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Deliverable D2.1 FIRST VERSION OF USER REQUIREMENTS AND DATA MODEL

Work Package WP02: SPO

affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project

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[1] **R:** Document, report; **DEM:** Demonstrator, pilot, prototype; **DEC:** Websites, patent fillings, videos, etc.; **OTHER**; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot.

[2] **PU:** Public; **CO:** Confidential, only for members of the consortium (including the Commission Services).

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Glossary, Acronyms and Abbreviations

Acronym/Abbreviation	Description
TeNDER	affecTive basEd iNtegrateD carE for betteR Quality of Life
WPx	Work Package
Tx.x	Task
Mx	Month (where x defines a project month e.g. M8)
EU	European Union
IoT	Internet of Things
IoHT	Internet of Healthcare Things
GP	General practitioner, primary care physician
QoL	Quality of Life
Pwd	Person with dementia
AD	Alzheimer's Disease
PD	Parkinson's Disease
CD	Cardiovascular Disease

GLOSSARY	
Term	**Description**
Information security	Protection of information from unauthorized access, use, disclosure, disruption, modification or destruction (accidental or intentional).
Living environment	Pilot environments in TeNDER: home, day care centre, rehabilitation centre and hospital.
Scenario (Storytelling)	A short story describing the situations where assistance is needed and what assisting functionalities from the available would be best to resolve a situation. The scenario describes the users, their daily activities, challenges faced and motivations for technology usage. Provides a shared understanding about what users might want to do/have and help to construct the sets of functionalities that are necessary to address challenges that users are facing.
Persona	Also known as an archetypal user, is an invented person to represent a type of user in one of TeNDER defined scenarios.
Functionalities	Important measures for discovering discrepancies or specific anomalies and report them to the central management system

	for evaluation and consequent action; notifications, summary reports, actuators, alarms, etc.
Ambient monitoring	Monitoring of changes by sensors located in the living environment of specific ambient conditions.
Wearable monitoring	Monitoring by body-fitted sensors in a form of smart watch, bracelet, body straps, smart stickers, pendants, etc.
Person with dementia, AD	Person expressing cognitive complaints or having cognitive impairments or having diagnosis of disease causing Alzheimer disease or other type of dementia
Patient	Person having or is at risk of having the medical condition(s) whether or not he/she is currently receiving medicines or vaccines to prevent or treat a disease.
Carer	Someone who provides unpaid care for a relative or friend with care or support needs[1], denotes a two-way relationship: usually family member, friend, volunteer....
Caregiver	Someone who provides care or support to another person, denotes a one-way relationship, usually formal caregiver.
Stakeholders	All entities involved, from public policy makers, associations of care and health professionals to healthcare and social care providers.
Informed Consent	Decision, which must be written, dated and signed, to take part in a clinical trial or other scientific project, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her (legal) surrogate decision-maker. If the person concerned is unable to write, oral consent in the presence of at least one impartial witness may be given in exceptional cases, as provided for in national legislation.
Confidentiality	Property that information is not made available or disclosed to unauthorized individuals, entities, or processes
Formal care/ assistance	Help provided to persons with one or more disability by organizations, or individuals representing organizations (whether profit-making or non-profit-making, government or private), or by other persons (excluding family, friends or neighbours as described in informal help) who provide assistance on a regular, paid basis and who are not associated with any organization
Informal care/ assistance	Regular unpaid care and support to a person with one or more disabilities. An informal caregiver is likely to be a relative, close friend, neighbour or volunteer.
Quality of Life	An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment.

Accessibility	Extent to which products, systems, services, environments and facilities can be used by people from a population with the widest range of user needs, characteristics and capabilities to achieve identified goals in identified contexts of use.

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Executive Summary

TeNDER is a multi-sectoral project funded by Horizon 2020, the EU Framework Programme for Research and Innovation. From 2019 to 2022, it will develop an integrated care model to manage multi-morbidity in patients with neurodegenerative diseases.

TeNDER will perform 5 large-scale pilots that will target patients with Alzheimer's and/or Parkinson's along with cardiovascular diseases. In each pilot setting (i.e., in-hospital acute care, at home, and in day- and full-time nursing homes), patients will be monitored using sensors, cameras that capture movement, affective recognition technology, and wristbands that record basic vitals, etc. Meanwhile, TeNDER's technical, legal and ethical experts will ensure that all personal data is protected according the General Data Protection Regulation (GDPR).

TeNDER project aims to improve the quality of life of patients and those that surround them. According to identified participants form existing provision flow we describe herein, we develop co-creation methodology approach to develop common TeNDER toolbox. We intend to as broadly as possible asses real-world living environments of patients and define scenarios for project pilots. Scenarios will be framed in requirements and constrains of ethics, privacy as well as necessity of creating the navigation and draft plans for the components of TeNDER toolbox. Services created with this approach will create opportunities for facilitating communication between social and health care professionals, and extending the autonomy of patients that would live more independently.

This document presents the first report on user, functional and general requirements and first data model approach for TeNDER project. We are developing co-creation methodology approach according to the general requirements reported in service provision flow and our experience. Herein we provide the latest literature summary of relevant "State of Art" knowledge on patients' and other participants' opinions regarding the usage of technology in general and more specifically for monitoring patients' health. Additionally, we integrated the knowledge achieved from the previous research project ICT4Life. The ethical considerations are intrinsic part of the methodology and the system design. They are described in the methodological approach.

The best way to visualize the needs of the TeNDER end-users is by creating models (Personas). The surveys and interviews will be used to define and confirm requirements of various patients with different abilities, people that surround them and furthermore, health and care providers. The most important or repeatedly stated issues will be mirrored in the Personas as core characteristics. According to Personas we will define scenarios, that will be structured in a way that will demonstrate the usage of TeNDER application on each targeted user group and for all living environments. This document serves as a base for Persona and scenario development and we provide first drafts in annexes. Described first data model approach will support the development of technical TeNDER system by providing the definition of entities and data flows. Annexes to this deliverable thus contain first promotional material for addressing participants, a draft version of "TeNDER Research Book", tables with detailed descriptions of functional specifications, first version of user scenarios identified, and detailed definition of entities.

1. INTRODUCTION

TeNDER project is creating an integrated care and personalized ecosystem for assisting people with chronic diseases like Alzheimer's, Parkinson's and comorbidity with cardiovascular diseases through the use of affect based micro tools, with a view to supporting and extending healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities. These micro tools will be able to recognize the mood of a person and thus adapt the system's probes to the person's needs via a multi-sensorial system, even in the most severe cases, and where available match it with clinical (from Electronic Health Records EHRs, and clerical patient information), while preserving privacy, monitoring the ethical principles, providing data protection and security, with the result of an increased quality of life. TeNDER aims at supporting the management of health and wellbeing while empowering the participation of citizens and facilitating the transformation of health and care services to more digitised, person-centred and community-based care models, thereby enabling better access to healthcare and the sustainability of health and care systems.

This deliverable presents the first version of user, functional and general requirements and the first data model approach, providing a common methodological guide for all Pilots. TeNDER project assures that the integration of care will be adjusted to the end users' needs, assuring their participation through the co-design process.

1.1 Objectives

The main purposes of TeNDER ecosystem are the improvement of quality of life for the patients and their caregivers and carers (mostly, close family members to the patients), together with the improvement of working conditions of health and social care professionals involved in the service chain for the above cited diseases: comorbid seniors suffering cardiovascular diseases (CVD), Parkinson's and Alzheimer's disease (or similar dementia). We focus on developing TeNDER from an inclusive approach, thus creating the opportunity for patients, carers, caregivers and their healthcare professionals to provide a creative contribution through the co-design process. All the participants are thus involved in the formulation of our solutions iteratively. Through co-design process we define typical users as "**Personas**" and typical set as "**scenarios**". Thus, we will improve our knowledge of end users' real needs, facilitate the validation of the system and ensure long-term benefits.

TeNDER co-creation process will bring together the teams from different sectors of research health and social care, that will be involved in TeNDER iterative testing. For primary end-users (persons/patients) some technologies are readily available on the market, but often they are lacking end-users' requirements and usability feedback when being developed.

TeNDER relies on an initial perception of what the people that are using it really want, need and what are the conditions for introducing the technologies. The lack of targeted monitoring and user friendly features on technologies already on the market indicate that it is of most importance to involve all participants in all stages of co-creation and subsequent real scenarios testing.

In fact, this innovation action incorporates results from previous research projects such as ICT4Life that were also based on the constant consultation interactions between all end users

(patients, caregivers, and healthcare professionals). Furthermore, working conditions of professionals include process management and multi-disciplinary coordination and thus we need to have the insight of their needs and priorities. Using this approach, we will identify models and best practices for effective collaboration and exchange of information among related stakeholders.

TeNDER will develop tools for different care situations (by disease/by scenario). What is more, people with disabilities usually have problems that will be identified and addressed through a modular, personalized approach. WP02 (Co-design Process) will first emphasise the co-creation from a general perspective and secondly, adapt to the individual perspective; we have created scenarios (fictional stories) and Personas (fictional characters) that will be representative for Pilots and could be used to personalize the technological solutions later-on.

We will thus ensure that all the Pilots released in TeNDER are aligned and the participating organizations have a grounded view on the existing provision flow in the different countries. What is more, the process of developing a common view on general user requirements, will be iteratively reassessed. We will together define processes and methodologies for feedback gathering, testing and other requirements for the final TeNDER system.

1.2 Co-creation process-the first phase

In this first phase we will summarize the existing situation in the different countries involved, integrate knowledge from previous projects and from the state of the art relevant literature. According to this, we have started defining a common approach towards the primary (patients, that are and must be at the core of the co-creation process) and secondary users (their caregivers and health care professionals), for inclusive research of their common and differential needs.

The key outcomes in this deliverable are the report on existing service provision in Germany, Italy, Slovenia and Spain, user and functional requirements and the data model approach. The methodology used for connecting general and user requirements with technology and data is the development of user scenarios based on the Personas (included in Annex 4). Developing scenarios, that involve the Personas as well as other key actors, will later-on also enable stakeholders to better understand the richness and diverse integrated care solutions provided by TeNDER. Scenario use cases will create Personas for each disease covered (regarding their living arrangement, in relation with their daily activities and challenges faced, their basic health status and medications taken, and daily mood). Thus, the knowledge accumulated by the end users' organizations can be shared with the technological partners, supporting them to better visualize by whom, how, where, the TeNDER technologies will be used.

2. The existing care services provision flows (care pathways)

To address proper stakeholders, we reviewed the existing provision flow in countries involved in Piloting of the TeNDER platform.

2.1 The care services provision flow by countries involved

Slovenia

A person who suspects to have symptoms of dementia first visits a general practitioner (GP) that evaluates the symptoms. If needed, the person receives a prescription for a specialist: psychiatrist or neurologist (dementia can be diagnosed only by a medical doctor with specialization in psychiatry or neurology). The person with dementia can be temporarily hospitalized in Psychiatric or Neurological clinic if having severe psychiatric or neurological symptoms.

Institutionalized care for persons with dementia is coordinated and controlled by the Ministry of Labour, Family, Social Affairs and Equal Opportunities in Slovenia. Compulsory insurance guarantees the insured persons payment for health care services (includes home visits, treatment and care at home and in social care institutions by the nurse) [2].

There are service tools for dementia patient in Slovenia [3]

- home care services: home care and mobile services;
- social services;
- institutionalized care (day care centres, nursing homes, nursing hospitals);
- NGO-s.

Home care is a part of public services (shall be co-financed by local communities at least 50%) and is provided as collaboration of social worker, direct care provider, beneficiary and a key responsible family member. The service at home may be performed any day, up to a maximum of 20h per week. The care is provided by professionals, formal caregivers and lay persons [3]. Mobile services are provided as collaboration of professional, beneficiary, and family members, relatives, and guardians. Social services are provided by professional associates after a verified welfare program[3].

Institutionalized care may be provided in a social welfare institution, in another family or in another organized form: nursing homes, special social institutions, training institutes, care centres and other legal or other persons who fulfil the statutory conditions for pursuing the activity. Institutional care (public institutions or private with the concession) at the institution may be provided as full day care or as day care: (1) full day care or in the form of day care (24h) – temporary (short-term); (2) institutionalized care /day care centres (max 10h per day, 1 or 5 days per week). The care is provided by carers, housekeeping carers, guardians, work instructors, animators, social workers, psychologists and other professionals. The beneficiary can have the possibility to use all-day connection via personal telephone alarm for remote assistance. The care can be provided 24h and 7 days per week.

[3] program is verified by the Social Chamber of Slovenia

Nursing homes can organize day care for elderly people. Some of the nursing homes provide advanced dementia care units (as closed units) - patients can be placed into such units only with the court order.

NGO-s also provide community based dementia care social services (counselling and companionship).

Spain

The way in which persons with dementia and persons with cardiovascular disease are cared for follows the same mechanism. The primary health care is the gateway to the health system for any individual in the population. After medical evaluation, if necessary, these patients are referred to a neurologist or cardiologist, who completes the process of diagnosis and treatment. Afterwards, the most frequent follow-up is carried out by the primary care professionals and the specialized consultation carries out a more time-spaced follow-up.

There is a decentralized health system in Spain, so each Autonomous Community usually develops its own protocols. In the Community of Madrid in 2012 a document was signed to ensure the best medical practice with those affected by Parkinson's. According with this protocol when a person goes to their general practitioner with symptoms that can be Parkinson's Disease, the general practitioner performs an anamnesis and rules out possible causes of the symptoms. In case, that after this process the doctor continues to suspect that it is Parkinson's Disease, he refers the person to the specialist (neurologist) who will be in charge of performing in-depth examinations and making the diagnosis of the disease.

In order not to overload the system, the neurologist establishes semi-annual visits to monitor the patient after the diagnosis of the disease, and follow the correct medication adjustment. The neurologist maintains close contact with the general practitioner. In case that the patient perceives worsening, he can go to his general practitioner that assesses if the advance of the specialist's appointment is necessary or simply internal consultation between doctors can resolve the situation.

In 2006, Law 39/2006, of December 14, on the Promotion of Personal Autonomy and Care for People in Dependency in Spain was approved. This law provides for a system of evaluation of the dependency and depending on the degree of affectation it grants different aids or resources for citizens

The most important available resources are:

Home Care: Primary health care constitutes a team of health professionals who also attend to these patients in their homes when they need it. This team usually consists of two people, a doctor and a nurse.

Nursing homes: There are public and private nursing homes in Spain. Public nursing homes take in people whose medical and social situation requires this attention. For the most part, they are elderly people with advanced dementia whose families are unable to provide them with constant, daily care. The health professionals in these institutions are: nurses, nursing

assistants, doctors, physiotherapists, occupational therapists, social workers and psychologists.

Italy

General practitioner (GP) can diagnose privately dementia but not officially. If the GP suspects Alzheimer's disease or dementia, the GP then sends the person to geriatricians, neurologists and psychiatrists whom can diagnose dementia and/or Alzheimer's disease [4,5]. Also structural and functional neuroimaging techniques (Magnetic Resonance Imaging, Positron Emission Tomography,[6,7,8]] I FP-CIT Single Photon Emission Computed Tomography) are used for the diagnosis. In Italy, citizens must purchase a ticket in order to have access to services within the National Health Service. People who are over 65 years old and those suffering from an officially recognized chronic and disabling disease do not have to pay.

The regions have legislative powers over health and welfare but home care services are financed entirely by Local Councils. A care system was set up in the framework of the National Plan for Elderly people which includes:

Home Care (community care): with social importance (home help, meals and personal care); with health importance (medical, rehabilitative and/or nursing care); integrated.

Integrated Home Care Services: is a combination of integrated and coordinated health and social activities which seek to keep an elderly person at home as longer as possible. Health services are medical care (Geriatric, Psychiatry), nursing, rehabilitation, medicines and prosthesis supply. Social services are: personal care, meals, house work, laundry, administrative services.

Day Centers: semi-residential structure, within the public District, which hosts disabled elderly people for a short-term period (they are open during the day, 5 days a week, 7 hours a day, and admit 20 elderly persons). They provide healthcare services (prevention, therapy, and rehabilitation), and social care services (personal care and promotion of personal autonomy, entertainment, job therapy, and social activities).

Nursing homes: residential structure, organized into small groups ("nuclei"), which provides healthcare, social care, and functional rehabilitation for people with disabilities. Patient care can be extensive or intensive. The first area comprises temporary accommodation for long-term care and rehabilitation (while hospitalization is limited only to the acute stage). The second area comprises intensive rehabilitation, with high medical importance, plus a hospice for terminal patients which provides palliative care (reduction of pain; social protection for patients and their family; family support). Doctors, nurses, social workers and psychologists are available at the Nursing Home [7,8].

Germany

Dementia is usually first diagnosed by the general practitioner. However, a psychological and neurological assessment needs to be conducted by a specialist of neurology or psychiatry, where the patient is referred to by the general practitioner. The diagnosis of "Alzheimer's Disease" is usually a diagnosis by exclusion, meaning that if no other origin of the symptoms can be found, this disease is assumed.

The diagnosis further requires a physical examination and blood-testing. Also structural imaging techniques, like computer tomography or magnet resonance imaging, are used for providing brain scans. New testing methods, e.g. amyloid imaging or blood or CSF specimen testing for amyloid and tau protein, are not routinely used.

Need for care: According to the German law, a person requires care if has impairments in autonomy or in general abilities due to the disease. Thus, persons who cannot handle or compensate for their physical, mental or psychological impairments or burdens due to health issues are all targeted. Also, the anticipated need for care has to last at least for 6 months, with a severity according to § 15 SGB XI.

Types of services for people with dementia:

Care at home: In Germany, care at home is the most frequently chosen type of care, especially when the disease is still in early stages. Persons with dementia, who are at least classified to caring level 2, receive a nursing allowance, which they can spend on professional help, like caring services or voluntary workers. However, at the beginning of the disease, the patient is mostly cared for by relatives alone. Here, the financial support allows them to reduce their own working time in order to care for the patient. With the progression of the disease and the increase of the allowance due to the caring level, the use of various services increase.

Shared-flat caring: Shared-flat caring is a new innovative method, where persons requiring care life together in a flat, while non-residential nursing services care for them. This special type of living is financially supported by nursing care insurances. However, in Germany this type is not yet common.

Nursing/ care home: This type of living is usually considered in later stages of the disease, when a higher level of professional care is needed. Here, the person is being cared for 24h per day, 7 days per week, and lives at the institution, which is partly paid by the nursing insurance. According to the stage of the disease, different levels of care are provided, with later stages requiring highly protected environments with, for example, closed doors.

There are several other services offering support in the respective type of living. Most generally the following services exist: **non-residential nursing services, mobile social services, voluntary workers, day-/night nursing services**.

3.2 The summarized care services provision flow

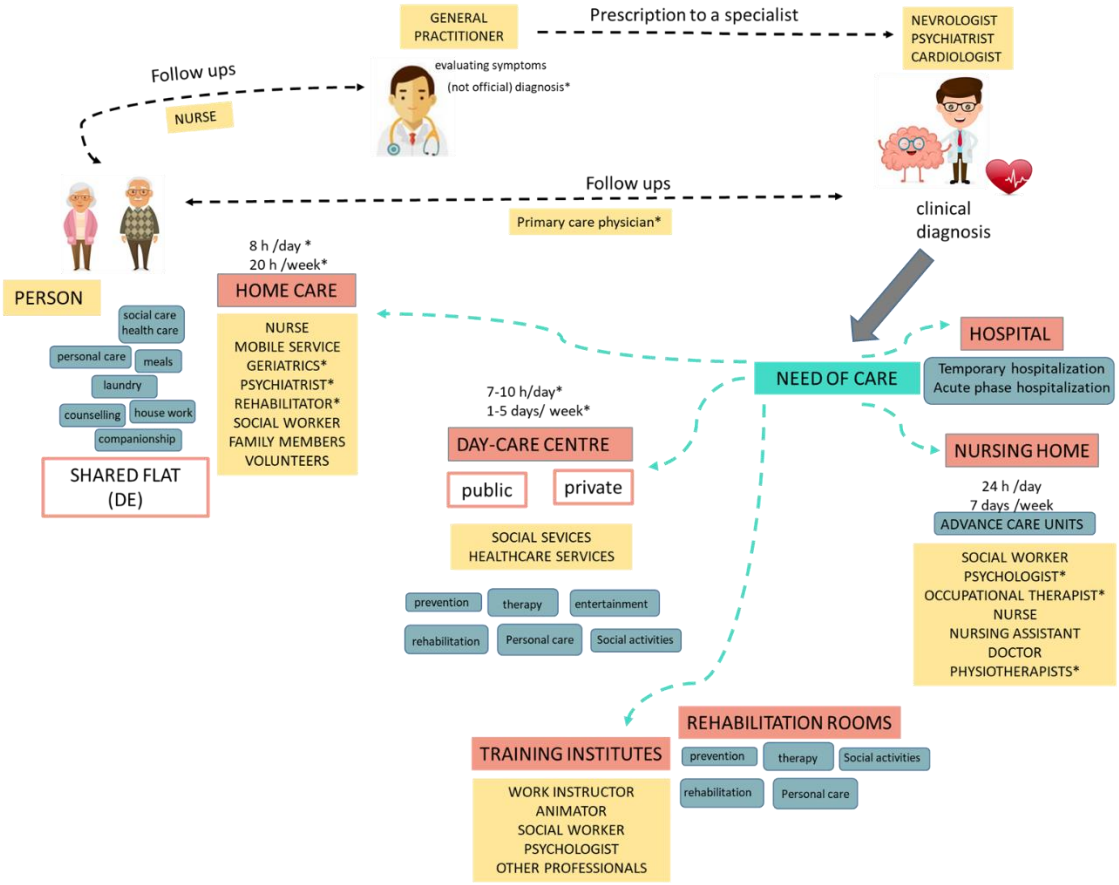


Figure 1: Existing services provision summary for countries involved

In Figure 1 we summarize the existing provision flow for all the countries involved in TeNDER Pilots. Several varieties exist in each country involved, however, we create a summarized pathway and service flow including all related health and social stakeholders included. The Figure presents the different stakeholders involved in integrated care and pathways that TeNDER solutions will address (celeste arrows). *specific for the country

3. Preliminary research and literature overview

In this section, a brief summary of relevant state of the art knowledge on patients' opinions regarding the usage of technology in general and more specifically for monitoring their health. Additionally, some of the results achieved from the iterative testing of the ICT4Life system are also presented.

With regard to the inclusion of technology in the daily lives of patients, it has been seen that patients' priorities may differ from those of careers and professionals, so it is important to take all perspectives into account when developing technological tools and making care plans [9].

Patients identify technology as something useful, which allows them to use it for leisure, to increase their freedom and independence [10]. They show interest in using technology, although they are less motivated by constant monitoring at home and are concerned about incorporating light and sound warnings and camera-based technologies into their daily lives [11,12]. Another concern shown is the security of storage of information collected by the technology [13].

Informal careers find that technology incorporated into their lives and the people they care for daily lives provides them with increased peace of mind and relief from the burden of care. Similarly, formal careers embrace the fact that technologies can ease the monitoring of people in need of care as well as possibility of interactions with other stakeholders [10]

Health professionals consider that technologies reduce their workload and allow them to devote more attention to patients that require it. However, they believe that for technology to enrich rather than weaken the patient-physician relationship, medical humanism must be in the center of the design thinking behind emerging technologies and software. Most importantly, considerable effort will be needed to plan how technology improves the quality of human interactions rather than simply focusing on efficiency, both among team members and with patients and their families [14].

Families as informal careers give preference to patient safety rather than autonomy when they are responsible for patients. When patients are under the responsibility of formal caregivers, they give preference to patient autonomy rather than patient safety [15].

One of the challenges in technological tools is to achieve a balance between safety for all users and preserving their autonomy and privacy [16].

Some of the results deriving from the research with end users of ICT4Life system (Parkinson's patients, Alzheimer's or similar dementia, their caregivers and health care professionals, will be assessed by the TeNDER consortium in order to check their suitability for this current innovation project:

Patients:

- Very positive assessment of participating in the co-design process, given that most of the existing technologies are lacking fine adjustment to their needs.
- Interfaces development together with end users (especially those with cognitive or movement impairments) were critical for assuring the acceptance of the technology.
- Cultural differences affected the requisites and acceptance of the technology by patients.

- Previous professional occupation and age correlated strongly with the capabilities to understand and use the technology (having worked with computers correlated positively; higher age, correlated negatively).
- Requested that the system might be turned on or off under their own premises, requesting a large, easy to use button, to turn off the cameras at home.
- Patients using the prototypes considered that they felt empowered, less afraid/alone, and that the ICT4Life system preventing them from calling to emergency services, going to hospital emergency services or leaving their home, thus contributing to reducing costs for the Health care systems and to improve the QoL of patients.

Caregivers:

- Co-designed the alerts sent by the system, that they receive in their cellular phones, one of the most valued features.
- Valued positively the training materials (videos, presentations, pdf documents) that were included in the ICT4Life app, guiding them on how to better channel their support to the patients they took care of.
- Considered that ICT4Life monitoring and alert system reduced their burden as caregivers, thus increasing their QoL.

Healthcare professionals:

- Healthcare professionals requested that the ICT4Life system provided short reports by demand that included the main health indicators for each patient since the last medical consultation, such as use of emergency services, falls, freezing events, alert events sent to caregivers.
- The system was considered especially useful by healthcare professionals to have objective data to base their medical consultation.

4. Methodology for co-creation process

The co-creation process in TeNDER project will contribute to the definition of the relevant functionalities with devices/sensor equipment sets for different environments - Pilots. We will use surveys and interviews for the creation of Personas and scenarios. During the piloting phase end-users will be involved in the co-creation process with the use of defined tools. The main purpose of the later step will be to assess the piloted scenarios and provide feedback for the technical development of the TeNDER solution.

The detailed procedure will be presented in Research Book that is included as first draft in annex 2.

4.1 First definition of end-users and other participants

According to known provision flow, experiences from previous projects and literature, we identified end-user groups for primary (patient-person) and secondary (carers, caregivers, professionals) end-users as shown in Table 1. To assure the inclusive research, we will address all the groups of end-users to co-create sets of functionalities for Pilot testing. Each participating end-user organization will include at least 20 patients, 20 carers/caregivers, and 10 participants from professional group in surveys for each country and perform at least 9 interviews including users from patients, carers/caregivers and professionals. The approach is described below.

Table 1: End-user groups

PRIMARY END-USERS	**SECONDARY END-USERS**			
Patient Types	**Carers and Informal Caregivers**	**Formal Caregivers**	**Health Professionals**	**Other Professionals**
- AD - PD - CVD	- family - friends - volunteers	- day-care centre workers - home-care providers - residential-care - non-residential care	- general practitioner - nurses - psychotherapist - clinical neurologist - geriatrics - pharmacologist - psychiatrist - physician - radiologist - speech therapist - cardiologist - music therapist - occupational therapist - physiotherapist	- movement scientist - social workers - work instructor - animator - nurse assistant - psychologist - rehabilitator - administrative

4.2 Common methodological background for the end-user requirement

The main tools used in survey and interviews will be questionnaires. The protocol requires the recruitment of patients affected by AD, PD, CVD, heterogeneously represented by gender, with an age of ≥60 years. Main demographic and personal variables for Persona definition will be:

- Stage of the disease (mild/moderate/severe);
- Type of the disease (AD/PD/CVD);
- Areas of living (rural/urban, hospital/rehabilitation);
- Gender (male/female);
- Age.

Different scenarios, using similar sensor will be used at four different living setups:

- Home;
- Day Care;
- Hospital;
- Rehabilitation Room.

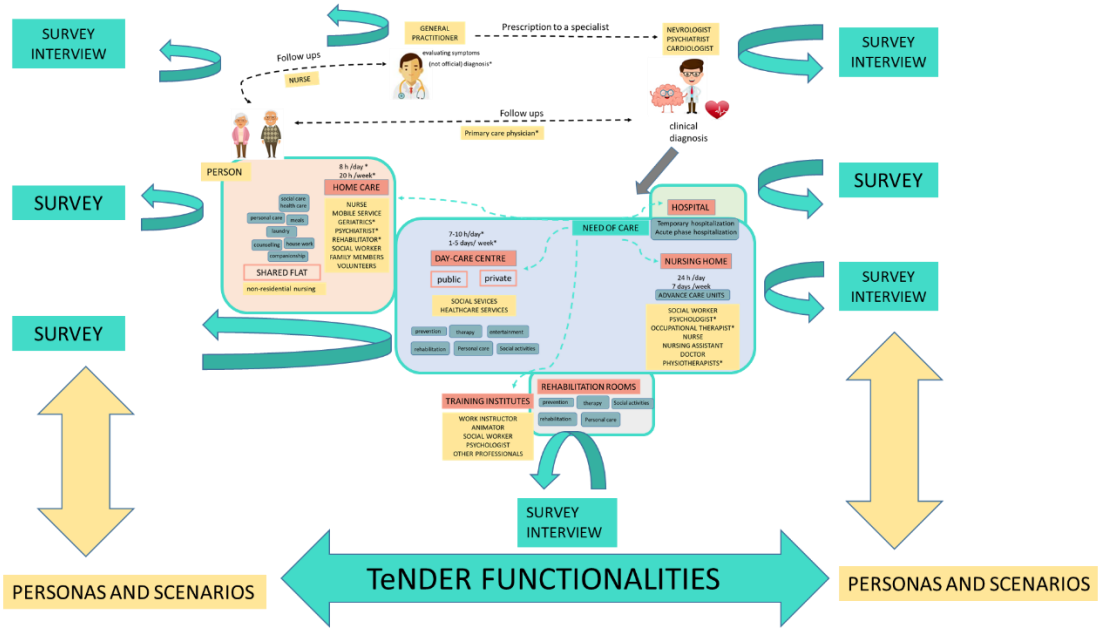


Figure 2: Co-creation process for TeNDER solutions

In Figure 2 we summarize the stakeholders identified form provision flow and different environments for Pilot testing of TeNDER services. In this process, we will include all users in creation of the solutions – TeNDER functionalities.

In the TeNDER user requirements specification, we will include participant in the phase of information gathering and validation. For end-users, we are in the process of identifying suitable standardized questionnaires and will prepare *ad-hoc* questionnaires when required and for some of them we will conduct one-to-one interviews. Prior to participation in the questionnaire or interview, all participants will be offered an information sheet to sign and an informed consent form to sign after receiving written and oral information about the

research and their GDPR rights concerning their data. The participant will be included as following in Figure 3.

Figure 3: End-user involvement in requirements specification process

Ethical considerations

Participation in TeNDER co-creation process will be on the bases of ethical considerations, which include:

- **Informed consent**: four main elements ensure informed consent validity:
  1. disclosure of information;

2. capacity of the individual or representative to make a decision;
3. comprehension of the information;
4. voluntary nature of the decision.

- **Participants:** they will be fully informed about the co-creation process, namely regarding its aims, framework (Project TeNDER), organizations involved in it, how the information will be used, in order to ensure that the participants are able to make an informed decision as whether they will participate in or not. The informed consent must be declared in written form, dated and signed. In case a person is not capable of giving consent, the legal representative of the person will declare the decision. In case the care receiver has the legal status of diminished capacity, documents supporting this should be filed (in copy) with the informed consent document. If a person has the legal status of diminished capacity the information should be presented in a form adapted to the capacity limitations.
- **Voluntary participation:** participation in the co-creation process is totally free without any form of coercion, and the participants are free to withdraw their participation at any time, without any negative consequence.
- **Confidentiality:** participations must be sure that any information capable of identifying them will not be made available, and can only be accessed by the persons who are entitled to process the data. These functions must be stated in the informed consent form.
- **Anonymity:** in the continuation of the previous consideration, and in order to protect the identity of the participants, each participant will be attributed a code, with the personal data that can identify the participants, only being accessible by the persons who are entitled to process the data and are stated in the informed consent form. The data should be anonymized at the earliest possible time.
- **Principle of the relevance of the information:** only information that is relevant for the aims of the co-creation process / project TeNDER will be collected.

Researchers shall conduct the surveys and interview, as a part of TeNDER co-creation process in compliance with the following ethical guidelines. The words used to talk about dementia can have a significant impact on how people with dementia are viewed and treated in our community. The words used in speech and in writing can influence others' mood, self-esteem, and feelings of happiness or depression. A casual misuse of words or the use of words with negative connotations when talking about dementia in everyday conversations can have a profound impact on the person with dementia as well as on their family and friends. It can also influence how others think about dementia and increase the likelihood of a person with dementia experiencing stigma or discrimination. Appropriate language used by the researchers must be:

- Accurate,
- Respectful,
- Inclusive,
- Empowering,
- Non stigmatising,
- Respecting individual preferences of terminology and contact form.

It is important to know that 'dementia' describes a collection of symptoms that are caused by disorders affecting the brain. It is not one specific disease. The following terms/phrases are preferred when talking about dementia:

- Dementia,
- Alzheimer's disease and other forms of dementia,
- A form of dementia,
- A type of dementia,
- Symptoms of dementia,
- A person/people with dementia,
- A person/people living with dementia.

The following terms/phrases should not be used:

- Dementing illness,
- Demented (person),
- Affliction,
- Senile dementia,
- Senility,
- Sufferer,
- Victim.

It is important the researchers realize not everyone will like to be referred to as a carer or caregiver. If possible, ask what the person's preference is before using this term. In this context the terms apply to someone that is providing unpaid care to a person with dementia, which is different to a professional or paid carer.

In communication, researchers should remember that while there are some symptoms of dementia that will be experienced by most people to some degree, the nature and severity of symptoms can also be very different for each person, and symptoms are likely to change over time. It is advised to describe the symptom itself e.g. memory loss, change in mood or behaviour, word finding problems and describe the impact it is having e.g. difficulty communicating.

In order to avoid confusion about what is the scope of the study, researchers should:

- ensure that potential participants understand the performed cognitive abilities assessment tests are used only as an inclusion criteria and are not in any case valid as a diagnostic tool;
- ensure that the person understands that he or she does not have to take part in the TeNDER co-creation process in order to gain clarification about his/her cognitive health (e.g. if he or she already has some concerns);
- explain that what is currently being proposed is participation in the study which in some cases will result in inclusion in TeNDER pilots;
- ensure that the person understands that he or she can refuse to answer or stop participating in the TeNDER co-creation process study at any time.

Researchers should try to ensure that the information resulting from the assessment of inclusion criteria is not disclosed with the participants as it may result in some people experiencing unnecessary distress (i.e. being upset about having a condition which they in fact don't have). To avoid harm and to promote wellbeing, researchers should be attentive to how participants make sense of information about cognitive capabilities that is

communicated throughout the TeNDER project so that it does not fuel existing fears about dementia. To prevent unnecessary distress only experienced personnel should conduct the informed consent conversations. For hospital environment: in case of medical statements or questions the physician investigator should be available to respond.

Contacting end-users - survey

The main objective of the survey is to collect very specific information on aspects related to the social, cultural and health situation of those involved, as well as their handling of new technologies and their perception of their usefulness. For this purpose, we will use the web tool to facilitate the registration and analysis of the data.

The survey will consist of different topics administered with blocks of questions. The topics addressed with survey will be: technology acceptance, living arrangement, daily activities and challenges faced, basic health status and medications taken, and daily mood reflection. The surveys may be self-administered, in those subjects whose personal characteristics allow it, or supported by an interviewer, in the case that they require help to complete them.

The collection of these data will take place between the defined dates with each of the 5 end user partners (SPO, SERMAS, SKBA, UNITOV and APM)

The quantitative data analysis will be carried out by using the previously mentioned tool and other data analysis software (Excel, R). These will be for the preparation of Personas and final drafting of the user requirements.

Personal approach - interview

A smaller group of patients, caregivers (professional/family) and health professionals will be included in personal interviews. The individuals will be selected to best represent the developed Personas. Each end-user partner will conduct at least 9 interviews including users from patients, carers/caregivers and professionals. The objective of personal interviews is to identify qualitative information about the needs of the different types of users of the TeNDER platform. The topics will be demographic data and living arrangements, Quality of life, daily routine challenges, technology usage and experience, caring process and technology facilitation.

This following steps in the process will be followed for the development of the interviews:

1) First, the potential candidates will be contacted by phone/personally and a brief common explanation of the project will be given. Likewise, the subjects will be informed about the impact and extent of his/her participation with reference to the voluntary nature of the participation. If the person agrees, he or she will be handed out the written informed consent form, asked whether all information needed was provided, and invited for the interview. The method for the interview will be face to face or by telematics.
2) Development of the interview: The user will be welcomed and thanked for participating. Afterwards, the user will be informed that an audio recording of the interview will be made to facilitate the transcription of the data obtained and its subsequent analysis, sign the informed consents and will be given all the appropriate explanations about the development of the interview. Once everything is clear, the interview begins.
3) Development of the structure of the interview: In the final part of the document as an annex, the structures of the interviews are specified according to the type of user:

a) Patients,
b) Caregivers,
c) Health professionals.

4) Farewell: At the end the user will be thanked for selfless participation in this research. The user will be invited to contact us at the telephone number given in the informed consent if she / he has any questions regarding this matter or TeNDER project.
5) Transcription of the audio record of the interview.
6) Qualitative data analysis and interpretation.
7) Scenario development.

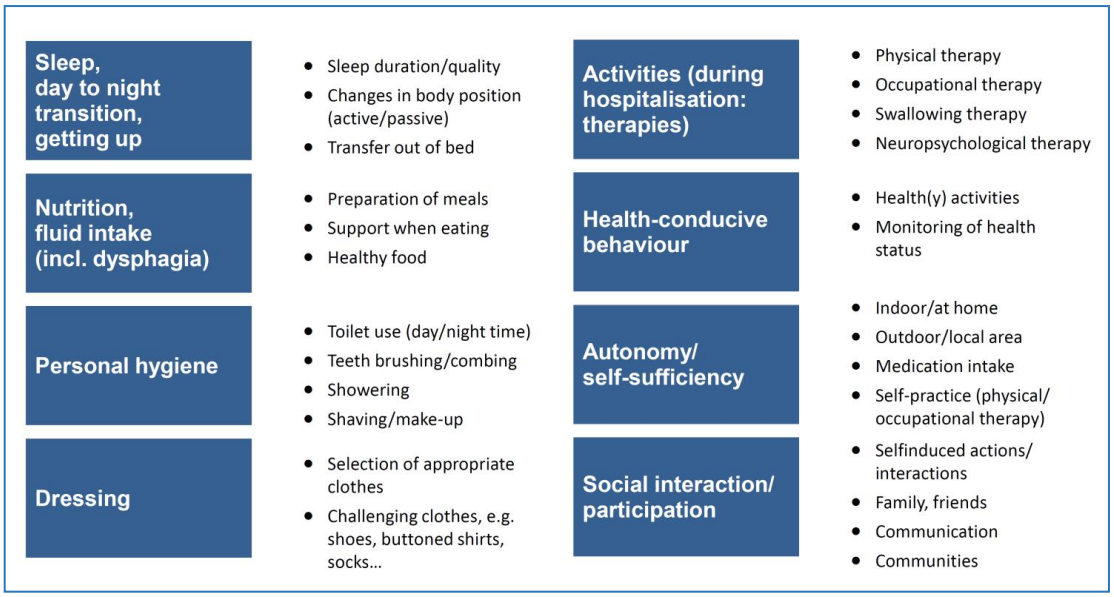
Development of Personas

We provide a preview of a development description for one of the pilots for hospital environment. We will define the process for each environment and pilot regarding the requirements gathered form co-creation. The functionality of the TeNDER system should accommodate end-users' needs. In the hospital settings a lot of information is generated through a multitude of caregivers. Therefore, the methods to evaluate and quantify relevant data are important to develop valid Personas [17]. Personas generally include the following key pieces of information [16]:

1. Fictional name;
2. Job titles and major responsibilities;
3. Demographics such as age, education, ethnicity, and family status;
4. The related goals and tasks they are trying to complete;
5. Their physical, social, and technological environment;
6. A quote that sums up what matters most to the persona as it relates to relevant products and services;
7. Pictures representing that user group.

The best way to visualize the needs of the TeNDER end-users is by creating models (Personas) based on data of various patients with different abilities. SKBA, for example, will define two personas, one with focus on motor deficits and one with focus on cognitive deficits. To ensure that every aspect regarding the pathologies represented by the Personas is covered, SKBA will screen the data from interviews and out of the hospital information system from at least 9 end-users with the respective pathologies: dementia and stroke. In addition to the demographic and clinical characteristics, expectations and insights from caregivers or therapists will be added. Standardised assessments will also be integrated into the data collection, e. g., Barthel Index, MMSE, MFAS.

To provide comprehensive monitoring and support, the needs of each Persona will be structured and assigned to all respective phases of the day. The following figure shows the phases of the day in a hospital setting, enriched with consideration of the situation at home after discharge:



All information will be collected in a matrix, the end-user profile. The importance of specific disabilities, problems, or issues will be rated together with the patient / caregiver and the respective health professionals. The most important or repeatedly stated issues will be mirrored in the Personas as core characteristics.

5. Introduction to user requirements, scenarios and system requirements

This section aims to as broadly as possible asses real-world living environments. Functionalities in scenarios must cover all the stages of user activities based on the selected use cases. This will be of most importance for demonstration of project results. Through internal consultation and deriving from experts' advice, literature review and the results from former projects, a common table including the first version of TeNDER requisites has been developed.

The goal of the WP2, is to as broadly as possible asses real-world living environments of patients and define scenarios for project pilots. Scenarios will be framed in requirements and constrains of ethics, privacy as well as necessity of creating the navigation and draft plans for the components of TeNDER toolbox. The first set of all the intended functionalities and equipment presented below, is based on the experience of the project partners and research of available domain literature. Final selection of functionalities and equipment for broad deployment in pilots will be made on the basis of the written opinions of end-users, calculation of the time and price of implementation and on the basses of final reports from the laboratory and from result of initial testing of the functionalities / equipment on selected initial test group of end-users.

The developed scenarios will be the base of the final Pilots of the system. Each scenario will be structured in a way that it will demonstrate the usage of TeNDER application on each targeted user group in all living environments. It involves the dedicated contribution from end-user entities and medical bodies in TeNDER to analyse the available technologies, as well as to further collect needs and requirements of each specific category of end-users in terms of services solution characteristics, interface and contents as well as current fields of

interaction among the involved actors: health professionals, caregivers and associations, local authorities in the pilot countries. State of the art literature will be analysed, compiled and reported to illustrate and align the needs and constrains for users in the categories defined.

5.1 Requirements objectives and description

The TeNDER project output will be a complete system vision incorporating the needs of all actors as well as supported by the medical and social evidence. The focus are the patients from the three groups of diseases (AD, PD and CVD). Different functionalities, based on user requirements, are associated with scenarios for pilot environments and each group of patients. This complex structure, presented in table 2, will result in detailed TeNDER architecture with main components, data model and data flow with the description of the anonymization techniques that will be implemented. A detailed Functional requirements table is presented in Annex 3, where users and ethical aspects are also specified.

Table 2: Functional requirements

Functional requirements	**Scenario setting / Patient group**						
	Private home		**Hospital**		**Day-Care**		**Rehabilitation room**
Medical examination schedule	Reminds of therapies, appointment	AD PD CVD	Reminds of therapies, appointment	AD	Reminds of therapies, appointment	AD PD	
Adherence to drug treatment	Monitor medication intake	AD PD	Monitor medication intake	AD	Monitor medication intake	AD PD	
Health state	Blood pressure Body weight Breathing frequency	CVD			Blood pressure and glucose, breathing, weight	PD	
Emotional state detection	Emotional status: aggressive, sad, happy, angry, apathetic, anxious; Changes in tone, stuttering	AD PD	Emotional status: aggressive, sad, happy, angry, apathetic, anxious;	AD CVD	Emotional status: aggressive, sad, happy, angry, apathetic, anxious	AD PD	
	Euthymic, dysthymic, joy	CVD					
Nocturnal activities	To identify incontinence, urinary infections, or possible causes of insomnia; Hours of deep sleep; Hours of light sleep; Nº of night awakenings	AD PD	To identify incontinence, urinary infections, or possible causes of insomnia; Hours of deep sleep; Hours of light sleep; Nº of night awakenings	AD CVD			

	Nº of urination		Nº of urination					
	Hours of deep sleep; Hours of light sleep; Nº of night awakenings	CVD						
Global localization	Manages global location of Caretaker (location tracking) Heartrate, physical activity	AD						
Room-level localization	Movement tracking Recognition of unusual behaviours Heart rate, physical activity	AD PD CVD	Movement tracking Recognition of unusual behaviours Heart rate, physical activity	AD CVD	Movement tracking Recognition of unusual behaviours Heart rate, physical activity	AD	How is the patient's performance: balance, body posture, walk, coordination, mobility of the different corporal areas, in order to assess the patient´s state Compare the patients performance in sessions over time	PD
					Freezing, loss of balance Abnormal behaviours	PD		
Safety and wellbeing	Temperature Lights Water spills Electrical appliances Entrance door Refrigerator door All windows Fall detection	AD, PD	Temperature Lights Water spills Electrical appliances Entrance door All windows Fall detection	AD	Fall detection	PD		

The TeNDER approach involves four different living environments, each targeting three diseases. There will be five pilots across four different European regions. This approach will generate five different pilots for AD, PD and CVD; each with different selection criteria and different use cases, different number and relations between actors in the pilot plot, defined levels of access to communication and input devices, base system requirements, and expected results.

Before deploying to general population, first equipment sets will be tested and prepared in laboratory. In the next step small group of representative end-users will be selected to perform the initial testing and iteration. Lastly the TeNDER architecture will be deployed at large population sample.

6. Data flow

First of the data flow diagram presented in the picture below is depicting the partitioning of a system into several layers and their interfaces, together with their sources "Input", and destinations "Output". This preliminary draft is serving for general understanding of the system architecture and presentation of its main elements. In this part of the project, we need to understand how and what kind of data is acquired, where it is processed and how it is stored for ensuring preparation of equipment sets for laboratory testing as well as fulfilling all ethical and legal requirements, before the beginning of the project pilots.

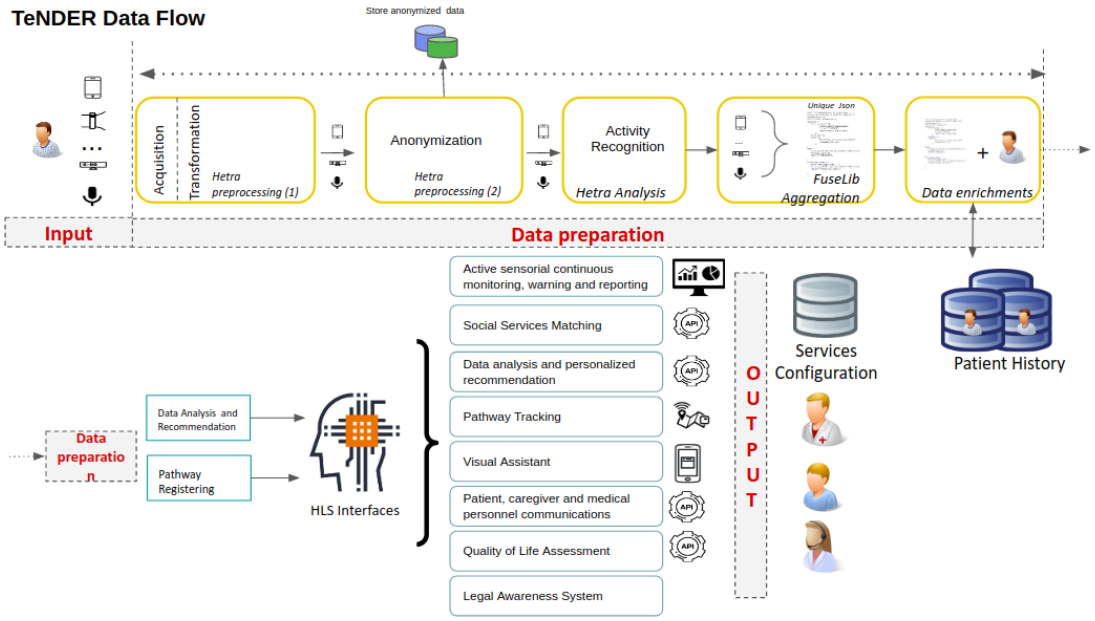


Figure 4: Data Flow diagram

Visual symbol and Icon are used to represent the flow of the information, data sources, and where data is stored. Based on this assumption, data flow provides a graphical representation of the TeNDER system at the level of detail, providing an easy-to-understand picture of what the system does.

The first section called "Input" of the diagram represents a patient in a scenario with all the associated and permitted devices. During the "Data preparation", modules will be used to ensure reliable and local raw data acquisition, storage and process, and finally anonymize all signals captured by the patients' devices. Once the data is prepared it will be sent and

aggregated in the cloud and enhanced with the EHR in order to provide medical verified information to the output service.

Based on user requirements, "Output" will be presented in a set of user interfaces with calendars and notifications. We will use bootstrap and use smartphones, PCs, bracelets, projectors, etc. for various enhanced visual and mechanical notifications.

The High Level system modules will be:

- module for mood and emotion recognition;
- activity tracking and recognition that includes skeleton recognition, binary sensors recognition, voice and sound recognition.

Services that interact with the High-Level subsystem modules will be:

• **Active Sensorial Continuous Monitoring, Warning and Reporting**; This service will offer patients the monitoring of their biological, behavioural variables such as heart rate, body postures, and various activity recognition (among others). The service will be in charge of continuously capturing relevant data from the patients and their environment to detect anomalies.

• **Social Services Matching**; This set of services is mainly devoted to bringing the social supply to the patients. The ambition is to integrate medication, medication intake, exercises, nutrition and non-medical assistance functionalities (daily routines, from cleaning to administration, shopping, occasional travel or basic finances like paying bills) and related monitoring into connected modules which local careers can access and make decisions/provide support services.

• **Data Analysis and Personalized Recommendation**s; The objective will be to generate knowledge by a continuous data analysis focus on all patients' information identifying patterns and models of best practices in coordination, treatment, recommendations offered, interaction design, etc. Knowledge will be offered to medical and social professionals while using platform services with information on alternatives used by other professionals of the platform in the actions they are taking.

• **Pathway Tracking**; This service employs all data flow across the System and will analyse the patients' non-clinical activity, providing all stakeholders with relevant information to optimize time management in the patient healthcare chain.

• **Virtual Assistan**t; This service will collect general information, together from caretakers, caregivers, carers, health and other professionals to have accurate information about appointments, medication intake. There will be two kinds of reminders: medication administration and medical appointment.

• **Patient**, **Caregiver and Medical Personnel Communications**; Service offering social communication among users of the system platforms at different privacy levels and with different objectives.

• **Quality of Life Assessment**; This service will allow users to measure and learn about the impact of their communications via TeNDER channels. Additionally, this service will allow for central processing to match questionnaires related to QoL.

• **Legal Awareness System (GDPR);** This service will be in charge of certifying and guaranteeing that data shared will be in compliance with GDPR.

6.1 Data flow for living scenarios

The data collected on a low level subsystem will be analysed and send to central system. With this central system we will be able to connect, formal and informal caregivers, health professionals and other related professional for each person in all pilot plots. First low-level system architectures for all living environments presented below are based on previous experiences of user and technical partners in the project, and are intended for first good representation of the final system. This part of the system can and will change according to the first round of user requirements collections and reports from the initial laboratory testing of equipment sets by technical partners.

6.1.1 Data flow for Home environment

For home living low level sub-system with continuous sensorial inputs for data acquisition is required to support users with medical examination schedule, adherence to drug treatment, detecting emotional and health state, nocturnal activities with sleep and toilet usage monitoring, geo-fencing and room-level localization with activity recognition, safety and wellbeing features, mostly related to safe and despite disability enabled prolonged living at home.

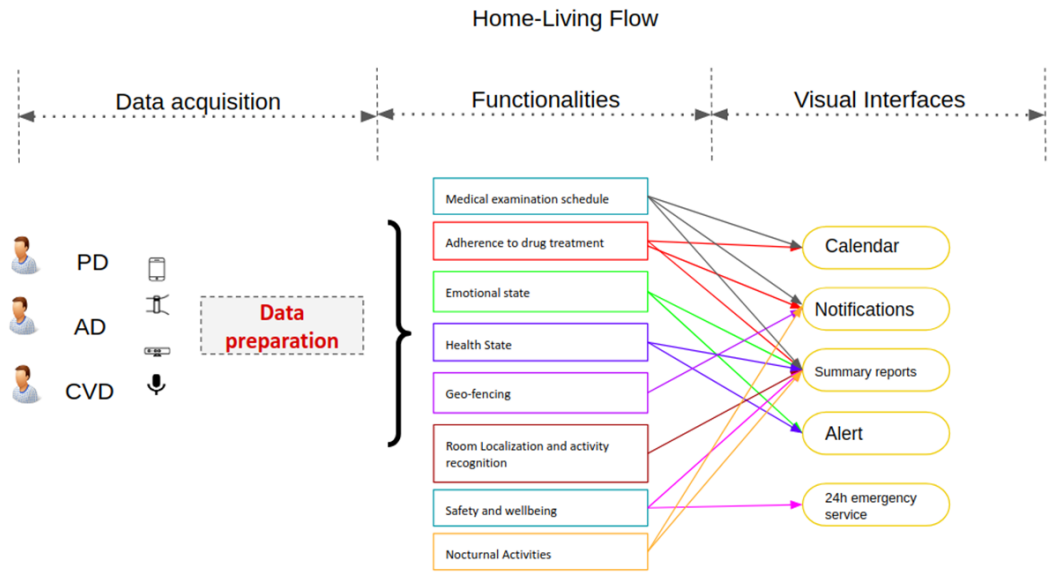


Figure 5: Data flow for Home pilot

6.1.2 Data flow for Day-Care environment

In Day Care low level sensorial inputs should provide for medical examination schedule, adherence to drug treatment, detecting emotional and health states, geo-fencing and room-level localization with activity recognition, safety and wellbeing features which are mostly related to safe, and despite disability, prolonged living at home.

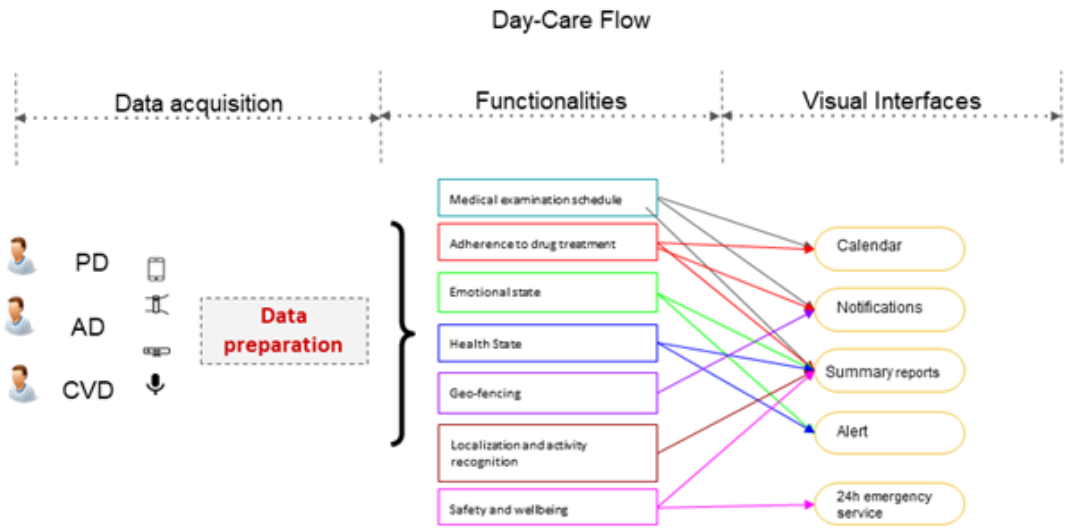


Figure 6: Data flow for Day-Care pilot

6.1.3 Data flow for Rehabilitation room environment

In Rehabilitation room low level sensorial inputs should provide for continuously monitoring of health state with room-level localization and detailed activity with posture recognition for evaluation of a patient progress.

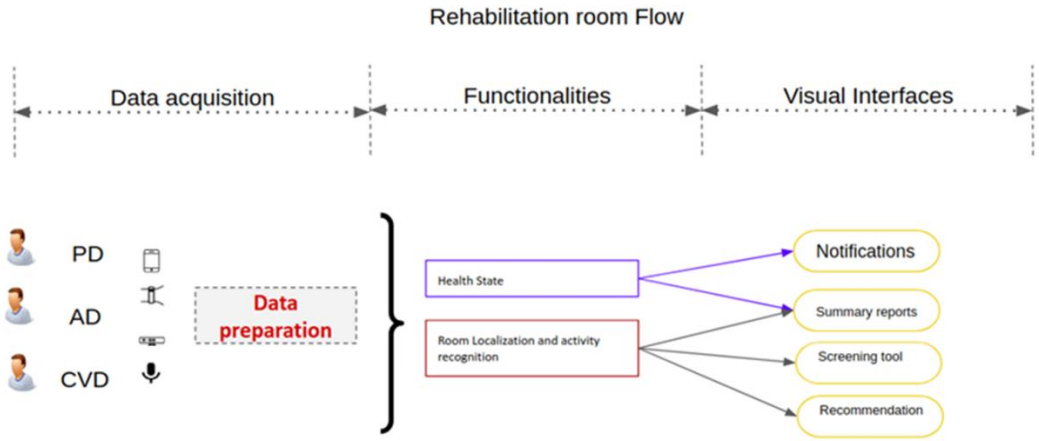


Figure 7: Data flow for Rehabilitation room pilot

6.1.4 Data flow for Hospital environment

In Hospital environment, low level sensorial inputs should provide for appointments on medical examination and therapies, room-level localizations, adherence to drug treatment, continuous non-intrusive health state monitoring, and activity levels of the patients.

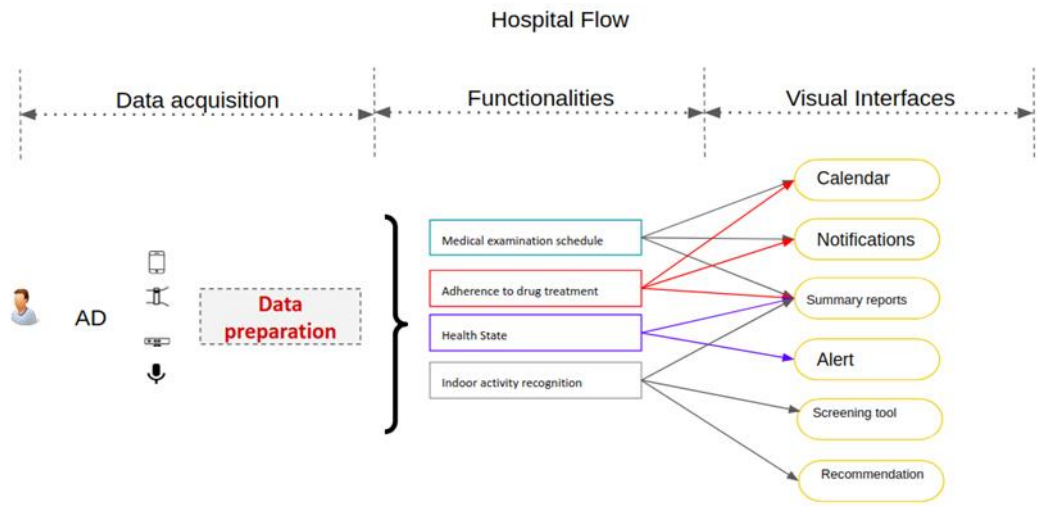


Figure 8: Data flow for Hospital pilot

7. Data model

Herein we represent the first draft of a data model for TeNDER. TeNDER's data Model contains several different entities that are used to store information about each of the concepts required to deliver the expected user functionality. This is the first report of the Data model according to the TeNDER structure. Figure 9 below contains the main concepts and the main relationships among them to represents the semantics of the data model, more information is included in Annex 5.

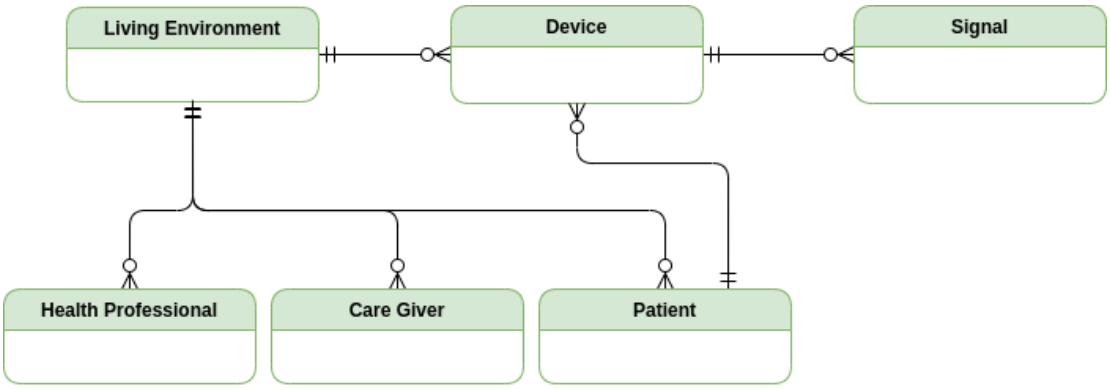


Figure 9: Data model

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THE PROJECT

affecTive basEd iNtegrateD carE for betteR Quality of Life (TeNDER) is a multi-sectoral project funded by Horizon 2020, the EU Framework Programme for Research and Innovation. From the end of 2019 to the end of 2022, TeNDER will develop an integrated care model to manage multi-morbidity in patients with neurodegenerative diseases, mainly, Parkinson's, Alzheimer's and other forms of dementia.

CONTEXT

In Europe alone, the World Health Organization estimates that more than 10 million people are living with dementia, and that by 2030 these numbers will likely double. The prevalence of Parkinson's Disease is also set to rise, according to the European Brain Council, with more than 1.2 million patients currently living in Europe.

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TeNDER EU Project

TeNDER

An integrated care model for patients with Parkinson's, Alzheimer's and other forms of dementia

This project has received funding from the European Union's Horizon 2020 Research and Innovation Framework Programme under grant agreement No. 875325

ANNEX 2 TeNDER Research Book (TRB)

H2020 European Project

affecTive basEd iNtegrateD carE for betteR Quality of Life

Project Number 875325
H2020-SC1-DTH-2019

Large Scale pilots of personalised & outcome based integrated care

Index

Document Change Records

Version	Date	Description	Author
0.1	17/02/2020	First Draft of Research tools and Exploitation Plan	SERMAS
0.2	26/02/2020	Revision and first summary draft	SERMAS

COMMON RESEARCH STRATEGY AND TOOLS

This document is the first draft of the common research tools, such as common consent forms, inclusion and exclusion criteria, protocols for interacting with the end users, questionnaires, are being developed to assure the comparability of the results, deriving from a common research strategy. Legal and ethical requisites and Data management plan are also considered when interacting with patients, their caregivers and health professionals. Quality of Life assessment questionnaires are being developed jointly among end users' organizations of the TeNDER consortium, thus contributing to shared results connected to WP2, WP6 and WP7.

A common exploitation strategy is also being developed, including periodical comparisons of the information generated according to the following criteria: by country; according to disease (taking in account co-morbidities and poly-pharmacy); by scenarios (crossing in the same country and between countries): in daily care centres, at home and in a rehabilitation centre; Between the study group and the control group; by gender. It will be further developed and tested with real end users over the next months of 2020.

Criteria for users' selection

Recruitment of participants is without discrimination based on:

- Sex
- Race
- Ethical or social origin
- Competence or proclivity towards technology

The trial protocol requires the recruitment of patients affected by AD, PD, CVD, heterogeneously represented by gender, with an age ≥60 years. Case studies are subjected to a simple randomization that will lead to the creation of two arms: 1) the control group and 2) the experimental group (the patient management based on electronic information sharing and monitoring by technological devices).

Patients

General Inclusion criteria:

- Age ≥ 60 years.
- Understand local language.
- Have a caregiver or reference person.
- Able to move and walk in their homes.
- Enough autonomy to take decisions.
- Acceptance to participate themselves and their caregivers and have signed the informed consents.
- Compliance with scenario setting: having internet at home, for home set scenarios

General Exclusion criteria

- Oncological history of primary and secondary tumors.
- Chronic therapy for immune diseases, chronic infectious diseases.

- Pyramidal and/or extrapyramidal signs on neurological exam.
- Patients whose caregiver is unwilling to participate / help; Patients / caregivers are unwilling to work with the technologies used in this project.
- Florid alcohol or drug abuse

General inclusion and exclusion criteria for disease

	Alzheimer's (AD) or Dementia	Parkinson's (PD)	Cardiovascular diseases (CVD)
Inclusion criteria	- Persons expressing cognitive complaints or having cognitive impairments (MMSE score of 19 to 28 pts) or having diagnosis of other disease causing dementia (Dementia with MMSE score of 19 to 28 pts or Diagnosis of Alzheimer's according to NINCDS-ADRDA criteria [5]).	- Confirmed diagnosis of Parkinson's disease. All patients will provide a report with an assessment from the neurologist.	- Suffering from Cardiovascular Disease (classification NYHA, stage II/IV) -Coronary heart disease; acute coronary syndrome; been a coronary catheterization for stent placement
Exclusion criteria	- Advanced stages of the disease (for example Alzheimer's disease: avoid GDS 6-7).	- Parkinsonism secondary to vascular disease, treatment, etc.	- Patients who have had a heart attack less than 4 weeks ago, poor life expectancy (<6m) aortic stenosis.

Caregivers

Inclusion criteria:

To be able to consent and to comply with at least one of the following requisites:

- To be employed by a private company or directly by the patients to provide direct care and thus support daily activities.
- To live with and/or take care of a relative (or other close relationship) affected by Parkinson's disease or Alzheimer's disease or/and other dementia.
- To provide logistic support to a family member or a close friend affected by Parkinson's disease or Alzheimer's disease or/and other dementia.

Exclusion criteria:

- Caregivers not able to consent.
- Caregivers not aware of the daily needs of patients.

Health Professionals

Inclusion criteria:

To be able to consent and to be qualified and working in a medical area specialized in the care of Parkinson's, Alzheimer's or/and dementia and cardiovascular diseases (including general practitioners, nurses, social workers and others).

Exclusion criteria:

- Not working as a health professional.
- Working practice not connected to Alzheimer's, Parkinson's and other dementias.
- Conflict of interest.
- Not to be able to consent.

TEST PLAN FOR SUBJECTS OF STUDY TO BE MONITORED AND TO TEST TENDER PLATFORM

Pilots definition

Preparing the spaces

TeNDER will provide 4 different scenarios according to the patients' pathways (home, day-care centre, rehabilitation centre/rooms, and hospital). Finally, TeNDER will seek a concrete measurement for a quality of life shift of people using the TeNDER system by employing psychologists for pre and post-piloting assessment of quality of life, with the involvement of different care stakeholders, ranging from caregivers, social workers, patients, health professionals and support staff dealing with clerical information.

It involves the dedicated contribution from end-user entities and medical bodies in TeNDER to analyse the available technologies, as well as to further collect needs and requirements of each specific category of end-users in terms of services solution characteristics, interface and contents as well as current fields of interaction among the involved actors: health professionals, caregivers and associations, local authorities in the pilot countries. State of the art literature will be analysed, compiled and reported to illustrate and align the needs and constrains for users in the categories defined.

Two spaces (near between them) have to be prepared:

- Lab with sensors deployed by Tech partner, when testing them
- Room with table and seats, with the app and/or webapp for professionals.
- At least one camera will be required for video recording the interaction with the technology of the participants.
- Make sure we have different spaces to interview patients and caregivers separately. Both interviews will be recorded (preferably audio recorder)

Order of the interaction with participants

- Information sheet (signature)
- Informed consents for data and image recording (signed)

- Entry interview to determine individual baseline for both intervening and control group.
- Quality of life surveys
- Interaction with TeNDER functionalities/devices by disease and scenario.
- Exposure to lab with sensors (if applies)
- Assessment of technology by participants

Protocol of interaction with the technology

- Let participants to freely use the technology. Pay attention to the time it takes for them to find their way and eventual difficulties, but don't forget to reassure them in the process and offering the support of the researchers if needed. Do not do it for them!
- Identify the “routes” they take when using the technology
- Ask them their free first impression on the technology and gather all their comments or suggestions all over the testing process
- Ask them if they understand it and if they know how to use TeNDER technology
- Ask them to perform concrete tasks, like entering their personal information, including a new professional or caregiver, or a medical appointment in the calendar. Receive input on what to keep and what to improve.
- Make sure that their walkthrough includes all the relevant screens to be tested
- Pay special attention to accessibility aspects: can they use it? What has to be adapted or improved regarding accessibility?
- Go beyond usability dimensions and ask for improvement suggestions in general. Try not to influence the participants when they offer their sincere opinions. Repeated opinions requests might useful to identify the real needs and opinions of the end users. New opinions can lead to innovation. They are thus all important for us.

TeNDER Research Book will include the following documents to be used by all TeNDER organizations and participants working in the TeNDER large scale pilots:

- Informed consents (in progress, led by VUB) and Information sheet to be signed
- Questionnaires, by profile of end users and scenario, that are now being internally discussed. Draft questionnaires in progress list can be found below.

a) Questionnaire intelligent monitoring-system – Patients

b) Questionnaire intelligent monitoring-system –Caregivers

c) Questionnaire intelligent monitoring-system – Health professionals

Annex 3 FIRST USER REQUIREMENT

Dementia or Alzheimer Disease (AD)					
Environment	Functionalities	Outcomes	Users	Communication	Ethical
Private home	Medical examination schedule	- Reminds of therapies, appointment	- Caretaker - Carer - Caregiver - Health professionals	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Adherence to drug treatment	- Monitor medication intake	- Caretaker - Carer - Caregiver - Health professionals	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Emotional state detection	- Emotional status: aggressive, sad, happy, angry, apathetic, anxious; - Changes in tone, stuttering	- Caretaker - Carer - Caregiver - Health professionals	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Nocturnal activities	- To identify incontinence, urinary infections, or possible causes of insomnia - Hours of deep sleep - Hours of light sleep - Nº of night awakenings - Number of urination	- Caretaker - Carer - Caregiver - Health professionals	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative

	Global localization	- Manages global location of Caretaker (location tracking) - Heartrate, physical activity	- Caretaker - Carer - Caregiver - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Room-level localization	- Movement tracking - Heartrate, physical activity	- Caretaker - Carer - Caregiver - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Safety and wellbeing	- Temperature - Lights - Water spills - Electrical appliances - Entrance door - Refrigerator door - All windows - Fall detection	- Caretaker - Carer - Caregiver - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
Hospital	Medical appointment and examination schedule	- Reminds of therapies, appointment	- Caretaker - Caregiver - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Adherence to drug treatment	- Monitoring medication intake	- Caretaker - Caregiver - Health professionals	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or

					legal representative
	Nocturnal activities	- To identify incontinence, urinary infections, or possible causes of insomnia - Hours of deep sleep - Hours of light sleep - Nº of night awakenings - Number of urination	- Caretaker - Caregiver - Health professionals	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Emotional state detection	- Emotional status: aggressive, sad, happy, angry, apathetic, anxious	- Caretaker - Caregiver - Health professionals	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Room-level localization	- Movement tracking - Recognition of unusual behaviours - Heart rate, physical activity	- Caretaker - Caregiver - Health professionals	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Safety and wellbeing	- Temperature - Lights - Water spills - Electrical appliances - Entrance door - All windows - Fall detection	- Caretaker - Caregiver - Health professionals	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
Day-Care	Room-level localization	- Movement tracking - Recognition of unusual behaviours	- Caretaker - Caregivers - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or

		- Heart rate, physical activity			legal representative
	Adherence to drug treatment	- Medication intake monitoring	- Caretaker - Caregivers - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Medical appointment and examination schedule	- Reminds of therapies/appointments	- Caretaker - Caregiver - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Emotional state detection	- Emotional status: aggressive, sad, happy, angry, apathetic, anxious	- Caretaker - Caregiver - Health professionals	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative

Parkinson Desease (PD)					
Environment	Functionalities	Outcomes	Users	Communication	Ethical
Private home	Medical examination schedule	- Reminds of therapies, appointment	- Caretaker - Caregiver - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Adherence to drug treatment	- Monitoring medication intake	- Caretaker - Caregiver - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be

					turned off by patient or legal representative
	Emotional state detection	- Emotional status: aggressive, sad, happy, angry, apathetic, anxious; - Changes in tone, stuttering	- Caretaker - Caregiver - Health professional	- Calendars - Notifications Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Nocturnal activities	- To identify incontinence, urinary infections, or possible causes of insomnia - Hours of deep sleep - Hours of light sleep - Nº of night awakenings - Number of urination times	- Caretaker - Caregiver - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Room-level localization and activity recognition	- Movement tracking, - Heart rate, physical activity.	- Caretaker - Caregiver - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Safety and wellbeing at home	- Temperature - Lights - Water spills - Electrical appliances - Entrance door	- Caretaker - Caregiver - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient

		- Refrigerator door - All windows - Fall detection			or legal representative
Day-Care	Medical examination schedule	- Reminds of therapies, appointments	- Caretaker - Caregiver - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Adherence to drug treatment	- Monitoring medication intake	- Caretaker - Caregiver - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Health state	- Blood pressure and glucose, breathing, weight	- Caretaker - Caregiver - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Room-level localization and activity recognition	- Freezing, loss of balance - Abnormal behaviours	- Caretaker - Caregiver - Health professional	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Nocturnal activities	- Counting toilet usage	- Caretaker - Caregiver	- Notifications	Permission granted by

			- Health professional	- Summary reports	patients or legal representative. Can be turned off by patient or legal representative
	Safety and wellbeing	- Fall detection	- Caretaker - Caregivers - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
Rehabilitation room	Room-level localization and in-depth activity recognition	- How well or bad is the patient performance a session - Describe different exercises capable of measuring balance, body posture, walk, coordination, mobility of the different corporal areas, in order to assess the patient´s state - Compare the way that patients performance the	- Caretaker - Caregivers - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative

		sessions over time			

Cardiovascular Diseases (CVD)					
Environment	Functionalities	Outcomes	Users	Communication	Ethical
Private home	Adherence to drug treatment	- Monitor medication intake	- Caretaker - Carer - Caregiver - Health professionals	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Emotional state detection	- Euthymic, dysthymic, joy	- Caretaker - Carer - Caregiver - Health professionals	- Calendars - Notifications Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Nocturnal activities	- Hours of deep sleep - Hours of light sleep - Nº of night awakenings	- Caretaker - Carer - Caregiver - Health professionals	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Room-level localization	- Movement tracking - Recognition of unusual behaviours	- Caretaker - Carer - Caregiver - Health professional	- Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal

		-Heartrate, physical activity			representative
	Health State	-Blood pressure -Body weight -Breathing frequency	- Caretaker - Carer - Caregiver - Health professional	-Notifications -Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
Hospital	Room-level localization	-Movement tracking -Recognition of unusual behaviours -Heartrate, physical activity	- Caretaker - Carer - Caregiver - Health professional	-Notifications -Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative
	Nocturnal activities	-Hours of deep sleep; -Hours of light sleep; -Nº of night awakenings -Nº of urination	- Caretaker - Carer - Caregiver - Health professional	-Notifications -Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative

	Emotional state detection	- Emotional status: aggressive, sad, happy, angry, apathetic, anxious	- Caretaker - Caregiver - Health professionals	- Calendars - Notifications - Summary reports	Permission granted by patients or legal representative. Can be turned off by patient or legal representative

ANNEX 4: USER CASES BY LIVING ENVIRONMENT AND DISEASES

Private Home
A. Dementia (Alzheimer's or similar) John is a 68-year-old patient who lives alone. Recently, he has been diagnosed with an early stage of dementia. His family is concerned because he is a very active and independent man and continues to do his daily chores (shopping, walking) and sometimes does not give notice that he is leaving home. They are worried that he might become disoriented and not know how to return home on one of his outings. His relatives would like John to be safer and to be able to detect if he leaves his usual walking area and if so, to be able to find him easily. In this scenario, the sensory equipment should be able to detect the patient's wandering and location inside the house, and also to detect if he leaves the house. For this purpose, a real-time location will be implemented. All patients will be equipped with a light commercial bracelet and a Bluetooth scanner will be installed at the entrance of the house. The selected bracelet will have a long battery life (at least 10 days) and will be waterproof. It can be worn at all times without the need to remove it. Caregivers will be notified if the bracelet is removed. The Bluetooth scanner is a small, unnoticeable device that monitors the signal strength of the bracelet and estimates the user's position with a GPS system. The Bluetooth scanner will also be connected to local Wi-Fi through local routers and will be able to transmit raw data directly to the cloud or locally to an attached storage and send data/reports to the cloud only when critical events occur. Notifications and alerts will be sent to the mobile devices of the caregivers and professionals involved. Participants will have the option to access the notification server through their personal mobile devices. A calendar can be implemented to plan secure time zones and important events.
B. Parkinson's Ian is a 73-year-old patient diagnosed with Parkinson's. He lives with his wife Anne, 70, who has difficulty walking. They fend for themselves and together they do housework and meals. Recently, the social worker has found that Ian is suffering from flare-ups of his disease so he is less well balanced and at risk of falling. In addition, when she has visited the couple at home, she has observed that it is cold, as they leave windows open without realizing it. Additionally, she notices that they use the stove without due precautions. The social worker is concerned about the safety of both of them. She is worried that Ian will fall and no one will be warned. She is also worried that they might be under risk due to the couple: forgetting to close windows; cooking and forgetting food on the fire; forgetting to turn off the gas; stove burning them. She would like to detect early when Ian and Anne are no longer safe living alone at their house. To do this, she needs to know how many times a day events arise that threaten Ian and Jane's safety. In this scenario, the sensory equipment should be able to detect changes in home security and well-being, detecting situations such as: falls, status of lights and electrical appliances, status of room temperature and air quality, water spills in kitchen and bathroom, state of refrigerator doors, state of doors and windows (open/closed, locked/unlocked), state of kitchen and stoves, gas spills.

Notifications and alerts will be sent to the social worker and caregivers when critical events occur in real time. Delayed reports will be generated by TeNDER system on the mobile or web devices of the caregivers and health professionals involved.

C. Cardiovascular disease

George is a 62-year-old patient diagnosed with mild heart failure and suffering from high blood pressure. He lives alone and lately his blood pressure control is not being effective. George goes out every morning to do his walk and exercise routine prescribed by the cardiologist. But lately, he has noticed that he gets tired more easily and feels a little dizzy. Both George and his family fear that he may suffer a cardiac event during his walks.
Health professionals are concerned about George's situation, as he may be experiencing a change in his heart condition. They would like to know George's vital signs both when he's at home relaxing and during his exercise routine (such as heart rate, blood pressure, breathing rate)

For this use case/scenario, all patients will be equipped with a light commercial bracelet that detects vital signs of heart rate, blood pressure, breathing rate. The bracelet selected will have a long battery life (at least 10 days) and will be waterproof. It can be worn all the time without removing it. The Bluetooth scanner will also be connected to local Wi-Fi through local routers and will be able to transmit raw data directly to the cloud or locally to an attached storage and send data / reports to the cloud only when critical events occur.

Notifications and alerts will be sent when critical events occur on the mobile devices of the caregivers and professionals involved. Participants will have the option to access the notification server via the web application on personal mobile devices.

Day-Care

A. Dementia

Marge is a 60-year-old patient who lives with her daughter Nicol. Marge has started with an early stage of dementia. Nicol makes sure her mother follows her medication prescription. During the day Marge goes to a day care center, requiring some coordination to assure that she keeps on taking her medication. Marge would like to have reliable information on her mother's medication intake. Using TeNDER electronic pillbox and app, Nicol, the doctor, and the day-care center nurse are all coordinated and informed about Marge's adherence to treatment.

For this scenario, the sensory team should be able to detect when she is taking her medication incorrectly. The patient will get a smart pillbox, connected to the network, and any caregiver and health care professional will be able to monitor on the smartphone app or the WebApp when the medication was taken. Reminders will be sent to the patient to assure that the medication intake adjusts to the doctor's recommendations. The calendar with alerts can be set by the patient herself, authorized caregivers and health personnel of the day care center.

Notifications and alerts will be sent real time when critical events occur on the mobile devices of the caregivers and the day care center nurses. Delayed reports will be forwarded on demand to health care professionals. Participants will have the option to access the

notification server to check the accuracy of the system and to remind their medication patterns.

B. Parkinson's

Miguel is a 72-year-old patient, diagnosed with Parkinson's and living in an elderly home. In his free time, he spends his time walking around the centre and its surroundings. His relatives have shared the professionals at the care centre their concern, as they consider that on certain days Miguel's mobility and balance do not allow him to move around safely and insist that on those days Miguel could fall during his walks. They ask that he should not be allowed to walk by himself on that days. This situation is complicated for the professionals at the centre, as Miguel is an independent and active man and does not like to be accompanied everywhere. For this reason, both the professionals and Miguel's family would like to be able to be warned in case Miguel starts the day with more difficulty of movements and would be warned if he needs help during his walks.

In this scenario, the sensory team should be able to detect wandering, laziness and the presence of slower or abnormal movements in the patient, in order to be able to notify that his mobility situation has worsened; as well as to detect his location and if he falls down, freezes or have gait difficulties. For this purpose, real-time indoor location will be implemented in the private home. All patients will be equipped with a lightweight commercial smart belt and a Bluetooth scanner will be installed in each room. The selected belt will have a long battery life (at least 10 days) and will be water resistant. The Bluetooth scanner is a small, inconspicuous device that monitors the strength of the belt signal and calculates the user's position relative to the floor. The Bluetooth scanner will also connect to local Wi-Fi through local routers and will be able to transmit raw data directly to the cloud or locally to the attached storage and send data/reports to the cloud only when critical events occur.
Notifications and alerts will be sent when critical events occur on the mobile devices of the caregivers and professionals involved. Participants will have the option to access the notification server via the web application on personal mobile devices.

C. Cardiovascular disease

Antonio is a 62-year-old patient who has mild cardiovascular disease. In the last few months his health has worsened following a hospital admission for heart failure. His son is somewhat concerned because he has noticed that Antonio has become less communicative and stays locked up in his apartment for a long time. In the mornings he goes to a day centre, where the workers and his friends have also noticed him very sad and in low spirits.
People close to Antonio are worried about his mood.

In this scenario, an affective computing module will be employed that will apply advanced techniques of deep learning and computer vision to extract relevant characteristics (i.e., general, facial, speech, or behavioural) that can allow for the estimation of patients' expression and mood. This information will be extracted through the use of smart phone devices and used as input for higher level services that will support the patient.

Notifications and alerts will be sent when critical events occur on the mobile devices of the caregivers and professionals involved. Participants will have the option to access the notification server through the web application on personal mobile devices.

Hospital
A. Dementia Jane is a 78-year-old early-stage Alzheimer's patient who lives with her husband David at The Alzheimer's Therapy Center. Their apartment consists of 3 rooms: a bedroom with a closet and two beds, a living room with seating options, a table and a television, which leads to a balcony or terrace, and a small bathroom with toilet, sink and shower. David is a little worried because recently he has noticed that Jane gets very nervous for no reason and starts to perform tasks that she doesn't finish, such as, opening windows, opening taps, going in and out of the apartment and starts to move around very upset. Sometimes she is even aggressive, which makes David suffer. The health care professionals at The Alzheimer's Therapy Center are concerned about Jane and David's safety and well-being, especially during the hours when Jane and David are alone. They would like to detect when Jane begins to have this nervous breakdown so that they can anticipate any situation that could threaten their safety, or detect an alarm situation so that they can come to the rescue on time. In this scenario, the sensory equipment should be able to detect abnormal movements in the patient, such as: nervousness, repetitive movements, abnormal night-time activity, in order to notify an alert situation. For this purpose, real-time indoor monitoring and location will be implemented. All patients will be equipped with a lightweight commercial smart belt and a Bluetooth scanner will be installed in each room. The selected belt will have a long battery life (at least 10 days) and will be water resistant. The Bluetooth scanner is a small, inconspicuous device that monitors the strength of the belt signal and calculates the user's position relative to the floor. The Bluetooth scanner will also connect to local Wi-Fi through local routers and will be able to transmit raw data directly to the cloud or locally to the attached storage and send data/reports to the cloud only when critical events occur. Notifications and alerts will be sent when critical events occur on the mobile devices of the caregivers and reports provided under request to the health care professionals involved, including real time alerts to hospital professionals when requested by them.
B. Parkinson's Fred is a 77-year-old patient in the hospital. Freud has Parkinson's and complains of lack of sleep. Hospital health professionals say Fred gets up a lot at night to go to the bathroom and are concerned that he does so without warning and is not in good physical condition to walk alone, as he could fall. In this scenario, the sensory equipment must be able to detect night-time activity in the room, as well as detect and warn of a fall. It will also detect the quality of the patient's sleep. To do this, a real-time location will be implemented inside the room. All patients will be equipped with a lightweight commercial bracelet and a Bluetooth scanner will be installed in each room. The selected belt will have a long battery life (at least 10 days) and will be water resistant. The Bluetooth scanner is a small, discreet device that monitors the strength of the belt signal and calculates the user's position in relation to the floor. The Bluetooth scanner will also connect to the local Wi-Fi network through local routers and will be able to transmit raw data directly to the cloud or locally to the attached storage and send data/reports to the cloud only when critical events occur.

Notifications and alerts will be sent when critical events occur on the mobile devices of the caregivers and reports provided under request to the health care professionals involved, including real time alerts to hospital professionals when requested by them.

C. Cardiovascular disease

Carol is a 74-year-old patient who has been admitted to the hospital for cardiovascular disease. These past few days, Carol says she loses breath when she goes to the bathroom and feels dizzy. Her family and health care professionals are concerned about the situation, which may be getting worse. They would like to know the vital signs of Carol at the time she goes to the bathroom (heart rate, blood pressure, respiratory rate).

For this scenario, all patients will be equipped with a light commercial bracelet that detects vital signs of heart rate, blood pressure, breathing rate. The selected bracelet will have a long battery life (at least 10 days) and will be waterproof. It can be worn all the time without removing it. The Bluetooth scanner will also be connected to local Wi-Fi through local routers and will be able to transmit raw data directly to the cloud or locally to an attached storage and send data / reports to the cloud only when critical events occur.

Notifications and alerts will be sent when critical events occur on the mobile devices of the caregivers and reports provided under request to the health care professionals involved, including real time alerts to hospital professionals when requested by them.

Rehabilitation Rooms

A. Parkinson's

Lisa is 80 years old, diagnosed with Parkinson's. Every day from Monday to Friday she goes to a rehabilitation center to maintain and improve her muscle tone and mobility. Her situation is changing and it seems that her ability to move has worsened in recent months. Maria is a physiotherapist at the center and she would find it helpful to know Lisa's mobility status based on her severity. Maria would like to know the data of the activity and movements that Lisa does in each rehabilitation session. With this knowledge, they could make a more individualized exercise chart and pay more attention to Lisa's situation.

In this scenario, the sensory team should be able to detect wandering, laziness and the presence of slower or abnormal movements in the patient, in order to be able to notify that his mobility situation has worsened; as well as to detect if he falls. For this purpose, real-time indoor location will be implemented in the private home. All patients will be equipped with a lightweight commercial smart belt and a Bluetooth scanner will be installed in each room. The selected belt will have a long battery life (at least 10 days) and will be water resistant. The Bluetooth scanner is a small, inconspicuous device that monitors the strength of the belt signal and calculates the user's position relative to the floor. The Bluetooth scanner will also connect to local Wi-Fi through local routers and will be able to transmit raw data directly to the cloud or locally to the attached storage and send data/reports to the cloud only when critical events occur.

Notifications and alerts will be sent when critical events occur on the mobile devices of the caregivers and professionals involved that request it. Participants will have the option to access the notification server via the web application on personal mobile devices.

ANNEX 5: FIRST DRAFT OF DATA MODEL AND ENTITIES

Data model for the low-level subsystem and services provision

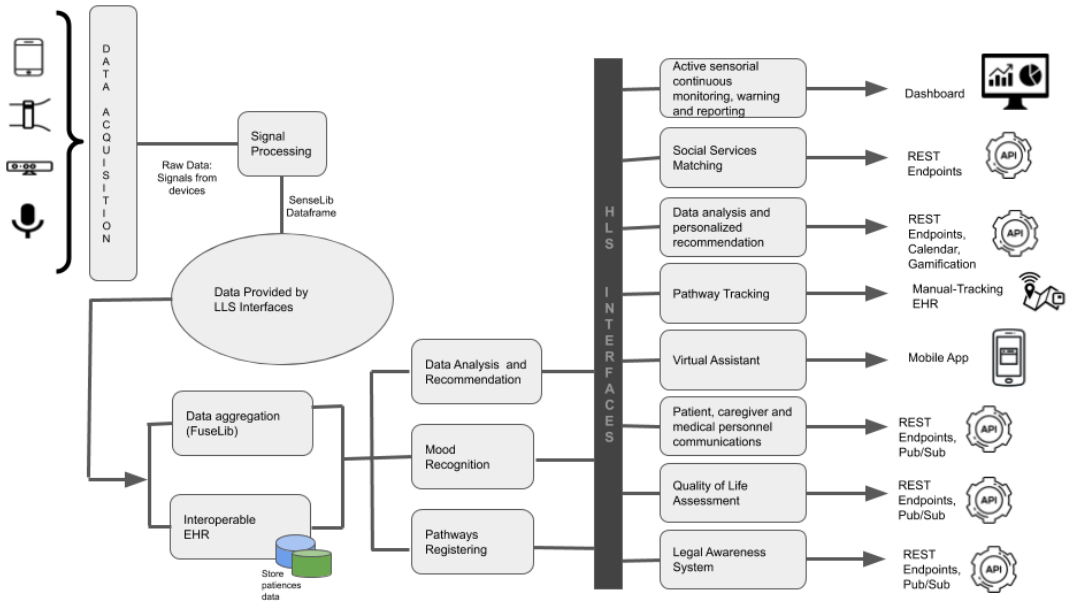

Figure 10 Data Flow for the low-level subsystem and the services provision

Section 1 List of entities

Entity	Attributes
Human Section	
Person/Persona	<id> <name> <surname> <gender> <birth date>
Patient	→ Person <disease> <stage>

	<role> <events captured>
Health professional	→ Person <field specialization> <patients>
Caregiver	→ Person <patients> <type>
Living Environment Section	
Living Environment	<id> <rules> <ip-address> <geo-data> <telephone number> <personas>
House living set	-> Living Environment <size> <room numbers> <devices>
Hospital	-> Living Environment <apartments> <rooms> <number of apartments> <therapy sessions timetable> <therapy sessions groups number>
Hospital Apartment	-> Living Environment <name> <size> <room numbers> <hospitalization period> <devices>
DayCare Center	-> Living Environment <max-workers>

	<rooms>
Rehabilitation Rooms	--> Living Environment <room> <has-timetables> <session-timetables> <single-session-duration>
Room	<id> <name> <size> <has-mirror> <patients> <devices>
Equipment Section	
Device	<id> <type> <Signals> <Patient>
Bracelets	-> Device
Environmental Sensors	-> Device
Cameras	-> Device
Sleep monitoring Sensor	-> Device
Smartphone / Tablets (Gui interfaces)	-> Device
Binary Sensors	-> Device
Microphones	-> Device
Speakers	-> Device
Blood-pressure sensor	-> Device
Body temperature	-> Device

sensor	
Body weight sensor	-> Device
Breathing frequency sensor	-> Device
Heart-rate sensor	-> Device
Accelerometers	-> Device
Gyroscope	-> Device
Panic button	-> Device
Bluetooth scanner	-> Device <is-outdoor>
GPS sensor	-> Device
Toilette usage counting sensor	-> Device
Routers	-> Device
Extenders	-> Device
Storage	-> Device
PC	-> Device
Screen	-> Device
Pill dispenser	-> Device
Doors and Windows switches	-> Device <doors-statuses>
Stove / Cooking status detector	-> Device
Water spillage status detector	-> Device
Light & Electrical appliance status detector	-> Device
Refrigerator door switch	-> Device

	<doors-statuses>
Signals Section	
Signal	<type> <value> <timestamp>
Heart beat rate	-> Signal
Body temperature	-> Signal
Blood pressure	-> Signal
Breathing frequency	-> Signal
Body weight	-> Signal
Acceleration	-> Signal
Skeleton	-> Signal
Colour	-> Signal
Audio	-> Signal
Voice	-> Signal
Activation	-> Signal
Image	-> Signal
Drug adherence	-> Signal
Geo-fencing data	-> Signal
Toilet usage data	-> Signal