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Deliverable 7.2
First Report on Best Practices and in eHealth and Certification

Work Package 7: Quality of Life assessment and progress indicators

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

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Disclaimer

The TeNDER consortium consists of the following Partners.

Table 1 - Consortium Partners

No	Name	Short name	Country
1	UNIVERSIDAD POLITECNICA DE MADRID	UPM	Spain
2	MAGGIOLI SPA	MAG	Italy
3	DATAWIZARD SRL	DW	Italy
4	UBIWHERE LDA	UBI	Portugal
5	ELGOLINE DOO	ELGO	Slovenia
6	ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	CERTH	Greece
7	VRIJE UNIVERSITEIT BRUSSEL	VUB	Belgium
8	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	HOPE	Belgium
9	SERVICIO MADRILENO DE SALUD	SERMAS	Spain
10	SCHON KLINIK BAD AIBLING SE & CO KG	SKBA	Germany
11	UNIVERSITA DEGLI STUDI DI ROMA TOR VERGATA	UNITOV	Italy
12	SLOVENSKO ZDRUZENJE ZA POMOC PRI DEMENCI - SPOMINCICA ALZHEIMER SLOVENIJA	SPO	Slovenia
13	ASOCIACION PARKINSON MADRID	APM	Spain

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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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Acronyms and Abbreviations

Acronym/Abbreviation	Description
AD	Alzheimer's disease
API	Application Programming Interface
CVD/CVDs	Cardiovascular disease(s)
D	Deliverable (e.g., D7.2 = Deliverable 7.2)
EU	European Union
GDPR	General Data Protection Regulation
HomeSet	Home setting
Horizon 2020	EU Framework Programme for Research and Innovation (2013-2020)
PD	Parkinson's disease
QoL	Quality of Life
RGBD camera	Red Green Blue-Depth
T	Task (e.g., T7.2 = Task 7.2)
UIs	User Interfaces
WHO	World Health Organization
WP	Work Package

Contents

List of Figure

List of Tables

Executive Summary

Deliverable 7.2 (D7.2) will report on common practices observed during the piloting of the TeNDER system, which could feed into general healthcare approaches or protocols. The short-term aim of this 'First Report' has been to envision 'ideal' implementation scenarios and compare these to the 'status quo' scenarios end-user partners described during the first wave of pilots using use-case template (see ANNEX 1). Through this comparison, gaps have been identified, which will inform the implementation of the second- and third-wave pilots.

The long-term aim (to be reported in D7.4 Final Report on Best Practices and in eHealth and Certification) is to arrive at a standard use-case scenario that captures the steps required to implement the TeNDER system. This, together with the user manual produced by Work Package 6, and other elements, will help standardise the use of the system, so that it is accessible for different types of patients with chronic conditions.

This deliverable will therefore describe (1) the process we followed to identify gaps, as well as best practices and how they currently align with the "Refined eHealth European Interoperability Framework," (2) the recommendations that stemmed from this exercise, and (3) the next steps towards a standardised use-case description.

1 INTRODUCTION

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

Five sites across Europe will pilot the TeNDER system in three waves. The first wave has been completed, and this deliverable (D7.2) reports on the use-case templates end-user partners filled in during the implementation process. Piloting has targeted and will target patients who suffer from dementia (including Alzheimer's disease), Parkinson's disease, and/or cardiovascular diseases, with or without comorbidities.

In each pilot setting (i.e., in hospital, at home, or in rehabilitation and day-care centres), patients are 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 ensure that all personal data is protected according to the General Data Protection Regulation (GDPR).

By combining user-friendly technologies and substantial research experience, TeNDER hopes to contribute to integration efforts in health and social care, especially amongst Europe's ageing population.

1.1 Contribution to other deliverables

TeNDER's core aim is to improve the quality of life of patients and those who surround and care for them. First, by facilitating communication between social and health care professionals, and extending the autonomy of patients. Second, by making TeNDER's model for integrated care fit for widespread implementation that it can benefit patients beyond the project's implementation cycle. It is with this goal in mind that the work of Task 7.2 will inform the creation of a TeNDER standard use-case.

This is closely linked to several Work Packages (WPs) and associated Deliverables, which contribute to interoperability from different perspectives and expertise. WP1 on data protection, ethical impact, and interoperability ensure that the development and implementation of the TeNDER system complies with rigorous ethical standards (research, etc.), data protection regulations, and standardisation and interoperability efforts. It is thanks to the tasks associated with WP1 that we have a standard set of legal pre-conditions that need to be met (see p. 2 of ANNEX 1).

Similarly, the technical Work Packages (WP4, WP5) work to establish the technical interoperability of the TeNDER system. Thanks to this, we are also able to put together a list of devices, tools, and architecture that need to be in place for the system to work (see p. 2 of ANNEX 1). Finally, Work Packages 6 and 7 which implement the pilots and assess QoL, provide the status quo scenarios and define what the 'ideal' scenarios will look like.

D7.2 will support this work by identifying common practices and gaps and working towards a standard use-case description that captures best practices in the use of the TeNDER system. This, together with the extensive work described above will hopefully help the TeNDER system accessible to different types of patients with chronic conditions.

1.2 Structure of the document

This section (**Section 1**) has briefly introduced the scope of this deliverable, situating it within the broader aims of the project and linking it to other deliverables.

Section 2 covers the process we followed to identify gaps and common practices in different pilot settings. It also covers the most relevant elements of the "Refined eHealth European Interoperability Framework," a toolkit that provides an alignment model to promote interoperability in projects such as TeNDER. Section 2 also summarises the use-case templates each end-user partner filled in.

Section 3 describes the recommendations and steps that will be followed in subsequent pilots.

2 BEST PRACTICES IN eHEALTH

Embedded in Work Package 7 (WP7), Task 7.2 is working towards a standardised use-case description of all the pilots, which builds on the best practices identified during the piloting of the TeNDER system.

Both, D7.1 on QoL Assessment Methodology and the SWOT analysis conducted for D8.7 First Report on Business Modelling identify lack of adoption assistive technology in general as a risk to the success of TeNDER. While some forms of assistive technology are becoming ubiquitous in higher-income countries, integrated systems such as the one TeNDER is developing and piloting are more complex in that its many components need to be interoperable at technical, organisational, and policy levels, etc. For instance, the World Health Organization (WHO) has recognised the huge potential for assistive technologies but have warned that "very few countries have a national assistive technology policy or programme" **[1]**. All these elements create barriers for adoption.

All Work Packages are contributing to the interoperability of the TeNDER system: from ensuring that we meet rigorous legal and ethical standards to the highly technical aspects of systems interoperability. This concern also acts as a backdrop to Task 7.2 where we seek to define cross-European best practices in eHealth that can help promote adoption in different contexts across the EU.

2.1 Aims and objectives

The broad aim of the project is to help improve the quality of life of patients and those who surround and care for them. Work Package 7 focuses on Quality of Life (QoL) assessment and progress indicators. Section 2.6.1 of D7.1 developed indicators for usability and technological acceptance for the first wave of pilots. D7.2 hopes to contribute to TeNDER's wider adoption by identifying common practices across very different piloting contexts, as well as by singling out gaps in 'status quo' implementation that should be addressed in subsequent testing waves. The final objective will be to arrive at a standardised use-case description of all pilots in the Final Report (D7.4 due M36 – possible extension due to delays).

2.2 Process

With the input of end-user and technical partners, HOPE drafted a use-case template for end-user partners to fill in during the first wave of pilots. This formalised the process, ensuring that despite the different locations and settings, the partners would be able to describe 'ideal scenarios' vs. what actually took place – referred to here as 'status quo'.

Depending on the situation and the number of patients each end-user partner recruited for the first wave, they each filled in **1-2 templates** describing instances of care using the TeNDER system. Despite some delays due to COVID-19, partners – while taking all precautions – were able to test several devices in three of the four settings: home set, in hospital, and at rehabilitation centres.

2.2.1. Use-case templates

The use-case templates (see ANNEX 1) formalise our data gathering approach. Guided by these templates, end-user partners:

- anonymously describe the actors involved in each instance of care (e.g., CVD, dementia, or Parkinson's patients; their caregivers; health professionals, etc.);
- provide detailed contextual information;
- give an account of the devices and pre-conditions met (i.e., devices, technical and legal elements from a list annexed to the templates);
- outline a 'Normal course', in essence what *ideally* should happen;
- describe the 'Actual course' (what actually took place), and associated profiles that may not have been foreseen by the 'actors' list, but who nonetheless played a role during the pilots.

Section 2.3 discusses each end-user partner's instances of care.

2.2.2. Integration of the "Refined eHealth European Interoperability Framework"[3]

The "Refined eHealth European Interoperability Framework" (ReEIF) **[2]** has been adopted to help us guide the process of identifying best practices in the implementation of the TeNDER system. The ReEIF, drafted with the support of the European Commission, focuses on ways to manage interoperability and standardisation challenges within the eHealth field in Europe.

This section will describe the ReEIF in detail, as it (1) has significant structuring value for decision-making processes and communications in projects; and (2) provides a common framework and language to analyse problems and identify eHealth solutions in Europe.

Interoperability is one of the biggest challenges in healthcare Information Technology (IT). To put it succinctly, Interoperability constitutes "the ability of different systems, devices and applications to exchange and make use of information" **[3]**. TeNDER, for example, uses different types of devices, networks, and platforms, which must speak the same language, otherwise they will not be able to work together and create an efficient smart system. Furthermore, this term operates beyond the context of software and hardware, it is equally important for policies and legal systems to be aligned with the implementation of a smart system that gathers sensitive information like health data.

Interoperability across contexts

Because interoperability essentially means building collaborations between different environments in the healthcare domain using electronic means, the use of standards is necessary. However, standardisation alone is not enough to achieve interoperability at regional and national levels. Therefore, the European Commission published in 2013 the eEIF and refined it in 2015, which is the version TeNDER has adopted.

The ReEIF unifies the language to improve its readability by providing a consistent glossary of terms. This updated version also plots the interoperability categorising activities and actors into six different subheadings.

Specifically, interoperability includes many different aspects that need to be considered (i.e., guidelines, legislation, governance). The implementation of interoperability can be successful only when all involved stakeholders are included in the process. The ReEIF introduces a shared model with all interoperability levels, see Figure 1. This is a non-technical model which can be

[3] See https://ec.europa.eu/health/sites/default/files/ehealth/docs/ev_20151123_co03_en.pdf.

adopted by different participants (i.e., healthcare professionals, decision- makers, information analysts).

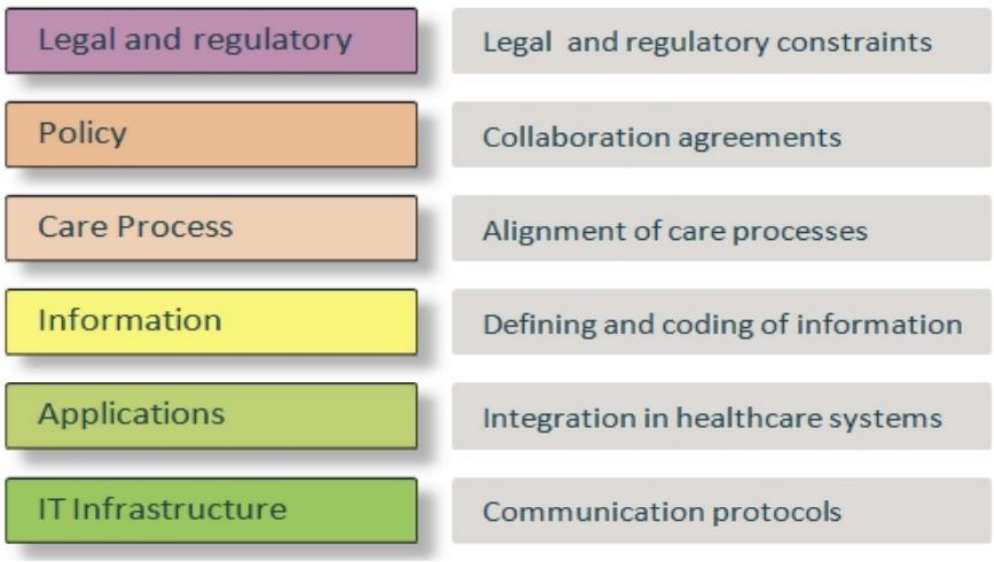

*Figure 1 - The Refined eHealth European Interoperability Framework **model** (Source: ReEif document)*

The ReEIF also provides two templates for the description of high-level use cases. The first template is used to describe the process in a functional way and includes the following components: Purpose, Relevance, Domain, Scale, Context, Information, Participants and Functional process flow. The second template refers to the realisation scenarios and translates the process in technical steps including the following components: Related Use Case, Scenario context, Actors, Transactions, Technical process flow, Associated Profiles, Possible issues, and Implementation examples. TeNDER adapted the second template for use during the first of pilots (see ANNEX 1).

The ReEIF, its scope, and definitions, are flexibly used in regional, local, national, and cross-border projects across Europe. The aim is to unify concepts and encourage better communication between all stakeholders involved.

2.3 Overview of instances of care captured by the use-case templates

Sections 2.3.1-2.3.5 provide a narrative summary of the instances of care captured by end-user partners during the first wave of pilots. In Section 2.4, we will table the gaps that emerged when comparing the 'ideal' situations end-user partners described and the 'status quo' descriptions. And finally, Section 2.4.1 will sum up the common practices that emerged throughout the first wave of pilots.

Pilot partners used several of the following devices available during the first wave according to the determined needs of individual patients:

Table 2 - Devices and descriptions

Device(s)	Description(s)
Mini-PC Mini-PC light	These mini-PC's have been installed and prepared for each set where the software needed to run the TeNDER ecosystem has been installed
Sleep analyser (Withings)	This device provides the following data and functionalities: sleep analyser records; health parameters in real-time to understand sleep patterns and deliver accurate health data; heartrate - each time a heart beats, it propels a mechanical wave through the patient's body, which is measured continuously with high precision by the pneumatic sensor; breathing - filters the patient's motion signal to extract breathing rate throughout the night; movement - movements generate mechanical waves, which are also captured by the pneumatic sensor. During the first wave of pilots this device was used to monitor the quality of sleep of patients (duration, depth, breaks, general score) and it shown to patients and caregivers on the TeNDER APP and to health professionals on the platform through dedicated interfaces.
smart-band	Fitbit Band Versa 2 - not only tracks basic vitals, but it matches gait and skeletal information gathered by the RGBD cameras.
	Xiaomi Mi3 - tracks basic vitals, in future it will also combine with the position tracking system and other modalities to provide fall detection capabilities. Bluetooth transfer possible.
Position tracker	Connects to the local wireless without the need for additional devices. During the first wave of pilots, this sensor provided useful data and information about the time spent by patients in a defined environment.
RGBD camera	Kinect Azure - connects to the Mini-PC (not light). Acquires RGB colour images and depth images which are then used to extract skeletal movements together with other sensors.
	Kinect 2 - Acquires RGB colour images and depth images which are then used to

	extract skeletal movements together with other sensors.
Microphone	This device provides the following data: meta information; date and time of event recognition; label (cry, laugh, or fall) of the recognised sound; raw date of the recognised sound segment, i.e., array of features extracted from audio; and prediction percentage.
Smartphone and/or Tablet	Used to visualise data. All user interfaces (UIs) are currently integrated via an open Application Programming Interface (API), providing a set of similar appearances and functionality interaction services. Specific and dedicated UIs are showed on the smartphone and tablet to patients and caregivers through mobile apps and to health professionals using the TeNDER web platform.

2.3.1 Servicio Madrileño de Salud

Due to restrictions associated with the COVID pandemic, the Servicio Madrileño de Salud (SERMAS) tested components of the TeNDER system in **HomeSet environments only**. During the first wave of pilots, SERMAS filled in the use-case template to describe one instance of care. The Polytechnic University of Madrid (UPM) provided technical support during installation and throughout the duration of the first wave.

The case in question describes a 70-year-old cardiovascular disease (CVD) patient with a history of arterial hypertension and atrial fibrillation who is monitored at one of SERMAS' health centres every month. The patient's vital signs are checked, as well as the values that regulate the correct dosage of their anticoagulant treatment.

The patient's attendant nurse suggested that they be included in the TeNDER project as he has been going to that clinic for a long time and enjoys walking. It was decided to test the **smart-band** to monitor his steps and heart rate, as well as the **smartphone** to visualise the data gathered from the smart-band.

All legal and technical pre-conditions were met. The health professionals closely associated to the patient were given access to the data collected by the smart-band sensors. In this case, a serious complication was averted. During a virtual review of the vital signs collected by the smart-band, the patient's referring nurse was able to verify extremely low heart rate values that were repeated frequently throughout the days and alternated with values in the normal range. The decision of the healthcare professional was to call the patient to arrange a face-to-face appointment at the health centre and perform an electrocardiogram, which led to the diagnosis of a heart rhythm disturbance that required surgery to implant a pacemaker.

2.3.2 Asociación Parkinson Madrid

Asociación Parkinson Madrid (APM) tested the TeNDER system in HomeSet and Rehabilitation Room environments. For the first wave of pilots, they filled in the use-case templates to describe two instances of care of patients with Parkinson's disease (PD) in each setting. UPM provided technical support during installation and throughout the duration of the first wave.

All legal and technical pre-conditions were met in each scenario.

In the **HomeSet environment**, APM, with the remote technical support of the UPM, set up the **smart-band** and the **sleep analyser** for a patient with Parkinson's disease.

In the **Rehabilitation room**, APM tested the smart-band and the Red Green Blue-Depth[4] (RGBD) camera. The subject of this instance of care attends physiotherapy sessions twice a week at APM. In each session, the patient wore **smart-band**, while the **RGBD camera** recorded her movements to evaluate her gait throughout the session. A **smartphone** was also provided to gather and visualise the smart-band data. A **Mini-PC** was installed to collect the RGBD camera data.

The patient reported feeling uncomfortable carrying the mobile at all times to consult the data sent from the smart-band. The patient also hoped to receive feedback via that same app, but unfortunately that functionality was not available during the first wave.

2.3.3 University of Rome - Tor Vergata

The University of Rome - Tor Vergata (UNITOV) tested components of the TeNDER system in the HomeSet and hospital environments together. Due to COVID related restrictions, the patients were not hospitalised, but rather were monitored at home and in the day hospital. UNITOV filled in one use-case template to describe a HomeSet pilot involving a patient with Alzheimer's disease and their caregiver (informal). Datawizard (DW) provided technical support during installation and throughout the duration of the first wave.

The patient is a 77-year-old female with Alzheimer's disease (AD), who has reported that her sleep quality has worsened. In addition, the patient has a history of hypertension (associated co-morbidity). The patient is followed by her husband in her daily activities.

Her neurologist suggested she participate in TeNDER project's **HomeSet environment** pilot, to monitor her sleep quality and to check her vital signs. Patient and her husband agreed.

All technical and legal pre-conditions were met. The patient, her husband, and her neurologist have access to the reports and data collected by the TeNDER devices, which in this case involved **smartphones** (for the patient and her caregiver); a **smart-band** (for the patient); a **Mini PC low-end** to which the following devices were linked to: a **microphone** for mood detection purposes; and most importantly, the **sleep analyser** to understand better the underlying causes of her worsening sleep quality.

[4] See https://www.tender-health.eu/project/glossary/#R.

2.3.4 Schön Klinik Bad Aibling

Schön Klinik Bad Aibling (SKBA) tested components of the TeNDER system in hospital and at their Alzheimer's Therapy Centre. The Center for Research and Technology, Hellas (CERTH) provided technical support during installation and throughout the duration of the first wave.

At SKBA's Alzheimer's **Therapy Centre**, a 61-year-old patient and his wife, who cares for him, stayed together in an apartment at for three weeks. During this time, the following devices were tested: the **sleep analyser**; the **smart-band**; and the **smartphone** (used for data visualisation).

All legal and technical pre-conditions were met. The researcher contacted the patient and the caregiver after checking that both meet the inclusion and exclusion criteria set in the study protocol. They were informed about the project, giving them ample time to ask questions and decide whether they want to participate.

When both, patient and caregiver, decided to participate, they selected the sensors they wished to use, signed the informed consent forms, and set an appointment with a TeNDER researcher. The researcher made sure that the participants received all necessary additional information and that there are no more questions.

At the participants' hospital apartment, the researcher installed several sensors and explained their functions and usage. The sleep analyser was plugged in and placed under the mattress in the patient's bed. For the smart-band, the researcher explained how to handle it, how and when to charge it, and what the different displayed notifications mean. Finally, the smartphone with the respective apps to visualise the collected sensor data was introduced and the handling explained.

In the **hospital setting**, an 81-year-old patient was admitted to SKBA's stroke rehabilitation centre. During this time, researchers tested the **sleep analyser**, the **smart-band**, and the **smartphone** (used for visualisation purposes only at this stage).

As in the previous use-case description, all legal and technical pre-conditions were met and the same protocols outlined above were implemented (i.e., the researcher was available to answer questions, explained everything in detail to ensure informed consent, installed the devices, etc.).

In the first scenario involving the patient with Alzheimer's, their caregiver had access to the data collected by the TeNDER sensors. In both scenarios, the health professionals closely associated with the patients receiving care also had access to the data collected by the TeNDER sensors. To share this data with the associated profiles, data sharing agreement were signed as part of the pre-conditions that needed to be met before conducting the pilots.

2.3.5 Spominčica - Alzheimer Slovenija

Due to restrictions associated with the COVID pandemic, Spominčica - Alzheimer Slovenija (SPO) tested components of the TeNDER system in the **HomeSet environment** only during the first wave of pilots. SPO filled in the use-case template to describe two instances of care of two patients with dementia and their caregivers. Elgoline (ELG) provided technical support during installation and throughout the duration of the first wave.

The first use-case description concerns a patient and their carer who live together. However, the patient must be left alone at home sometimes during the day. Piloting is performed to test: (1) the usability of monitoring a patient's sleep habits, and (2) the benefits of having sleep quality reports, as well as to monitor the patient's (3) presence at home/outside (hours per day) and his/her activity (number of steps); presence in specific room of the house (how much time is spent in the living room and how much in the hall) in order to gain insight into how best to manage daily activities and the challenges patients face. The 'reminders' functionality was also tested.

All technical and legal pre-conditions were met. In addition to the **sleep analyser** and the **smart-band**, SPO also tested **two localisation sensors** (in the living room and in the hallway), as well as the use of the **tablet** to review the reports and a smartphone for the carer to set reminders for the patient. Several devices were connected to an unobtrusive **Mini-PC** at the patient's home.

The patient and/or his/her carer may consult health professionals to improve sleep management, pain management, medication intake, etc. They can also consult social care professional about daily routines, care needs to assure safety, etc.

SPO's second use-case description captures a different scenario where the carer does not live with the patient in question. In this case, the patient's health is deteriorating, they have hip problems, and it has been observed that the patient is experiencing fatigue and showing signs of depression and anxiety.

All legal and technical pre-conditions were met. In addition to the **sleep analyser**, SPO also tested one **localisation sensor** together with the **smart-band**, as well as a **microphone** for emotional reports and possible fall detection. The **tablet** and **smartphone** were used to view the data reports. Several devices were connected to an unobtrusive **Mini-PC** at the patient's home.

2.4 Gap analysis and common practices

Table 2 below includes (1) the 'normal course' descriptions end-user partners defined in the use-case templates. In essence, these 'normal course' descriptions capture what *should* happen ideally and can therefore be construed as 'ideal scenarios' in the context of a gap analysis. (2) These 'ideal scenarios' are then matched up with the 'actual course', i.e., what took place, also understood as the 'status quo scenarios'. Finally, the last column (3) identifies gaps between 'ideal scenarios' and the 'status quo scenarios' which will help us define next steps in Section 3.

Section 2.4.1 will collect important common practices observed during the first wave of pilots.

Table 3 - Gap analysis

EP[5]	Normal course	Actual course	Gaps
SERMAS	**CVD patient/HomeSet** Using the mobile application, the patient's	The patient has continuous access to smart-band data.	Alerts to health services have not been integrated into the TeNDER system yet.

[5] EP = end-user partner

	caregivers are able to know in real-time any heartrate alterations and confirm with the patient his or her situation (awake, good general condition) and alert health services if necessary. The patient should not always have access to smart-band data If heartrate decompensation occurs under regular general conditions, a patient has a direct line to their health professional instead of depending on the weekly standard review performed at the clinic. If the health professional does not read the notification (because they are on holiday, for example) the app should advise the patient that the correspondent health professional connected to TeNDER will not attend the message. In addition, the patient should be able to use the emergency button (direct dial to 112 emergency services in Spain) in case they need urgent assistance.	During the virtual review of the vital signs collected by the smart wristband, the patient's referring nurse was able to verify extremely low heartrate values that appeared frequently throughout the days and alternated with values in the normal range. The decision of the healthcare professional was to call the patient to arrange a face-to-face appointment at the health centre and perform an electrocardiogram, which led to the diagnosis of a heart rhythm disturbance that required the placement of a pacemaker within a few weeks.	It might be a good approach to manage access to features related to the smart-band data if the healthcare professional feels that the patient is becoming anxious it.
APM	**PD patient/HomeSet** The patient wears the smart-band daily. They charge the sensor when the charge is low, and then put it back on. Patients, health professionals, and caregivers can see the information collected by the sensors. The patient receives a warning when the wristband is low on battery, e.g., 10% remaining. This warning is repeated if the wristband is still not charging at 5%	The patient wears the bracelet most of the day, only taking it off at certain times but occasionally forgetting to put it back on. Accidentally, the patient presses the button on the side of the wristband and stops collecting information, so for a while no data is sent. On some occasions it has not been clear to the patient how to re-activate the app so that the data can be sent again.	It is important that the smart-band application runs continuously in the background so that even if users accidentally press the side button the data will still be sent. Patients, health professionals, and caregivers are not able to see all the information collected by the sensors; this is something that has been worked on, but there is still room for improvement, particularly regarding

	battery remaining. A final warning is given before the wristband switches off. The warning may include vibration to make it easier for the patient to detect. A low battery warning can also be sent to the caregiver to assist the patient in case he/she forgets or does not know how to charge the smart-band.		the data collected via the sleep tracker.
	PD patient/Rehabilitation ctr. During the session, data is collected on the exercises that the camera recognises, and instructions are given to the camera via voice commands; the camera then returns the information by repeating the instruction to confirm that it is working properly. The patient does their session as usual, in their group with the rest of their peers. The only difference with a non-piloted session is that they would have to stand in a fixed position for the camera to record their movements. In future waves the information collected in this scenario will be displayed in graphs intended not only for professionals, but also for patients and their carers, so that they can see the evolution of their work in the rehabilitation room. A system is in place to adapt voice commands to each user, similar to what mobile phone voice assistants do when configured.	At some specific moments the system does not pick up the instruction properly and confuses it with another one. After repeating the command slower and closer to the camera, the system identifies the exercise. Voice commands do not recognise the instructions, the therapist has to repeat them or enter the exercises manually through the application. This situation is a bit annoying for the patient because the normal development of the session is continually interrupted, and the rhythm of the exercises is disrupted leading to loss of concentration. The smart-band did not send the data to the mobile app.	The issues with the voice commands and the misunderstandings that ensued, as well as the issues with the smart-band failures have been improved upon, however, both features need to be refined further. The patient understands that this is a pilot project but insists on the need to address the underlying issues causing the interruptions, as well as on the smart-band that stops collecting information. (This latter point was partly addressed by explaining to the patient that pressing the side button on the smart-band interrupts the data traffic and this can easily happen when performing the exercises.) In terms of the graph displays, it is possible and is being worked on for inclusion in the second wave. This is very important as the mobile app becomes meaningless in this scenario if feedback of this kind is not included.

UNITOV	**AD patient and caregiver (informal - spouse)/ HomeSet** Patient, her husband, and the neurologist are aware of patient's sleep quality and vital signs during monitoring. Patient and her husband have an overview about these parameters; In addition, her husband may check her mood when he is not at home (mood detection data from microphone) using the TeNDER app. The neurologist may assess with precision the patient's sleep quality and cross-reference her day-to-day vitals with those measured in consultation. Using TeNDER app, her husband is also able to follow her vital signs in real-time, and alert services if necessary.	During the monitoring, the neurologist is able to assess the patient's quality of sleep. However, some reports on the quality of sleep of the patient were missing or unavailable. The final decision was to schedule a visit with her to prescribe a new therapy (to improve her quality of sleep). The patient is very satisfied with this monitoring. Her husband is happy because when is not at home, he can check her mood with the smartphone app.	Health professionals are not able to see all the information collected by the sensors. Some reports are missing or unavailable.
SKBA	**AD patient/Therapy ctr.** Continuous tracking may reveal abnormalities that might have been missed otherwise, e.g., the patient's heart rate might show abnormalities that could indicate a serious condition. When not detected, the condition might pose a health risk to the patient. During the whole duration of the study the researcher is available via phone and personally for short-term assistance.	The patient uses the TeNDER sensors provided by SKBA researchers. Due to cognitive impairments associated with Alzheimer's disease, in most cases the patient needs support from the caregiver to check the data on their respective smartphone apps. The researcher regularly checks (via smartphone) whether or not the sensors are collecting the data as required by the protocol or if further support is needed. During the whole duration of the study the researcher is available via phone for short-term assistance.	Under normal conditions, parameters would not be tracked constantly. Thus, important findings could be missed. While it is good that parameters are constantly tracked, it should be possible to decide case-by-case whether s/he receives the information or whether this should be limited to the caregiver/ health professional as it might create anxiety. (Especially for patients with AD, the information might be too overwhelming.) Communication between patients/caregivers and

		In case of incidental findings, the patient, the caregiver and the treating physician are informed where the patient has given consent to reveal this data. Patient continues to rely on caregiver due to the specific functionality loss associated with AD. The patient and their caregiver have continuous access to basic vitals data. Communication between patients/caregivers and professionals is not as seamless as it could be.	professionals needs to be improved. Integration of additional sensors recommended for second wave: mood and fall detection, GPS-tracking.
	CVD patient/Hospital Via constant tracking, abnormalities can be detected that might have been missed otherwise. (Patients with CVDs could especially benefit from a real-time detection of abnormal heart-related values to be able to immediately act upon it, e.g., slow down or inform somebody.) During the whole duration of the study the researcher is available via phone and personally for short-term assistance.	The patient uses the TeNDER sensors provided by SKBA researchers and checks the measured data on the respective smartphone apps. The researcher regularly checks via a smartphone whether the sensors are collecting the data as required by the protocol or whether further support is needed. During the whole duration of the study the researcher is available via phone and personally for short-term assistance. In case of incidental findings, the patient and the treating physician are informed where the patient has given consent to reveal this data. Furthermore, the investigator is available to explain the meaning and purpose of the data to the patient and the caregiver.	The patient has continuous *access* to basic vitals. As in SKBA Use-case 1 (above), this access should be granted case-by-case. Communication between patients/caregivers and professionals needs to be improved. Integration of additional sensors recommended for second wave: Fall detection, sleep apnoea detection.
SPO	**AD patient living with caregiver/HomeSet**	The patient and the carer were introduced the	The patient continues to rely mainly on their carer. No reduction on

	People with AD often experience problems with spatial orientation, they can become confused in their own homes or lost outside. Real-time indoor/outdoor positioning could help prevent such incidents. Data related to sleep quality and daily activities are evaluated together to adapt daily routines and to help plan non-pharmacological interventions for a patient. Reports are used to verify events and for consultation purposes with the health professional if the patient agrees to share their data. The patient and the carer can access reports for the previous day: sleep report, the overall report on the presence in specific rooms of the living environment, and the overall time the patient spends outside every morning. The carer can create reminders for dedicated tasks that the patient should complete during the day; these are displayed on the patient's tablet. If the patient finalises a task, it is marked, and the carer receives feedback that the patient completed what was recommended/planned. This way the carer is reassured that the patient was able to complete the relevant task even when left alone for some time. A binary sensor is installed on the apartment door and would be used in combination with localisation sensors provide information on person with AD leaving the apartment.	TeNDER and they answered the first questionnaire. The researcher introduced the technology, and the participants were familiarised with the sensors. The sensors were installed and connected; the testing began. The researcher checked in with the patient and their caregiver via phone and conducted occasional visits, providing support concerning the report visualisation and (when needed) support on how to use the App on phone and tablet. The carer input reminders for the patient through the App. The patient didn't respond through the App concerning the dedicated tasks assigned to them. The patient was wearing the smart-band connected to a localisation sensor and together with a carer they could see the report of hours spent in a specific room and hours spent outside the apartment. However, the patient occasionally forgot to wear it. The patient used the sleep analyser and after revising the reports, the sleep score was low. In this case, the patient agreed to share the reports with their health professional, the professional was asked to see the reports and communicate with the carer and the patient about possible interventions to improve sleep quality. However, there was no	this dependency observed. The reminder function was not well accepted or used. And interactions with the patient's health professional were considered insufficient. For the location functionality to work, the smart-band needs to be worn by a patient at all times. Thus, if the smart-band is taken off, the location functionality is not supported. The function with the reminders only works if the user (patient that is receiving and marking the reminder for the action done; and the carer who inputs the reminder and checks whether it is marked as done) is logged into the App and the App is open. The patient did not check the reminder as he/she was not logged into the App at that time of the day. The level of communication between patient-caregiver-professional was low. Carer needed to assist the patient a lot to view the reports. Environmental sensors not yet integrated.

	The carer helps the patient use the technology and also with checking the reports. Patient and/or carer may choose to consult with the professional about sleep management, routines, care needs to ensure safety, etc.	clear follow-up in this regard. Patient was mainly relied on care provided by the carer.	
	AD patient <u>not</u> living with caregiver/HomeSet People with AD often experience problems with spatial orientation, they can become confused in their own homes or lost outside. Real-time indoor/outdoor positioning could help prevent such incidents. The patient would wear the smart-band to enable the fall detection functionality. A patient who lives separately form their carer would use the system and the carer would be able see the reports and use the communication channel to remind the patient to perform tasks during the day. The carer would also use the calendar and reminder function to foster daily activity management. The report on general emotional state and possible falls detection of a patient that lives alone are displayed as a report for the previous day. Data on sleep quality and activities are combined to adapt daily routines and non-pharmacological interventions. They can also use professional recommendations to develop healthy activities and sleeping habits.	Testing involved the installation of a sleep analyser, a localisation sensor together with a smart-band, a microphone for mood recognition (this function was unavailable, however) and possible fall detection, tablet and phone for viewing of the reports. All devices were connected to a local PC at the patient`s place. The researcher met the patient and their carer in the patient's living environment and introduced TeNDER. Both participants answered the first questionnaire. The researcher explained the technology and the participants were familiarised with the sensors. The sensors were installed in the patient's home, and testing began. The researcher checked in with the participants via phone and paid occasional visits to provide support. The carer was not present at the patient's home most of the time and provided some reminders for the patient through the App. The patient did not respond through the App, however. The patient used the sleep analyser and could access the reports using the App.	Mood detection and calendar functions are missing. Therefore, emotional reports were unavailable. The level of communication between patient-caregiver-professional has not been achieved. Reports were not good enough to be used for longitudinal assessments and care management interventions. Fall and mood detection sensor are not sending information in real-time.

	The carer helps the patient in using the technology and checking the reports when visiting a patient. The patient and/or carer may choose to consult a health professional concerning sleep management, routines, safety measures, etc.	The carer also had access to the patient's sleep reports. Using sleep sensor, the patient and the carer were able to visualize sleep habits (regularity, sleep duration, possible breaks, time spent in deep/light/REM phases, and overall sleep score). In this case the patient agreed to share the reports with their health professional. However, did this not necessarily take place, the reports only served to inform minor interventions that could be carried out by the patient's carer.	

2.4.1 Best practices

Thanks to the Research Protocols established in Work Package 6, and training materials produced, end-user partners follow very similar steps to recruit and to test. Therefore, the same pre-conditions are met each time. Meanwhile, technical partners have provided instructions to troubleshoot common system errors.

Though it is difficult to glean substantial best practices in the first wave of pilots, we nonetheless identified at least three, which are additionally supported by research. Indeed, descriptive reviews on the ethical design of intelligent assistive technologies (IATs) identify **[4]** six core ethical considerations that should be met to improve the adoption of IATs in the field of dementia care. These are autonomy, privacy, beneficence, non-maleficence, interdependence, and justice. The following practices, together with TeNDER's research and system design, contribute to meeting ethical principles that protect patients, build trust, and thus, potentially increase the incidence of adoption.

i. From the very beginning, end-user partners recognised the importance of clear communication and being available to support participants and answer questions. It is therefore recommended that this approach is built into the TeNDER system at the ***policy level***.
ii. The benefits of continuous tracking have been established, particularly in the SERMAS use-case. Therefore, this should continue to be part of the ***care process and applications***.
iii. Finally, the continuous review of the ***legal*** standards has been extremely important to build trust with technologies that capture sensitive information.

3 NEXT STEPS: Towards a standard use-case description

In subsequent piloting waves, the following elements should be prioritised to match the implementation of the TeNDER system with the 'ideal scenario':

- To improve the communication, the TeNDER app for patients/caregivers and the TeNDER web app for professionals need to be fully integrated and functioning. This way, the communication is easier and faster, as all information is summarised in one place. The centralisation of all information in the TeNDER (web-) app should replace the need to use other apps (e.g., Withings or Fitbit app), which is currently the case.
- It has been observed across every instance of care that continuous access to smart-band data (heartrate, etc.) can lead to anxiety, therefore, it is recommended that it should be possible to manage access to it. This would need to be determined both from the care and legal perspectives.
- Patients, caregivers, and professionals have observed that it is difficult to visualise the information collected by the different sensors, and that the reports are sometimes unavailable or altogether missing. This problem must be addressed.
- It has been observed that in the context of Alzheimer's, the reminder function is underused. To help address this issue, it has been suggested that a sound notification could be implemented and easily done by the caregiver, for example.
- The possibility of real-time events for fall detection, but also for the emotional state that could indicate the need to be checked in real-time would be beneficial, as the carers can't be present at all times. However, these are currently not functioning in real-time.
- Reports for longitudinal assessment need to be improved; this links back to the missing and unavailable reports, which impact the ability to gather sufficient data for longitudinal assessments.
- Binary and environmental sensors will be integrated into the system and added to the list of devices on the use-case template.
- Charging reminders for the smart-band will be implemented in during the second wave of pilots.

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ANNEX 1 - Use-case templates

User Partner:	
Country:	
Pilot ID:	

Title	[Scenario: HomeSet, Daycare, Hospital, or Rehabilitation]
Actors	[Type of user: choose from **patient (AD, PD, and/or CVD)**, **health professional**, **caregiver**]
Context	[Detailed description of context]
Tools and architecture	[List of tools, architecture, and/or processes to be used. **SEE ANNEX I FOR LIST OF DEVICES**]
Pre-conditions	[Detailed description of conditions needed for testing – these should include **legal and regulatory** standards that need to be met, and **technical elements**. **SEE ANNEX II**]
Normal course	[Detailed description of what should take place]
Alternate course	[Description of what could take place]
Actual course	[Detailed description of what took place]
Associated profiles	[Links to other scenarios/applications]

ANNEX I – List of devices

Devices	
Smart bands (measures basic vitals, accelometer)	**Screen**
Environmental Sensors	**Bluetooth scanner**
Cameras (RGBD sensor)	**Routers**
Smartphone / Tablets (Gui interfaces)	**Extenders**
PC (mini-PC - low end; mini-PC)	**Storage**
Binary Sensors (for door status)	**Refrigerator door switch**
Microphones	**RGB-depth camera**
Speakers	
Sleep tracker (measures breathing frequency, heart rate)	

ANNEX II – Conditions list: legal and regulatory, and technical elements

Legal and regulatory	
Permission granted by patients or legal representative. Can be turned off by patient or legal representative.	Informed consent signed
Data sharing agreement with the professional signed	

Technical elements	
Sleep sensor:	Access to 230V AC mains voltage
	Access to 2.4GHz WiFi network
Localization sensor:	Access to 230V AC mains voltage
	Access to 2.4GHz WiFi network
Local Mini PC:	Access to 230V AC mains voltage
	Access to 2.4GHz WiFi network or wired ethernet connection to router
Dedicated Router (optional):	Access to 230V AC mains voltage
	Wired ethernet connection to ISP router
Kinect Azure Sensor:	Access to 230V AC mains voltage
	Wired connection to mini-pc USB3 port
RealSense Sensor:	Wired connection to mini-pc USB3 port
Fitbit/mi band wearable:	Requires charging
	Bluetooth connection with smartphone
Microphone:	Wired connection to mini-pc USB port