developed a connection with eXperta platform (product from http://www.munitecnia.es/) for supporting the digital signature of the receipts. LDAP is the authentication model used.

There are some external connections with the service interoperates for carrying out its duties: General Treasury of the Social Security, the Tax Agency, the SEPE (State public employment Service) and the Ministry of Justice, all of them, Spanish official entities.

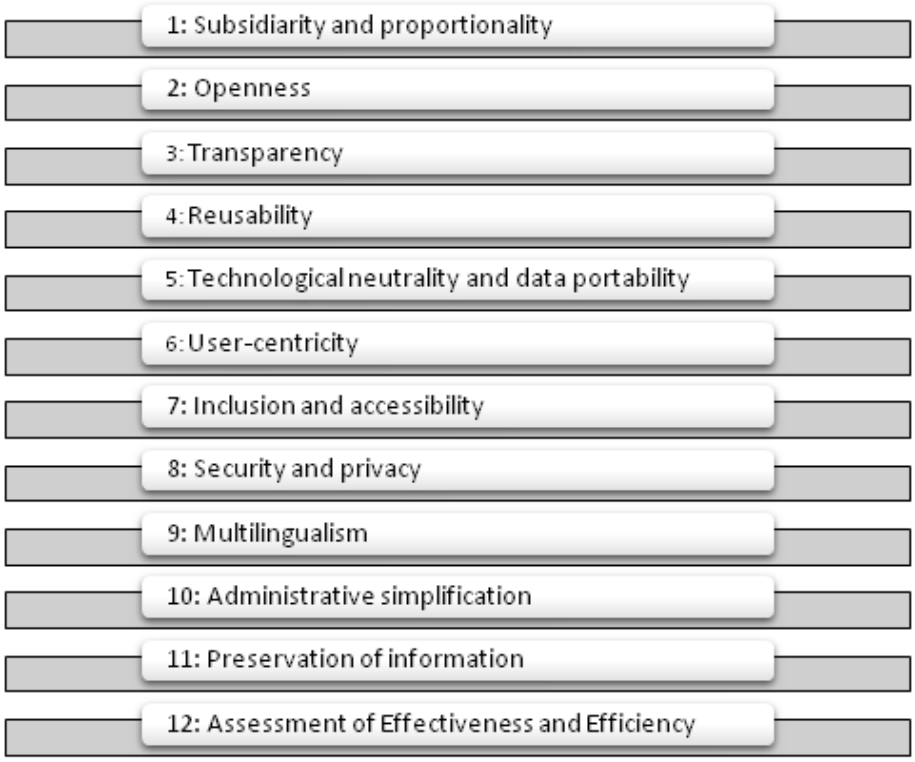

Figure 3. Interoperability principles of European public services

5.2.3 Security

Table XIX. List of security non-functional requirements

No.	Description
NFR22	*Security standards*: The solution shall accomplish the security standards stated in https://ec.europa.eu/eip/ageing/standards/healthcare/e-health_en. It is compulsory that the supplier enumerates which standards from that URL are adopted in the solution.
NFR23	*Communications between systems*: All the communications between systems shall have a protection using the highest standards and fulfilling those required when norms and legislation are applicable. The approach shall be reasonable based on the type of communication, the channel and the information transmitted i.e., wearable devices communicating with a host element located in old adult house will have a lower level of protection that the health information travelling from the old adult house to the cloud repository.
NFR24	*Authorization and authentication*: The solution shall have a clear structure of authorization and authentication processes adapting each level to the sensitivity of the information being managed i.e., accessing general information may be implemented by a user and a password or preferably by biometric reading for old adults and caregivers but the more sensitive the information is the more level of security has to be implemented i.e., double step authentication. This shall be organized by defining user profiles as a starting point and be able to configure accesses in a more granular and specific way. The system must prevent non-authorized accesses and keep track for auditing and security purposes.
NFR25	*Pseudonymization of data special care*: The solution shall develop a privacy policy with respect personal data taking special care when dealing with pseudonymized data.

NFR26	*Record and audit*: The solution shall provide a logging system for keeping evidence of policy breaches e.g., unauthorized access to personal and/or health information of old adults and caregivers.
NFR27	*Security and privacy risks impact assessment and mitigation plans*: The solution shall undertake an impact assessment of potential security and privacy risks arising because of the use of each service provided. The bidding companies should ensure that: • they follow the privacy-by-design and security-by-design approach to secure their complete infrastructure and building blocks. • services are not vulnerable to attacks which might interrupt their operation and cause data theft or data damage; and • they are compliant with the legal requirements and obligations regarding data protection and privacy acknowledging the risks to privacy from advanced data processing and analytics. They should also ensure that controllers comply with data protection legislation, by covering the following points. • 'Risk management plan' to identify risks, assess their potential impact and plan responses with appropriate technical and organizational measures. Based on the latest technological developments, those measures must ensure that the level of security is commensurate with the degree of risk. • 'Business continuity plans' and 'Back-up and recovery plans' to put in place the procedures needed for functions to operate after a disastrous event and bring all functions back to normal the earliest possible. • A 'data access and authorization plan' which determines who has access to what data and under what conditions, to ensure privacy. Unauthorized access and security breaches should be monitored and appropriate actions should be taken to prevent any recurrence of breaches.
NFR28	*Data encrypting*: The solution shall provide necessary equipment and measures to ensure user and data privacy by using encryption standards.
NFR29	*Firewall*: The solution, when applicable, shall provide necessary equipment and measures to ensure user and data privacy by installing a firewall.
NFR30	*HTTPS*: The solution, when applicable, shall provide necessary equipment and measures to ensure user and data privacy by only allowing access to data through a https-encrypted web connection
NFR31	*VPN*: The solution, when applicable, shall provide necessary equipment and measures to ensure user and data privacy by allowing access to data, if applicable inside and / or outside of the restricted domain, via VPN.
NFR32	*Breach notification to system administrator*: The solution, when applicable, shall notify the system administrator in case of security breaches by explaining the nature of the breach and how adverse impact of the breach can be mitigated.
NFR33	*CERT timely response*: The solution, when applicable, shall ensure a timely response to incidents reported by the national or equivalent entity in each country.
NFR34	*Security requirements profiles*: The solution shall provide for its future commercialization a security requirements profile document identifying security requirements for each class of security device. ISO/IEC 15408 Common Criteria for Information Technology Security Evaluation may apply as international standard for computer security certification.
NFR35	*Security policy site adaptation*: The solution shall develop and implement a data security policy according to each procurer local context.
NFR36	*Data stratification approach*: The solution shall implement a data stratification approach to address uncertainty about privacy and legal risks with a defensive philosophy.

5.2.4 Usability and configurability

Table XX. List of usability and configurability non-functional requirements

No.	Description
NFR37	*Usability standards*: The solution should accomplish the usability standards stated in https://ec.europa.eu/eip/ageing/standards_en, giving priority to "Healthcare" standards instead of "ICT and communication" standards. It is compulsory that the supplier enumerates which standards from that URL are adopted in the solution.
NFR38	*Operational languages:* The solution shall operate in Italian, German, Spanish, Catalan, and English languages. Besides, featured videos/training materials shall be available in these languages.
NFR39	*Multiple language support:* The solution shall implement multiple language support at user level, allowing a seamless service.
NFR40	*Language expandability:* The proposal shall be agnostic to language. used terminology shall be easily changeable and the solution shall be developed in a way so that additional languages can be easily added
NFR41	*UAAG:* The solution shall conform to the UAAG 2.0. at a minimum level 2 (AA).
NFR42	*WCAG:* The solution shall conform to the WCAG 2.0 at a minimum level 2 (AA).
NFR43	*Single web access point*: The solution shall have, for the system management and daily work, a single web access point for users independently from their profile (social service, health care, third party entities (i.e., NGOs), families…)
NFR44	*Multiple user interfaces*: The solution shall have different interfaces with different functionalities according to the different user profiles considering the different roles, skills, and knowledge, handicap states they have or may have.
NFR45	*User preferences setting*: The solution shall, when applicable, be able to set preferences for an individual user (e.g. language)
NFR46	*Old adult UI/UX*: The solution shall have an older adult centered UI/UX and take special care in this aspect (e.g. adapted, clear and simple information)
NFR47	*Easy access to systems*: The solution shall be accessible in ways adapted to IT skills of each user profile i.e., biometric readers, scanners.
NFR48	*Responsive design*: The solution shall, when applicable, have a responsive design.
NFR49	*Documentation according to user roles*: The solution developer shall provide extensive documentation of the elements forming the solution in several perspectives according to user roles. User and reference manuals for system users, short text information for not skilled users (i.e., older adults and caregivers) should be provided. Whenever advisable, the solution should make use of extra pictorial guidance to make sure end users will not be overwhelmed by the technical jargon.
NFR50	*Initial guidance*: The solution shall provide to new users an interactive guidance for the use of each specific tool or device including information about its purpose and use.
NFR51	*Non-intrusiveness*: The solution monitoring/assistive tools should be non-intrusive (i.e., using fridge opened sensor, bath presence sensors, bed sensors, etc.)
NFR52	*Functionalities tailoring*: The solution shall be formed by tailored functionalities and services and/or having the ability to be tailored to the user, context and environment.

NFR53	*User needs design approach*: In general, the design and development of solution should be guided by user needs and requirements in accordance with the following expectations: • A multi-channel service delivery approach, meaning the availability of alternative channels, physical and digital, to access a service because the users may prefer different channels depending on the circumstances and their needs. • A single point of contact should be made available to users, to hide internal administrative complexity and facilitate access to public service. • Users' feedback should be systematically collected, assessed and used to design new public services and to further improve existing ones. • As far as possible, under the legislation in force, users should be able to provide data once only, and administrations should be able to retrieve and share this data to serve the user, in accordance with data protection rules. • Users should be asked to provide only the information that is necessary to obtain a given public service.
NFR54	*Low maintenance*: The solution shall require easy and low-maintenance effort.

5.2.5 Data analysis

Table XXI. List of data analysis non-functional requirements

No.	Description
NFR55	*Relevant data provision*: The solution shall be able to provide relevant data to be analyzed i.e., from the clinical, social care and management perspective.
NFR56	*Full information provision*: The solution shall provide enough information of its stored data for it to be fully exploited. Metadata, deep explanation of the data models should be provided as part of the documentation of the system.
NFR57	*Big data analytics*: The solution shall provide tools for Big Data analytics of the data collected by the monitoring devices and other data sources. Data may come from: the existing systems of the Procurers, that can provide basic or detailed patient data (age, weight, height, BP, lab results, etc.); devices such as smartphones, wearables; the older adults themselves, by providing information to the system; the Care professionals (e.g. prescribed medication); non clinic data sources (e.g. cultural agenda, weather, local news, from an Open Data Portal; other databases or platforms being used at the premises.

5.2.6 Architecture, scalability and performance

Table XXII. List of architecture, scalability and performance non-functional requirements

No.	Description
NFR58	*Flexibility for new functionalities*: The solution shall be able to allow new functionalities (e.g., adding a new parameter, a new element to the system) to be included in the set of services it provides.
NFR59	*Flexibility for number of users*: The architecture of the solution shall be able to increase the number of users of each type according to their nature (i.e., the increase rate of health care managers is significantly lesser than the increase rate of old adults managed by the solution) without losing performance or demand non-proportional number of resources. This increase can be across different geographic regions.
NFR60	*Easy reproducibility*: The solution shall be formed by elements that are reproducible in form of new instances (e.g., another city, another hospital) in a straightforward way without the need of redesigning the whole system setup.
NFR61	*Flexibility for number of hardware elements*: The architecture of the solution shall be able to increase the number of elements (e.g., wearable devices) in a straightforward way without losing performance, demand a non-proportional addition of resources or lead to complex configuration tasks.
NFR62	*Modularity and modules interdependence*: The architecture of the solution shall be modular in its conception and provided to the procurers maintaining at a minimum the level of interdependence of the modules.
NFR63	*Flexibility for future systems and components*: The solution shall be able to cope with new components and elements that may appear in the future according to the high dynamicity of the market of devices (e.g., IoT devices) implementing an open approach.
NFR64	*Flexibility for future communication protocols*: The solution shall be able to cope with new protocols that may appear in the future with a sensible, flexible, configurable and open approach.
NFR65	*Performance dependence*: The solution shall allow an increase of the volume of data among the elements of the system, support enough number of users accessing each service and be able to increase the number of data entries of every type without losing performance or demand non-proportional number of resources.
NFR66	*Optimal performance configuration*: The solution shall, when applicable, have a set of configurable parameters for a system administrator be able to tailor the performance, storage capacities, etc.
NFR67	*Latency*: The solutions elements latency, when applicable, shall be reasonable for each type of element, system or procedure avoiding user dissatisfaction. In general, delays should be less than 0.5 mS
NFR68	*Loss of communication resilience*: The solution elements, when applicable, shall be resilient to loss of communication (e.g., Internet connection) or work storing changes when a loss of communication is detected.
NFR69	*Architecture resilience*: The solution shall support a resilient architecture to avoid single-point-of-failure, be able to seal-healing maintaining a sensible amount of redundance according to the sensitivity of each element, process and/or system.

NFR70	*Solution services availability*: The solution shall ensure the maximum availability of its services according to the market highest standards and the type of element. It is about continuous accessibility of health and social information by authorized professionals in order to ensure the best healthcare and social services. Systems availability have to relate to physical systems function (e.g., networks, storage): - redundant components at all levels to enhance availability (three-tier architectures/web/application/database tier), - deployment of primary and secondary data centre sites, - enhanced perimeter and internal security measures
NFR71	*Architecture adaptation to ASL BN*: The architecture of the solution shall be able to be provided in a modular way specifically adapted to ASL BN that is a health care provider. The solution architecture will have to be composed of effective modules and interfaces that can be combined, based on the organizational and technological structure of the ASL BN. The scalability and performance of the solution architecture is a function of the functional logic delegated to application levels which must be able to communicate with the software services in use at the ASL BN. The functional architectural model should include the following scalability layers: • Access Layer: the access point to the solution. Through this layer, ASL BN users and platform administrators will be able to access the features offered. • Application Layer: the layer in which the applications usable through a service-oriented architecture are located. The applications must be usable by all the ASL BN actors (doctors, nurses, health workers, administrators) interested in using its services. • Integration Layer: the management layer of the interactions based on services between the functional modules of the solution, the modules that manage the workflow and the modules available in the Electronic Health Record. • Data Layer: level in which all the modules that guarantee the persistence of data are placed, capable of guaranteeing the operation of web and mobile applications. The functional modules that will determine the scalability of the platform are associated with each of the functional architecture levels.
NFR72	*Architecture adaptation to UKA*: The architecture of the solution shall be able to be provided in a modular way specifically adapted to UKA which is a public healthcare provider and University. The solution architecture shall be composed of effective modules and interfaces that can be combined, based on the organizational and technological structure of the University Hospital. The scalability and performance of the solution architecture is a function of the functional logic delegated to application levels which must be able to communicate with the software in use at University Hospital. Several actors are involved in delivering care to frail old adult persons. (Doctors, Nurses, Geriatric Nurses, mobile and outpatient care services and other Caregivers). The electronic document currently available to be shared between the doctor and the patient and in part between Geriatric Nurse and Caregivers. The solution must be able to document the several services provided in order to enable billing and reporting to the health insurance funds and long-term care insurance funds.

NFR73	*Architecture adaptation to CSI*: The architecture of the solution shall be provided in a modular way specifically adapted to CSI which is a public entity providing social and healthcare services. The description of the model for CSI is as follows: Actors involved: Several actors are involved in delivering care to frail old adult persons that may feel lonely or isolated. These are, in decreasing order, the main ones: • Primary care practitioners (doctors, nurses, social workers) They are the reference professionals who usually attend the frail old adult person. Most often frail persons are initially cared for by the community health y services. • Caregivers (family, public and private caregivers). Support the patient when the process of loss of autonomy begins. • Others (Day care centers, nursing homes, third sector, volunteers) • Intermediate care facilities (geriatrician, nurses, social workers) • Professionals from the Social Services may also play a role in the detection of frail adult people. • Patients are often diagnosed at primary care. Usually when the doctor or nurse detect loneliness, the patient is referred to the social workers. Family can also consult the healthcare services when frailty or loneliness is detected. The electronic document currently available to be shared between the doctor and the patient is the folder "La Meva Salut" ('My health'). It grants the patient access to his/her health data. On the other hand, the primary care information system (Ecap) allows for virtual visits and phone calls. The social sector (social services and third sector) does not count on any electronic system. Support and communication are handled by phone. Moreover, the healthcare and social care electronic systems do not interoperate. Training programs to prevent and follow up frailty and loneliness highly depend on the person's needs. They can vary from punctual support for activities of daily living, to day care centers or the need for continuous support from a third person. Depending on the health and socio-family situation, the need for care will be greater or lesser. Communication between the patient and the primary care doctor or nurse, depends on patient's needs. Follow-up can be face-to-face, by phone or through videocall.

NFR74	*Architecture adaptation to SDR*: The architecture of the solution shall be able to be provided in a modular way specifically adapted to SDR which is a public body with competences in public community health and giving a service of social care to old adults. Its nature differs clearly from a hospital or a health care service. As it is usual at the City Hall, these services are managed by a responsible at the public body, but social care services are externalized by a call for procurement that is renewed periodically. The requirements of the call for procurement are established in terms of services, degree of service and information provision but not in the systems and elements the provide. Actors involved: • Municipality Social Department: Composed by a set of municipality workers and headed by the Social Services Manager. This municipality service is responsible for providing help to old adults and other groups of citizens with social needs by the provision of a range of personal, domestic, and technical care to enable people to continue living at home and in their environment, thus avoiding unwanted admissions to residential homes. • Municipality Health Department: This area implements community transformation programs, aimed primarily at improving the determinants of people's health, such as lifestyles and physical and social environments. It holds the social observatory and develop plans, strategies, and proposals for improvement of social health in a participative way. • Contracted external companies: For the provision of the social services, the City Hall periodically launches a call for procurement. The awarded company is in charge of providing the specific care services in a supervised manner by the municipal social services department. • Other municipality departments: At the municipality there some cross cutting departments with relevance regarding the solution to be provided, mainly the Computer Systems and Communications department in charge providing internal support to all municipality departments and responsible for the overall operation of all IT services and systems. After receiving a demand of a social care service, social care workers make a home visit to each person and collect a set of data based on a predefined form for performing an assessment of the kind of needs that should be provided. Once the initial service to be provided has been defined, information is collected on a regular basis for monitoring and adjustment of the degree of service provided purposes. This follow-up can be made face to face or by phone. As health care is the responsibility of the regional government and primary health care services are the responsibility of the municipalities, there is no effective communication between the two areas. When the municipality service detects there is a need beyond its competences bring it to the attention of the health services but currently not in an official way.

5.3 Parameters/measuring units' requirements

Table XXIII. List of parameters/measuring units requirements

No.	Description
PMR1	*Height*: The solution shall support the recording of height values for patients in cm.
PMR2	*Weight*: The solution shall support the recording of weight values for patients in kg.
PMR3	*Waist circumference*: solution shall support the recording of waist circumference values for patients in cm.
PMR4	*Blood pressure*: The solution shall support the recording of waist circumference values for patients in mmHg.
PMR5	*Blood glucose level:* The solution shall support the recording of patient's blood glucose levels in mg/dL.
PMR6	*Creatinine:* The solution shall support the recording of patient's creatinine values in mg/dL.
PMR7	*Albuminuria:* The solution shall support the recording of patient's microalbumin values in mg/dl.
PMR8	*Glycated hemoglobin DCCT:* The solution shall support the recording of patient's glycated hemoglobin in per cent according to DCCT.
PMR9	*Glycated hemoglobin IFCC:* The solution shall support the recording of patient's glycated hemoglobin in mmol/mol according to IFCC.
PMR10	*Body mass index:* The solution shall support the automatic recording of body mass index based on values for the height and weight of the patients.
PMR11	*Cholesterol – total:* The solution shall support the recording of patient's cholesterol (total) values in mg/dL.
PMR12	*Triglyceride Level:* The solution shall support the recording of patient's triglyceride values in mg/dL.
PMR13	*Cholesterol – LDL:* The solution shall support the recording of patient's cholesterol (LDL) values in mg/dL.
PMR14	*Cholesterol – HDL:* The solution shall support the recording of patient's cholesterol (HDL) values in mg/dL.
PMR15	*Creatinine clearance:* The solution shall support the recording of patient's creatinine clearance values in *ml/min.*
PMR16	*Physical activity:* The solution shall support the recording of patient's physical activity in steps/day.
PMR17	*Carbohydrate intake:* The solution shall support the recording of patient's carbohydrate intake in g/day.
PMR18	*Body fat:* The solution shall support the recording of body fat values for patients in percentage.
PMR19	*Body muscle mass:* The solution shall support the recording of body muscle mass values for patients in percentage.
PMR20	*EQ-5D questionnaire:* The solution shall offer the EQ-5D questionnaire to track patients' health outcomes. The questionnaire shall be administered at minimum when enrolling the patient, as well as when the project operational phase ends.
PMR21	*Sleep quality:* The solution shall support the recording of patient's sleep quality.

PMR22	*Possible future sensors:* The solution shall take into account possible future sensors for physiological parameter measurement that could be used in predictive algorithms giving the possibility and flexibility to add new parameters definition.
PMR23	*Total Body Water*: The solution shall support the recording of patient's Total Body Water values in percentage.
PMR24	*Stress level*: The solution shall support the recording of patient's stress levels.
PMR25	*Heart rate / pulse*: The solution shall support the recording of patient's pulse values in bpm.
PMR26	*Oxygen saturation*: The solution shall support the recording of patient`s oxygen saturation via finger sensor (pSO2)

The following paragraphs contains reference information to be used as validated frailty measurement scales and recommended intervention:

- Intervention and guidelines to address the common patterns of frailty in clinical setting. From "Treating frailty – a practical guide"[5]

Table XXIV. Summary of intervention and guidelines to address common patterns of frailty in clinical setting

Pattern	Screening and assessment	Intervention[6]
Unstable health conditions	Medical assessment	Medical management may include geriatrician review, medication review, intervention to increase compliance, referral for follow-up of medical conditions, for example memory clinic, continence clinic.
Under nutrition	Setting appropriate screening, e.g. Mini Nutritional Assessment[7]	Referral to a dietician for nutritional support, which may include education about foods rich in energy and protein, nutrition advice about general healthy eating and benefits of regular exercise to improve health and overall wellbeing, and nutrition support. The NICE clinical guideline 'Nutrition Support in Adults' provides high quality evidence for oral nutrition support in adults with malnutrition http://guidance.nice.org.uk/CG32 (Chapter 8 in particular)

[5] Fairhall, N., Langron, C., Sherrington, C. et al. Treating frailty-a practical guide. BMC Med 9, 83 (2011). https://doi.org/10.1186/1741-7015-9-83
[6] See additional file at https://static-content.springer.com/esm/art%3A10.1186%2F1741-7015-9-83/MediaObjects/12916_2011_428_MOESM2_ESM.DOC for more detailed recommendations.
[7] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR48

Pattern	Screening and assessment	Intervention[6]
Psychological factors	Geriatric Depression Scale (short form)[8]	The Victorian Government Health Information toolkit for depression http://www.health.vic.gov.au/older/toolkit/06Cognition/03Depression/index.htm Frail older depressed patients are particularly susceptible to side effects of antidepressant medication[9]. Antidepressant medication should therefore not be used as front-line therapy. Antidepressant medication is effective in the treatment of older people[10], and a comparison of treatments is outlined in the Cochrane review by Mottram and colleagues[11]. The NICE clinical guideline 'Occupational therapy interventions and physical activity interventions to promote the mental wellbeing of older people in primary care and residential care', http://guidance.nice.org.uk/PH16
Impaired cognition	Mini Mental Status Examination (MMSE)[12] and/or informant questionnaire (IQ Code)[13]	The NICE clinical guideline, 'Dementia: Supporting people with dementia and their carers in health and social care', http://guidance.nice.org.uk/CG42
Impaired vision/hearing	Brief clinical assessment	Referral for specialist medical assessment Facilitate liaison with local/national foundation for blindness and low vision, for aids and advice Facilitate self-management of aids for vision/hearing
Decreased mobility	Timed 4 m walk Timed Up and Go Lower limb strength: Timed sit to stand Balance: 4-point balance test Falls risk: Physiological Profile Assessment[14]	Appropriately designed exercise interventions are effective in preventing falls in older people living in both the community[15] and nursing care settings[16]. Exercise should be ongoing, challenge balance and be undertaken at least two hours per week[17]. Home safety interventions reduce falls rate in this high-risk frail group, and multifactorial falls assessment and intervention are also effective[18]. The team should intervene or refer to appropriate disciplines. Strategies to facilitate behavior change to enhance participation in intervention programs are outlined in the NICE Guidance 'The most appropriate means of generic and specific interventions to support attitude and behaviour change at population and community levels', http://www.nice.org.uk/PH6 [19]. We also encourage the implementation of the Recommendations on physical activity for health for older Australians http://www.health.gov.au/internet/main/publishing.nsf/Content/phd-physical-rec-older-guidelines[20].

[8] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR49
[9] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR27
[10] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR50
[11] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR27
[12] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR51
[13] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR52
[14] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR53
[15] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR28
[16] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR29
[17] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR43
[18] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR28
[19] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR33
[20] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR54

Pattern	Screening and assessment	Intervention[6]
Lack of participation in life roles	Clinical assessment	Barriers to participation should be assessed. Randomized controlled trials have demonstrated increased participation with intervention targeting risk factors, such as modification of the home environment[21] and specific training of community interactions[22]. Setting individualised goals and tailoring interventions to meet these goals may also be effective. Enlist help of significant others/carers to encourage goal attainment.
Problems with services or support systems	Clinical assessment	There should be early and ongoing engagement with support and education of formal and informal carers[23]. Caregivers and family should be taught about frailty, interventions to optimize function, and be involved in planning and development of management plans. Provision and co-ordination of services, with preference given to packages of care, followed by single services, followed by a residential aged care facility. The case co-ordinator must ensure the frail individual and their family/carers understand the services provided and how to promptly access greater assistance in times of increased need. Advice for assisting carers is provided in the NICE clinical guideline 'Dementia: Supporting people with dementia and their carers in health and social care' http://guidance.nice.org.uk/CG42 , Section 1.11.

- Loneliness:
  - De Jong Gierveld Loneliness Scale (1987)
  - The Social and Emotional Loneliness Scale for Adults-Spanish Version (SESLA-S; Yaben, 2008)
- Family support:
  - Gijon's social-familial evaluation scale (SFES)
  - Caregiver Burden Scale of Zarit (Zarit, Reever & Bach-Peterson, 1980)
- Fragility:
  - The Rockwood geriatric clinical frailty scale

[21] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR30
[22] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR31
[23] https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-9-83#ref-CR25

5.4 Organizational and staff requirements

Table XXV. List of Organizational and staff requirements

No.	Description
OSR1	*Change management plan*: The solution developers shall provide a change management plan describing the approach to change management the developers will follow and execute during the pilot operation phase. Appropriate materials development and, where necessary, events organization shall be included as part of the plan.
OSR2	*Quality management and certification plan*: the solution developer shall provide a quality management and certification plan for the future commercialization of the solution.
OSR3	*Written progress reporting*: The solution developer shall issue a written report on the progress the project during phases 1, 2 and 3 each three months and being delivered within two weeks after the end of the reporting period.
OSR4	*Online progress reporting*: The solution developer shall report on the progress of the project during phases 2 and 3 once a month in a scheduled online meeting within a week after the end of the reporting period.
OSR5	*Progress report contents*: The contents of the written progress report shall include technical progress, planned activities for the next period and other additional information affecting the development of the activity by the solution developer. During phase 3, additional information regarding the helpdesk and support team performance and results shall be provided.
OSR6	*Report on demand*: The solution developer shall report on demand by the procurers in phases 1 and 2 or by each procurer in phase 3. These requests will be asked in a sensible way and will contain the specific information the developer should provide and the report delivery time.
OSR7	*Installation of prototypes:* The solution developer shall install the necessary prototypes system at the premises of each of the procurers. All costs involved in the process of installation will be responsibility of the solution developers including freight, transport, taxes, permits, setup, start-up, etc. in a turn-key delivery approach.
OSR8	*Introduction of pilot system*: The solution developer shall introduce the pilot system at the premises of each of the procurers in close collaboration with procurer representatives. System introduction includes installation of the solution, preparation of user devices for rollout and personal in charge training. On-site testing will be done to reveal and resolve any issues that prevent the system from working properly at the premise.
OSR9	*Pilot operation maintenance*: The solution developer shall maintain the operation of all systems at each site at full quality. A developer's team shall be available to the site management to physically and/or remotely resolve any issues and problems that prevent the system from working as desired.
OSR10	*Helpdesk provision and technical maintenance*: The solution developer shall set-up and operate a help service and maintenance response team to address problems faced by end-users (patients, informal carers, healthcare professionals and other staff involved at the sites). This service shall be provided at each of the sites during phase 3.
OSR11	*Local language use*: The solution developer shall use the local language to develop activities in each procurer site, including pilot development, support and maintenance, when involving users and other entities other than the eCare involved procurers' staff. Although interfacing and support will be given by procurers in each site, fluent communication in other than local language cannot be guaranteed.

OSR12	*Data processing approach*: The data shall be processed with as few restrictions as possible and clear licenses for its use to allow better scrutiny of procurers' decision-making processes and realize transparency in practice.

5.5 Commercialization requirements

Table XXVI. List of Commercialization (CR) requirements

No.	Description
CR1	*Affordability and competitiveness*: The solution itself and its elements shall be affordable and highly competitive in the market.
CR2	*Cost of ownership*: The solution developers shall provide the solution at low total costs of ownership.
CR3	*Business plan*: The solution developers shall provide a business plan describing the approach for commercializing the solution (including market expansion plans, business models, etc.)
CR4	*Commercialization plan*: The solution developers shall provide a commercialization plan including the market analysis, risk management, principles for licensing, pricing, distribution, etc.)

5.6 Legal and regulatory requirements

Table XXVII. List of legal and regulatory (LRR) requirements

No.	Description
LRR1	*Information hosting*: All the programs that forms part of the solution shall be hosted on servers hosted in EU countries or in other countries in compliance with GDPR articles 44, 45, 46 and 47 to assure the applicability of European and local regulations regarding data security.
LRR2	*Personal data protection:* Personal data information shall be treated with special care applying the European and local regulations i.e., GPDR. Specific procedures for individual consent should be put in place and the proposal shall explain in a detailed way how it will be addressed by the solution. The personal data shall be processed with IT tools or paper means, in compliance with the principles of the EU Regulation and the Partners' Procedures and Guidelines. Particularly, the proposed solution shall keep the personal data for the time necessary to fulfil legal obligations and the data that is stored in paper or computer archives shall be protected with the appropriate security measures provided by current legislation, able to guarantee that only authorized operators can know the information concerning personal data. The proposed solution also shall adopt adequate technical-organizational security measures pursuant to art. 30 of the EU Regulation.
LRR3	*Privacy information to users*: The solution shall provide each user with complete information about privacy and security policies during the registration in the system and later at specific sensitive points or procedures. Where personal data relating to a data subject is collected the controller shall, at the time when personal data is obtained, provide the data subject with all the information in compliance with Article 13 of the GDPR.
LRR4	*Informed consent*: The solution shall provide informed consent form in either electronic or written/printable form according to user preferences. Consent of the data subject must be freely given, specific and informed to be able to use the requested services.
LRR5	*Consent for reusing personal data*: The solution shall provide a way for requesting a specific individual consent to re-use personal data for research purposes that will be collected separately from consent to use data for care purposes. Data used for research purposes shall be anonymized or pseudonymized whenever it is needed.
LRR6	*Consent withdrawal*: The solution shall provide mechanisms and procedures for managing withdrawal of an individual's consent in either electronic or written form according to user preferences. A policy for managing this type of incidences shall exist and be applied according to applicable law and regulations.
LRR7	*Personal data correction request*: The solution shall allow for any individual requesting to correct data related to his or her data where an error is found, and such correction should be included in a track changes log.
LRR8	*Consent for further communications*: The solution shall provide a way for requesting a specific individual consent to any further communication (e.g., marketing) before being included in a communication action.
LRR9	*Cookies consent*: The solution shall provide the user (prior to a successful registration) with information about the purpose of storage or access to information gathered by cookies and ask for the user's consent.

No.	Description
LRR10	*Italian specific regulations*: The solution shall develop and implement, when applicable, for the Italian procurer, policies and measures . It shall be compliance with Legislative Decree no. 101 of 10 August 2018, Provisions for the Adaptation of the National Legislation to the Provisions of the General Data Protection Regulation (Regulation (EU) 2016/679) that has amended the former "Privacy Code," Legislative Decree No. 196/2003 to implement the provisions of the General Data Protection Regulation (Regulation EU 2016/679). Furthermore, the proposed solution must also comply with the specific Data Protection Management System adopted by the ASL Benevento in order to guarantee, according to a standardized process, the protection of the rights of the interested party and the application of the current Legislative Decree. n. 196/2003 (so-called "Privacy Code") It should be noted that the Italian data protection authority ('Garante') has enacted a general guide on the application of the GDPR (only available in Italian here), which endorses all of the guidelines and opinions issued by the Article 29 Working Party.
LRR11	*German specific regulations:* The solution shall develop and implement, when applicable, for the German procurer, policies measures aligned with and according to the General Data Protection Regulation (EU) 2016/679 and the German Federal Data Protection Act[24].
LRR12	*Spanish specific regulations*: The solution shall develop and implement, when applicable, policies and measures aligned with and according to the "Ley Orgánica 3/2018" of December 5th about Personal Data protection and Digital Rights guarantee.
LRR13	*Medical device certification*: If the solution involves the integration and use of Medical Devices (MD) they have to be provided by the contractor. Besides, if the solution involves the integration and use of devices that correspond to the definition of Medical Device provided for by Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, they must be certified.
LRR14	*Re-use directive compliance*: The solution should be compliance with the European Directive on open data and re-use of public sector information (Directive (EU) 2019/1024). Particularly, to ensure a level playing field, the solution shall process non-discriminatory interoperable data to ensure its openness and reuse.

[24] https://www.gesetze-im-internet.de/englisch_bdsg/

6 Pilots' testing field description

This section provides a more detailed description of the elements that make up the context of each of the procurers. This information must be available to carry out the pilots in phase 3 of the project, but also serve as support to adequately define the solution from phase 1.

First of all, the actors are described on the basis of the parameters that are considered to be key for devising the solution. Also, some figures of participation in the pilots are provided, which will be necessary to adequately dimension phase 3 of the project, mainly those regarding the **number of old adults participating, number that should be taken as a minimum value, 40 as testers for the solution the other 40 as a control group. That is the total number of old adults participating in the whole pilot test.**

Secondly, a list of the portfolio of services is shown with the aim of informing about those activities currently underway where the proposed solution can be applied. Thirdly, a qualitative description of the available data that can be used during the development of the project is provided. Finally, indications are given on the possibilities for end-user engagement in each of the pilots.

6.1 Azienda Sanitaria Locale Benevento

The procedure for carrying out field tests at the ASL Benevento is as follows:

- The eCare Scientific Referent, with the collaboration of the Company Health Director, will contact 2 Referents of the territorial Health Districts in which the tests will be performed;
- The referents of the Health Districts (for clinical topics) together with the Head of Clinical Engineering (for technical topics) will coordinate the user-engagement operations and all the prototype field testing activities;
- The user engagement will be carried out by 2 General Practitioners among their patients;
- The user engagement will be carried out according to the criteria identified in the project;
- General Practitioners will monitor and support their patients during the field testing activities;
- For social activities, the referents of the Health Districts will involve the social services of 2 municipalities present in the territorial Health Districts;
- The field testing will take place in the Primary Care Complex Unit (UCCP) of the Health District of San Giorgio del Sannio and in the Primary Care Complex Unit (UCCP) of the Health District of Cerreto Sannita.

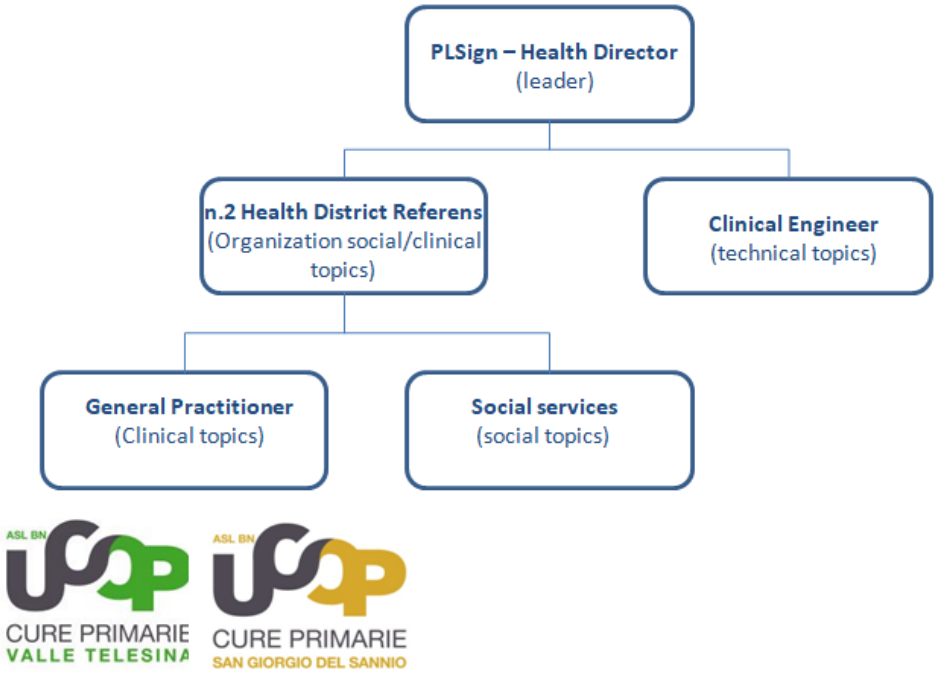

Figure 4. ASL BN process organization

- **User group actors**

Table XXVIII. User group actors at ASL BN's pilot

Name	Location	IT expertise	Number of users participating in testing in pilot field-testing
Old Adults	At home	Very low	80
Caregivers	At home	Medium	20
Health care professionals	Primary care- territorial district	Medium	4
Health care professionals	Integrated home health care office - territorial district	Medium	2
Social care professionals	"territorial areas" of the Province's municipalities	Medium	2
Social care volunteers	At home	low	2
Project Managers/facilitators	ASL BN headquarters	High	3
IT Managers	ASL BN headquarters/ Service providers	High	1

- **Service portfolio being provided to old adults**

Table XXIX. Service portfolio at ASL BN's pilot

Service portfolio being provided to old adults
Patient Home Support Program and Integrated Health Care Services
Chronic Patient Care Program
Neurological and physical rehabilitation services
Social welfare services in the "territorial areas" (with Province's municipalities)
Telemedicine (in start-up a remote assistance telemonitoring system)

- **Pilot data available**

Table XXX. Pilot data available at ASL BN's pilot

Type of Data	Description
Public Digital Identity	Citizen Personal Data
Assisted Registry	Assisted Personal Data
Healthcare Facilities & Operators Registry	-
Patient Healthcare Summary	-
Patient Healthcare Data to EHR	• Prescriptions (Pharmaceutical, Specialist, Hospitalization) • Reports (Outpatient Clinic, Laboratories, Radiology, Specialists) • Hospital discharge form • Vaccination sheet • Pathology sheet • Therapeutic plan

- **End-user engagement**

Table XXXI. End-user engagement activities feasibility at ASL BN's pilot

End-user engagement	Feasibility	Comments
Establish communication mechanisms among suppliers and end-users	Yes	Through general practitioners, who are the link between the ASL and the patients
Co-creation the design of the solution with end-users	Yes	Through general practitioners and the involvement of elderly associations

6.2 Consorci Sanitari Integral

The selection of participants at CSI will be made jointly with the different professionals involved in the research. A proposal of participants will be done by the doctor, the social workers and the nurse, and will be validated by consensus. A CSI coordinator will be appointed for the field testing.

The testing will be delivered simultaneously in all sites and patients but the prototypes are to be tested at patients' home. Although recruitment of old adults can be done from the hospital setting, intermediate care or primary health care, testing will take place at home.

- **User group actors**

Table XXXII. User group actors at CSI's pilot

Name	Location	IT expertise	Number of users participating in testing in pilot field-testing
Old Adults	At home	Very low	80
Caregivers	At home	Medium	20
Health care professionals	Primary care- territorial district	Medium	4
Health care professionals	Hospitals and long-term care - territorial district	Medium	4
Social care professionals	"territorial areas" of the Province's municipalities	Medium	2
Project Managers/facilitators	CSI headquarters	High	2
IT Managers	CSI headquarters/ Services providers	High	1

- **Service portfolio being provided to old adults**

Table XXXIII. Service portfolio at CSI's pilot

Service portfolio being provided to old adults
Training courses (health, leisure, new technologies)
Phone/email general support assistance service for old adults
Attention Chronic complex program
Connection with Council services (homecare)
Day hospital attention

- **Pilot data available**

Table XXXIV. Pilot data available at CSI's pilot

Type of Data	Description
Patient identity	-
Caregiver identity	-
EHR	Pseudo-anonymised data
Relevant clinical diagnosis & pharmaceutical prescription	-
Social diagnosis	-

- **End-user engagement**

Table XXXV. End-user engagement activities feasibility at CSI's pilot

End-user engagement	Feasibility	Comments
Establish communication mechanisms among suppliers and end-users	Yes	Through the local site coordinator
Co-creation the design of the solution with end-users	Yes	With the support of the local site coordinator

6.3 Universitätsklinikum Aachen

The Recruitment of participants for field testing will be done in coordination with medical staff of UKA. There will be a coordinator for the tests, too. The tests will take place individually per site. The prototypes will be conducted in the hospital, at the patients' homes as well as in nursing homes. The field test patients may include clinical and socio-sanitary scenarios.

- **User group actors**

Table XXXVI. User group actors at UKA's pilot

Name	Location	IT expertise	Number of users participating in testing in pilot field-testing
Old adults	At home	Very low	80
Caregivers	At home	Medium	20
Health care professionals	Primary care- territorial district	Medium	4
Health care professionals	Hospitals and long-term care - territorial district	Medium	4
Project Managers/facilitators	UKA/IZDM headquarters	High	2
IT Managers	UKA	High	1

- **Service portfolio being provided to old adults**

Table XXXVII. Service portfolio at UKA's pilot

Service portfolio being provided to old adults
Training courses (health, leisure, new technologies)
Phone/email general support assistance service for old adults
Connection with Council services (homecare)
Day hospital attention

- **Pilot data available**

Table XXXVIII. Pilot data available at UKA's pilot

Type of Data	Description
ePA	Pseudo-anonymised data
Patient Healthcare Data to EHR	• Prescriptions (Pharmaceutical, Specialist, Hospitalization) • Reports (Outpatient Clinic, Laboratories, Radiology, Specialists) • Hospital discharge form • Vaccination sheet • Pathology sheet • Therapeutic plan

- **End-user engagement**

Table XXXIX. End-user engagement activities feasibility at UKA's pilot

End-user engagement	Feasibility	Comments
Establish communication mechanisms among suppliers and end-users	Yes	Through the local coordinator. Local Language is a must.
Co-creation the design of the solution with end-users	Yes	With support of the local coordinator. Local language is a must.

6.4 Santander City Council

The procedure for developing the field-testing in Santander will start contacting with the Santander municipality pilot managers/facilitators. These persons will be the main contacts during the whole process and will be in charge of interfacing with the rest of people or entities involved in the task as well as coordinators for the site.

In the case of Santander, only social care service is involved. The municipality of Santander social care service responsible will be the person who will identify and recruit the participants for the field-testing. This person will also provide help in case any incidence happens with recruited old adults. Solution developer has to bear in mind that a flexible approach regarding participants has to be implemented as changes produced by unforeseen events may change some participants during pilot phase.

The participants, old adults target of the solution, will be identified at the beginning of the phase after a bilateral meeting in which the specific profiles will be agreed. The testing is delivered simultaneously for all patients participating in the pilot. There is only one central site for centralize the management activities (City Hall) and the prototypes to be tested will be located in participants' homes.

- **User group actors**

Table XL. User group actors at Santander's pilot

Name	Location	IT expertise	Number of users participating in testing in pilot field-testing
Old Adults	At home	Very low	80
Social care professionals	City Hall (referral)	Medium	2
Social care professionals	Service provider in its premises	Medium	2
Social care volunteers	At home	Medium	10
Pilot managers/facilitators	City Hall	High	2
Old adults' relatives	At home (maybe in another municipality)	Medium	20
IT Manager	At home /at work	High	1

- **Service portfolio being provided to old adults**

Table XLI. Service portfolio at Santander's pilot

Service portfolio being provided to old adults
Tele-assistance (by phone)
Food at home
Home assistance service (cleaning, feeding, accompaniment, mobility assistance)
Training courses (health, leisure, new technologies, …)
Phone/email general support assistance service for old adults above 70
Special Vulnerability Program to monitor 150 people

- **Pilot data available**

Table XLII. Pilot data available at Santander's pilot

Type of Data	Description
EHR	The City Council has no competence in clinical aspects as they are competence of the regional government. EHR will not be provided
Non clinic data sources (e.g., cultural agenda, weather, local news…)	Santander Open data Portal: http://datos.santander.es/
Other databases or platforms being used at the premises	Specific information for seniors to be included in the new city App currently ongoing. Providing details cannot be guaranteed.

- **End-user engagement**

Table XLIII. End-user engagement activities feasibility at Santander's pilot

End-user engagement	Feasibility	Comments
Establish communication mechanisms among suppliers and end-users	Yes	Local language is a must. Depending on availability and resources demand, local managers can act as interfaces.
Co-creation the design of the solution with end-users	Yes	Local language is a must. Depending on availability and resources demand, local managers can act as interfaces.

7 eCare change management approach

7.1 Axioms

The eCare project considers elements of both emergent and planned change models to define an approach that is feasible and relevant for the project. In this sense, the change management approach in eCare is based in the 4 simple axioms summarized by Alex Boulting article 'How To Choose The Right Approach To Change Management', as they are critical success factors for creating an organisational culture that can purposefully adapt to changing environments whilst maintaining current operations.

The eCare approach to change management leveraged this model, both at the Consortium and at the organizational level, is shown hereafter.

7.1.1 Axiom 1 – Creating a clear vision

A vision should be ambitious, concrete, action-orientated and inspiring. A clear vision will increase not only collaboration level, but it will invite meaning and sense-making into the Organisation. The eCare Consortium has been working from the scratch on the definition of a clear vision that encompasses the design and development of solutions that could enhance the possibility of older adults in a pre-frail/frail condition to stay healthier for a longer period, focused on a comprehensive management of their conditions, both in what regards prevention and self-management, supported by collaborative and co-creation processes in between the end users, caregivers and professionals from social and healthcare.

7.1.2 Axiom 2 – Trust in leadership

Trust is about making ourselves vulnerable - this is potentially critical for change management as employees are led into the unknown by their Organisation. Employees put their trust in leaders who they feel have the ability, benevolence, and integrity to create a positive outcome. An atmosphere of trust and fairness in an organisation not only builds change capability and performance, but also creates a psychologically safe environment where employees can be themselves and can experiment.

7.1.3 Axiom 3 – Supervisory support

It seems that the monitoring of performance against a goal rather than setting the goal itself is the key to motivation and transformation. Supervisors who demonstrate that they value an employee's contribution and that they care about their well-being can create a psychologically safe environment for feedback. Supervisory support is the tipping point between the success and failure of a change initiative. Employees are more positive towards change when they can see how their small, isolated change fits within the context of an overall strategic narrative. This will reduce the chance of employee burnout and increase their satisfaction.

7.1.4 Axiom 4 – Setting clear goals

In an environment where change is constant, Organisations should focus on setting challenging and specific development goals rather than performance goals or ability demonstration. Employees with learning goals have a higher need for achievement. They will seize opportunities to change because they are more likely to be intrinsically motivated, task interested, agreeable and conscientiousness.

7.2 Approach to change management in eCare

The approach undertaken in eCare takins into account planned change models form the change management theory and uses some of their elements to define an approach that is feasible and

relevant. Some considerations are discussed hereafter and then an outline of the change management approach is described.

7.2.1 Considerations

- **Programme constraints**

The eCare pilot phase in which the solution will be operational with real users and real sites which are led by the pilot site management entity and supported by its staff. The timeframe and the nature of the action might be very challenging to address all changes effectively. Healthcare and care professionals as well as old adults participating in the pilot might not adapt as well to the innovative solutions as expected. A certain resistance against change has to be overcome while implementing new technologies, devices and change overall behaviour regarding self-management, optimised care pathways and care coordination. Also, it has to be taken into account that professionals, and the companies or entities to which they belong, participating in the pilot will collaborate in an altruistic manner, i.e. not receiving any compensation for their extra effort. eCare should therefore plan change management actions before the actual operation. As the prototypes are being developed in the previous phase, first changes required will be analysed and appropriate informative materials, conversations with healthcare and care professionals and management will be initiated.

- **Procurers heterogeneity**

The nature of the project involving frailty in older adults requesting an integral and coordinated approach has led to a heterogeneous set of procurers composed by both form the healthcare field and from social care field. There are several differences to overcome in each phase of the project that have to be considered for the solution. Some of them are clear from the beginning: different languages, different countries, different size of each entity, different entities structures, differences in local culture, norms and regulations…These differences might be even more significant in the pilot phase when real people from each site form part of the activity. Each pilot should have a very specific planning taking into account all these elements, evaluation which elements composing the solution are more applicable, less applicable or not applicable at all.

- **Lack of full definition of project scope**

Owing the explorative nature of PCP projects, the full scope of changes that a solution will bring to the pilot's organizations cannot be known at the time of making the call for procurement. That means that it will be up to the suppliers to propose concrete implementations and should take care of the changes they will introduce. And, accordingly to the already stated heterogeneous nature of the set of procurers, each procurer context and sensibilities have to be considered by the awarded solution in a very careful and sensible way.

- **Recipients of changes heterogeneity**

And last, but not least, it is important to distinguish the recipients of change, not only people but also entities. It should be considered that each pilot ecosystem will be formed by different entities: public bodies, NGO, services and good suppliers…and different kind of binding among them: contracts of different kinds, voluntary services, etc. Also, there will be different kind of people involved. A special focus should be put in old adults with different situations in term of familiar, socioeconomical and other particular aspects. However, also professionals and other individuals involved have diverse profile and aims without forgetting the relatives of the old adults in frailty situation or risk. The proposer should have a way to consider all of them to form part of the solution at least, to avoid they form part of the problem.

7.2.2 Addressing barriers to technology adoption

Solutions for frailty management demands decision making both in the short term and medium term. All factors involved in frailty should be integrated into the solution to aid this kind of responsibilities in a sensible and appropriate way. Some barriers have been identified and to be overcome to satisfy the needs of the different stakeholders to facilitate widespread adoptions of software and hardware components of a solution.

- **Usability**

Usability is always a big challenge for digital tools and components for their widespread adoption. That not only affect to the old adult, for which is clear the difficulties for any device, tool or software owing to their lack of technical skills and to their own situation in relation to their state. On the contrary, it also affects to the professionals to which any new element to learn, to manipulate and to manage is another increase of the complexity of their daily work. Being aware that nowadays the technology evolves so quickly that any knowledge acquired can be obsolete in several months and there is an unavoidable and endless effort to be made to maintain the professional proficiency the usability of any new element becomes a key point that should be taken in serious consideration.

- **Economic benefit**

Although there is a clear evidence in a lot of different areas about the economic benefit of technology it is also true that technology by itself it is not the solution and the main driver for solving problems. Thus, each time a new technology is applied to any area of human activity a deep assessment has to be made in order to show its benefits in terms of objective numbers. That means addressing key performance indexes to be monitored before and after the introduction of any innovative action. Applicants are required to elaborate benefits for different stakeholders and to promote these benefits when their solutions are developed. Economic benefits seen such as total cost of ownership has to be clearly addressed.

- **Security and data privacy**

Although it is well known that health data are of special sensitivity there is a data scarcity about the real performance of existing digital tools. Measures based on an insufficient foundation raises the risk of control mechanisms to be inappropriate. Any issue related to these elements may have important consequences in terms of law breaking and also in terms of image. It can adversely affect care, security or can hamper innovation. A wise but defensive approach including comprehensive legal and governance requirements to ensure old adults' data are handled according to the highest European and local standards are ambitioned by eCare.

7.2.3 Iterative approach

An iterative approach to change management is called upon in eCare so the envisioned approach for eCare could include a process to identify changes, create and implement strategies for their management, and monitor and adjust the strategies' implementation to ensure effective change management. The eCare Project aims to be guided by user centred design, improving the solution over several iterations, which in turn will contribute to greater empowerment of older adults, since due to changes in different areas.

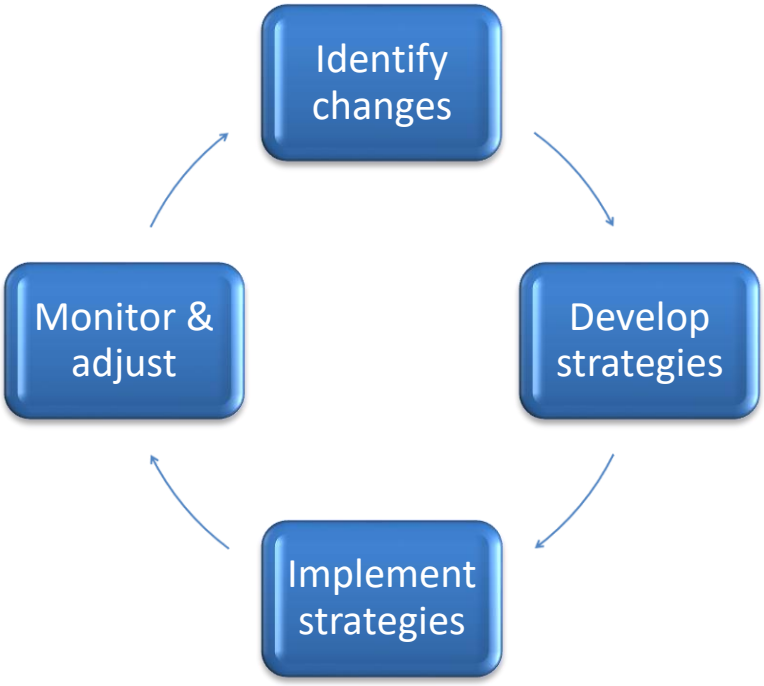

Figure 5. Approach to change management in eCare

- **Identify changes**

With the list of requirements, use cases and process models being developed at the time of writing, the procurers are defining the groundwork needed to be done by the suppliers to deliver a solution suitable for their needs. The use case and process model development process implies that by analysing the as-is situation of the procurers with regards to various processes and activities, and elaborating the envisioned direction for each of these, the consortium will have a good picture of the anticipated changes.

The identification process therefore starts from the moment requirements, use cases and process models are being developed, and lasts throughout the project, although the aim would be to identify most changes already when the first call for tender is completed and the supplier's ideas are available to the procurers. The consortium has some anticipated changes, which are explained hereafter and has to be taken as an initial set to be improved and enhanced by proposers according to their knowledge and experience:

- Although it is clear that old adults have not technical skills a total reluctancy to devices such smartphones have not being identified. In this sense, the usefulness of the devices allied with the natural curiosity of the human being can be a key element for adoption of devices like smartphones. Also, radio and TV devices, upgraded and adapted to the needs of the solution is foreseen as a very natural step ahead for their way of living. Also, those devices like health trackers, intelligent textiles… can form part of the solution always having in mind the usability as a key aspect. In this sense, avoiding human intervention or being as much as natural and effortless as possible (i.e. voice control) seems to be a desired feature.

- Frailty is a human state that requires the person to have a specific degree of self-manage or take actions is different daily situations. Providing old adults to manage their state is also a key aspect of the solution. Repeated training and reminding of those actions not properly addressed are foreseen to be highly positive for their state. Education and training require a substantial amount of professional time. Making

education more effective as well as more efficient seems to be realistic as education can be both standardised and personalised when appropriate sub-groups are distinguished. Also, identifying which pieces of education and training can be provided with less professionals' intervention and devising ways to provide them to old adults will have a significant impact in the whole ecosystem. Again, well established technologies like radio and TV connected with information collected from each old adult can provide adequate actions without overloading the health care or social system.

- Frailty and pre-frailty states are evolutionary processes that has different faces for different social and health care entities. An integrated, steady on time management solution needs to exchange data with existing systems and devices. An integration platform to ensure operability seems to be a must in this scenario. Health among others should be independent of vendor and mechanisms to interchange information in the way that aid to manage the frailty state has to be specified and developed. Although it is not realistic to expect that any system needed during the pilot phase is integrated in this way, measures to facilitate this integration in the future has to be taken.

- **Create strategies**

For each identified change, a specific strategy has to be devised in order to address it properly and successfully. eCare promotes the user centred design and improving the solution over several iterations. Yet, some requirements remain for the proposer to prepare for a potential role out at scale. The proposers need to provide a concept on how to support the role-out of the system technically, and even more importantly, which change management strategy they will follow.

A training concept on how to train the old adults needs to be provided while a training concept on how professionals make use of the system is necessary as well. A basic training for all users before first use is mandatory. This should be accompanied by a physically present trainer during the first days of use. The professionals will need to be trained in their attitude on how to deal with empowered patients. The strategies need to include a comprehensive change management. Due to changes in different areas of frailty care, old adults as well as healthcare professionals and need to be guided in order to minimise difficulties with the implementation of new devices, care procedures or managerial changes.

- **Implement strategies**

A change management plan should be elaborated at the beginning of the action identifying the measures to be taken. The plan has to be developed for each site and agreed separately with each procurer. The plan should be accompanied by a set of measures to be applied to facilitate a seamless management of the different changes identified.

- **Monitor and adjust**

Any result on the application of the strategies, measures and actions related to the change management should be properly monitored in all the sites. Successes, failures, and best practices should be collected and shared among the procures in order to boost progress based on a higher amount of information. Risk prevention and a proactive attitude should give rise to a better implementation in each site allowing adjust strategies, plans and specific actions according to the best practices in project management.