Co-funded by the Horizon 2020
Framework Programme of the European Union

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Deliverable D6.2

Report on First wave of pilots

Work Package 6: Large Scale Piloting and Validation

Grant Agreement ID: 875325
Start date: 1 November 2019
End date: 31 October 2022
Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019
Topic: SC1-DTH-11-2019 Large Scale pilots of personalized & outcome based integrated care
Funding Scheme: IA - Innovation action

Disclaimer

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Document Information

Project short name and Grant Agreement ID	TeNDER (875325)
Work package	WP06
Deliverable number	D6.2
Deliverable title	**Report on First wave of pilots**
Responsible beneficiary	UNITOV
Involved beneficiaries	SERMAS, UPM, MAG, UBI, ELG, CERTH, VUB, SKBA, SPO, APM
Type[1]	R
Dissemination level[2]	PU
Contractual date of delivery	30/04/2021
Last update	28/04/2021

Document History

Version	Date	Status	Authors, Reviewers	Description
V0.01	11/03/2021	Template	Maria Ricci & Andrea Cimini (UNITOV)	Project deliverable template
V0.02	11/03/2021	Draft	Špela Glišovič Krivec (SPO)	Comments, suggestions and inputs
V0.03	12/03/2021	Draft	Simone Hinterholzer (SKBA)	Comments regarding inputs/structure/suggestions
V 0.04	25/03/2021	Draft	Cristina Mª Lozano Hernández (SERMAS)	Structure inputs, suggestions and comments
V0.05	07/05/2021	Draft	Maria Ricci & Andrea Cimini (UNITOV)	Internal review
V0.06	07/05/2021	Draft	Špela Glišovič Krivec (SPO)	Inputs in Section 2 (Monthly activity) and Section 4 (outcomes) for Pilot 5
V0.07	10/05/2021	Draft	Jennifer Jiménez (APM)	Inputs in section 2 and Section 4 for Pilot 2. Some comments added regarding overview of the progress
V0.08	12/05/2021	Draft	Maria Ricci & Andrea Cimini (UNITOV)	Internal review. Addition of section 2 (Statement of data collection and priorities for the first waves of pilots)
V0.09	12/05/2021	Draft	Simone Hinterholzer (SKBA)	Inputs in section 3 (monthly activity) for Pilot 4 and inputs in section 5 for Pilot 4; general comments regarding inputs
V0.10	12/05/2021	Draft	Danaja Fabcic (VUB)	Input in section 4 on legal and ethical risk management
V0.11	13/05/2021	Draft	Andrea Cimini (UNITOV)	General revision, input in section for PIlot 3 (professionals)
V0.12	13/05/2021	Draft	Panos Karkazis (MAG)	Add description of the installation and verification processes

V 0.13	14/05/2021	Draft	Rodrigo Medina (SERMAS)	Inputs 3.1 Monthly activity, 4.1 Risk management, 5. Outcomes in Pilot 1
V 0.14	14/05/2021	Draft	Andrea Cimini (UNITOV)	Input in section for Pilot 3
V 0.15	15/05/2021	Draft	Gregor Verdnik (ELGO)	Input at section 3.2.2
V0.16	15/05/2021	Draft	Špela Glišovič Krivec, David Krivec (SPO)	Inputs in Section 3, Section 4, and Section 5 for Pilot 5
V0.17	17/05/2021	Draft	Jennifer Jiménez (APM)	New inputs section 5 for pilot 2
V0.18	18/05/2021	Draft	Maria Ricci & Andrea Cimini (UNITOV)	Internal review
V0.19	18/05/2021	Draft	Annelore Hermann (UPM)	Review of section 2 and general quality standards of the document
V0.20	20/05/2021	Draft	Simone Hinterholzer (SKBA)	Comments in section 3 table 5; Inputs in section 5 for pilot 4 (participant numbers)
V0.21	20/05/2021	Draft	Jennifer Jiménez (APM)	Comments in section 3 and updating in section 5
V0.22	21/05/2021	Draft	Maria Ricci & Andrea Cimini (UNITOV)	Internal review, inputs in Section 5 for Pilot 3, inputs in Conclusions section
V0.23	25/05/2021	Draft	Annelore Hermann (UPM)	General check-up and mark-up of state of the document; improvement of language in section 3.2.2.2
V0.24	25/05/2021	Draft	Nicholas Vretos, Thanasis Makropoulos and Dimitris Papadopoulos (CERTH)	Input in section 3.2.2 (Kinect v02)
V0.25	25/05/2021	Draft	Andrea Cimini, Maria Ricci (UNITOV)	Internal review
V0.26	26/05/2021	First peer review	Cristina Lozano (SERMAS)	General review
V0.27	27/05/2021	Review	Domingo Sánchez (SERMAS)	Minor changes - General Review
V0.28	28/05/2021	Second peer review	Jennifer Jimenez (APM)	General review
V0.29	28/05/2021	Complete Review	Maria Ricci and Andrea Cimini (UNITOV)	General review
V1.0	01/06/2021	Final	Gustavo Hernández (UPM)	Complete review and Final

Acronyms and Abbreviations

Acronym/Abbreviation	Description
EC	European Commission
#	Number of
WP	Work Package
SD	Standard Deviation
GDPR	General Data Protection Regulation
AD	Alzheimer Disease
PD	Parkinson Disease
CVD	Cardiovascular Disease
KPI	Key Performance Indicator

Table 1 TeNDER acronyms

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EXECUTIVE SUMMARY

The current document is the Intermediate Report on 1st wave of Pilots of the TeNDER project (from 01/03/2021 to 18/05/2021). It details the progress and the activity realised in the piloting phase, stressing the risks management and outcomes.
The scope of this deliverable is to report the results and outcomes achieved in the first wave of pilots from 01/03/2021 to 18/05/2021.
The comprehensive Report on first wave of Pilots will be submitted in a second version of the Deliverable 6.2 after the conclusion of the First wave of Pilots, in M21.

The document is separated in:

- Statement on data collection for the first wave of pilots, that includes general guidelines for the Pilot execution and priorities.
- Overview of the progress, that describes the activity performed from 01/03/2021 to 18/05/2021, reporting the activities, the devices installed and integrated, the recruitment of users and the general usage of devices.
- Risk management related to the piloting execution, general and specific for each pilot sites, including the Covid19 pandemic impact on the Pilots.
- Description of expected outcomes and a comprehensive report for each Pilot, that describes scenarios tested, the users involved, the devices assigned and the functionalities tested. Moreover, the section 5 reports discrepancies with protocols described in D6.1, mitigation and integration plan in each Pilot sites.
- Conclusion section that reports the description of the achievement of the expected KPIs.

1. STATEMENT ON DATA COLLECTION AND PRIORITIES FOR THE FIRST WAVE OF PILOTS

Due to the outbreak of Covid-19, public authorities across Europe decided in March 2020 that social distancing measures are necessary to slow down and to fight the spread of the virus. The personal contact to the pilot participants is necessary to recruit participants and to conduct the pilot with them. This is not possible or difficult in the next time due to Covid-19. The main target for the first wave of piloting is the data collection from the devices to the tender cloud and the training of the algorithms.

Taking all this into account, duties from end user partners during the first wave will be: selection, contact and recruitment of real patients for iterative testing. Professionals and caregivers are recruited as stakeholders during the first wave at the current state of the developed technology and report the feedback about it at that moment.
On the other hand, working cooperatively technical partners will assure the data collection in the TeNDER cloud and improve minimal needs from user. It is important to understand the technical progress it is related with the algorithms training and this is based on the data collected by the sensors.

2. OVERVIEW OF THE PROGRESS

The first wave of pilots started in March 2021 with the preparatory work and lab testing of devices and system integration.
The data gathering from real users started in April 2021, with the recruitment of the first patient in Pilot 4 on 07/04/21. The recruitment of users continued in April and May 2021 in all pilots' sites, and it should be completed in June 2021.
As described in D6.1, all users involved will test the TeNDER system for 45 days-2 months in Rehabilitation room, and in home scenarios.
In Hospital scenario the length of monitoring depends on the length of hospitalization.

3.1 Monthly activity

Project months	Corresponding dates	Pilot 1	Pilot 2	Pilot 3	Pilot 4	Pilot 5
M17	March 2021	Ethical approval obtained; Preparatory work (without participants)	Ethical approval obtained. Preparatory work	Ethical approval obtained; Preparatory work	Ethical approval obtained; Preparatory work; lab testing at the office (without participants)	Ethical approval obtained; Preparatory work for the piloting (workshops, presentations, documents); lab testing at the office (without participants); Mock-ups for the interfaces feedback gathering
M18	April 2021	Lab testing at the office without participants. Installation of devices. Home environment: 3 professionals, 3 patients and 3 caregivers recruited and using devices (data gathering).	Rehabilitation room scenario 20 patient recruited.	Lab testing; Recruitment of 10 patients and 10 caregivers; 1 patient and 1 caregiver drop out; Data gathering from 9 sets.	Hospital scenario: Recruitment of 9 patients and 2 caregivers	Lab testing at the office (without participants); 1 patient and 1 caregiver recruited in home scenario
M19	May 2021	Recruitment of professionals: 28. Home environment: 4 patients and 4 caregivers using devices (data gathering) State 14/05/2021	Rehabilitation room 27 patients recruited and 8 professionals (state of 17/05/2021)	8 professionals recruited	Hospital scenario: Recruitment of 5 patients and 4 caregivers (state of 17/05/2021)	Recruitment of 8 patients, 4 caregivers, in home environment and 4 professionals; Data gathering from sensors, first

Project months	Corresponding dates	Pilot 1	Pilot 2	Pilot 3	Pilot 4	Pilot 5
						questionnaires performed, user requirements collected and observations performed

Table 2 Monthly activity from 01/03/2021 to 18/05/2021 of the First wave of Pilots

3.2 Pilot phase activities

3.2.1 Activities

The Time schedule for the stakeholders involved is described in the following tables:

	T0 (baseline)	T1 (45 days-2 months from T0 or at the end of the monitoring)
Patient medical data documentation (MMSE, self-reported risk assessment etc)	**X**	
Check of appropriateness of collected data in TeNDER Platform (socio-demographic data) and initial assessment of barriers.	**X**	**X**
SF-36 questionnaire	**X**	
Affinity for technology	**X**	

Table 3 Time schedule for patients during the First wave of Pilots

	T0 (baseline)	T1 (45 days-2 months from T0 or at the end of the monitoring)

Document stakeholders involved in the caring process (patients, health professionals, social workers, etc.)	**X**	
Check of appropriateness of collected data in TeNDER Platform (socio-demographic data) and initial assessment of barriers.	**X**	**X**
Affinity for technology	**X**	

Table 4 Time schedule for caregivers during the First wave of Pilots

	T0 (baseline)	T1 (The end of the first wave of Pilots)
Document stakeholders involved in the caring process (patients, caregivers, health professionals, social workers, etc.)	**X**	
Check of appropriateness of collected data in TeNDER Platform (socio-demographic data) and initial assessment of barriers.	**X**	**X**
Affinity for technology	**X**	

Table 5 Time schedule for professionals during the First wave of Pilots

3.2.2 Devices installed and system integration

The central components of TeNDER that are used in the 1. Pilot wave are:

- **Mini-PC [1a]:**
- **Mini-PC light[1b].**

Two types of PCs have been chosen to cope with the TeNDER needs while all sensors that communicate with the Mini-PC through a HTTP GET method are first connected to the LAN. These sensors are:

- **Sleep sensor [2]**
  The Withing's Sleep Analyzer was chosen due to:
  - It allows us to capture sleep data through Withing API.

- It monitors the heart rate, respiration rate, sleep state and also has apnoea detection.
- It doesn't require other devices to run (only a wireless connection).
- It stores data on secure cloud positioned in the EU.

- **Fitbit Band Versa 2 [3]**
  The Fitbit band was chosen due to:
  - The possibility of creating apps (code) that can be inserted directly in the band. This allows to control the data flow.
  - It permits us to create a TeNDER scenario that includes only the band and the smartphone, skipping the pc.
  - It allows extracting raw measurements from the accelerometer which enables us to permit a procedure called re-association, which consists in matching the patient's band with the skeletons detected by the depth sensor, avoiding use of sensitive information while improving accuracy by using multiple modalities (skeletons, acceleration, patient's location).
- **Xiaomi Mi3 [4]**
  The Xiaomi Miband 3 was chosen due to:
  - Low price.
  - Water and dust resistance.
  - Long battery life.
  - Compatibility with the position tracker system.
  - It allows direct measurements transfer through Bluetooth (no cloud services are required).
- **Position tracker [5]**
  The position tracker main features are:
  - It connects directly to the local wireless connection (no additional device is required).
  - It measures the signal strength of all Bluetooth devices and sends it to the cloud.
  - Cloud is located in the EU.
  - Cloud supports API integration into the HeTra.

The rest of the sensors are connected using a USB port:

- **Kinect Azure [6]**
  The Kinect Azure was chosen due to:
  - Its ability to connect to the Mini-PC (Mini-PC light does not meet the Kinect Azure requirements).
  - Its ability to acquire RGB colour images and Depth images which are used to extract the skeleton using the body tracking SDK.
  - The skeleton data is sent to the TeNDER cloud.
  - In combination with Fitbit band and microphone we can detect fall detection.
  - In combination with Fitbit band, we can identify the skeleton.
- **Microphone [7]**
  - It may detect falls and emotions (happy, sad).
- **Kinect v02 [8]**
  The Kinect v02 was chosen due to:
  - Its ability to acquire RGB colour images and Depth images which are used to extract the skeleton using the body tracking SDK.
  - Using Kinect skeleton data, combined with data acquired from other sensors, can be used in order to detect human motion.

- Forwards / Backwards and left / right lean amount can also be employed in the loss of balance and fall down detection.

Sensors that are not ready due to various issues (technical or otherwise) and are therefore not used in the First wave of pilots are as follows:

- **Aqara Hub** – main features are:
  - It is used as a gateway for the Environmental sensor and the Binary sensor.
  - It connects to the local wireless connection.
  - The EU version of this device sends data by default to a Cloud located in the EU.
- **Environmental Sensor** - main features are:
  - It connects to the Aqara Hub.
  - It measures the temperature and humidity of the environment.
  - It sends the temperature and humidity of the environment to the TeNDER cloud.
- **Binary Sensor** - main features are:
  - It connects to the Aqara Hub.
  - When placed at the entrance door, windows or other objects (box/drawer with pills), it sends data on whether a door/window/object has been opened/closed.
- **Real-Sense** - main features are:
  - It connects to the Mini-PC or Mini-PC light.
  - It acquires RGB colour images and Depth images which are used to extract the skeleton using the body tracking module.
  - The skeleton data is sent to the TeNDER cloud.
  - This combined with Fitbit band and microphone, ca be used for fall detection.
  - This combined with Fitbit band, can be used to identify the skeleton.
  - Real-Sense requires the **body tracking module (for Real-Sense)**
- **Speaker** main features are:
  - It connects to the Mini-PC or Mini-PC light.
  - This provides vocal reminder and suggestions to users (primary users)

3.2.2.1 Software installation Procedure

Any system that aims to large scale deployments, such as the TeNDER does, it should provide an automated installation process of the software and also a monitoring mechanism in order to collect performance information from the local pilot sites. The above-mentioned features are very crucial for the users because they simplify the installation and validation procedures and at the same time require less involvement from the end-users. So, the end users can easily install the required software tools by executing automated scripts and at the end of the process can easily verify the operational status of the new services and the connection with the cloud infrastructure. So, TeNDER system provides the appropriate tools that perform the automated installation of the software in the mini-pcs deployed in pilot sites. In the rest of this section, we provide brief description of the installation process regarding the mini-PCs. The necessary prerequisites are the existence of a PC running an updated version of Windows 10 operating system (Professional, Enterprise, Education (Build 17134 or higher), Home (build 1903 or higher)) and of course internet connection. After we

ensure the existence of the pc, the all procedure can be completed by executing two scripts that are provided from an especial created code repository[1] in TeNDER's private GitLab instance.

3.2.2.2 Dependences Installation

The services that are part of the TeNDER system require some specific software (tools, libraries, frameworks etc.). The installation can be a challenging process for users who are not familiar with the design details of the platform. For this reason, TeNDER provides an automated script[2] which installs all the necessary software with the execution of one command. This software includes libraries, frameworks, tools (ex. Kinect Runtime, Docker Desktop, git etc.). After the end of the installation process a system restart is needed.

3.2.2.3 TeNDER software Installation

During the previous phase we prepared the mini-PC, in order to run the TeNDER services which are going to install now. The main components of the TeNDER system are the HeTRA server which runs on Windows 10 env, the data summarization service, abnormal detection service and the local database which run as docker containers. So, the second installation script[3] performs the following actions a) downloads the executable files of the HeTRA implementation b) downloads the docker images from the Docker Hub c) initiates all the services and d) creates a periodic job which check the operational status of the services and in case of a failure restarts service and also reports the current states to the TeNDER monitoring server.

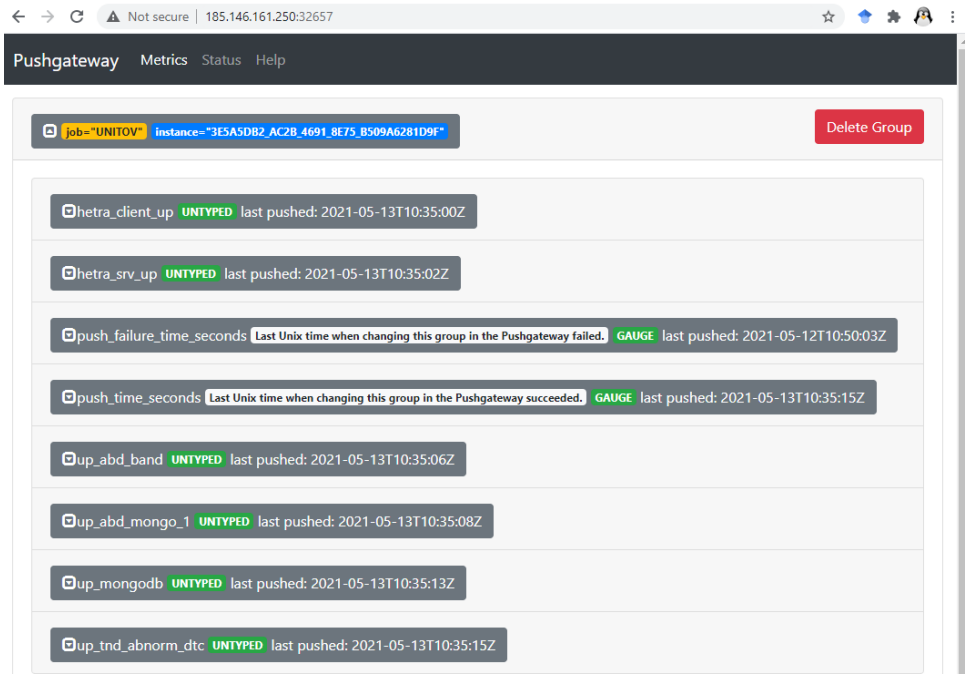

Figure 1 . Current operational state of the deployed services in pilot sites

3.2.3 Recruitment of users and general usage of devices

[1] https://tendergitlab.maggiolicloud.it/panos_k/tnd-install
[2] https://tendergitlab.maggiolicloud.it/panos_k/tnd-install/blob/master/install-pre.bat
[3] https://tendergitlab.maggiolicloud.it/panos_k/tnd-install/blob/master/install.bat

The overview of stakeholders recruited is described in Tab.5 (patients), Tab.6 (caregivers), Tab.7 (professionals). In addition, the Tab.5 reports the overview of the general usage of devices in the patient group.

CHARACTERISTICS		DISEASE			
		Total	AD	CVD	PD
Total	**N= 64**	31 %	17 %	52 %	
Age Mean (±SD)	69 (±10.72)	71 (±12.8)	71 (±8.9)	66 (±9.7)	
Sex					
MALE		35	20 %	17 %	63 %
FEMALE		29	45%	17%	38%
OTHER		0	-	-	-
Number of devices used					
FITBIT		37	24%	24 %	52 %
WHITINGS SLEEP SENSOR		22	68%	32%	N/A
KINECT AZURE		1	-	-	100 %
XIAOMI BAND		7	100 %	-	-
MICROPHONE		9	100 %	-	-
POSITION TRACKER		16	100 %	-	-
Kinect 2	1	-	-	100 %	
Daily hours of use Mean (±SD)					
FITBIT		18.5 (±8.67)	22.1 (±7.3)	21.5 (±8.1)	11.9 (±7.2)
WHITINGS SLEEP SENSOR		17.7 (±9.8)	16.8 (±10.5)	19.5 (±8.8)	N/A
KINECT AZURE		0 (±N/A)	-	-	0 (±N/A)
XIAOMI BAND		21.1 (±8.7)	21.1 (±8.7)	-	-
MICROPHONE		16.8 (±11.9)	16.8 (±11.9)	-	-
POSITION TRACKER		18.6 (±12.1)	18.6 (±12.1)	-	-
KINECT 2		10.7 (±3.8)	-	-	10.7 (±3.8)

Table 6 . Current operational state of the deployed services in pilot sites in the interventional group in the First wave of Pilots (01/03/2021-18/05/2021)

CHARACTERISTICS		DISEASE		
	Total	AD	CVD	PD
Total	**N= 25**	31 %	17 %	52 %
Age Mean (±SD)	58 (±18.8)	71 (±12.8)	71 (±8.9)	66 (±9.7)
Sex				
Male	35	57%	29%	14%
Female	13	67 %	33 %	-
Other	1	-	-	-

Table 7 Caregivers involved in the First wave of Pilots (01/03/2021-18/05/2021)

CHARACTERISTICS OF USE		DISEASE		
	Total	AD	CVD	PD
Total	**N= 49**	52%	11%	37%
Age Mean (±SD)	44 (±11.15)	71 (±7.7)	73 (±8.6)	66 (±5.2)
Sex				
Male	14	40%	10%	50%
Female	35	67%	13%	20%
Other	0	-	-	-

Table 8 Professionals involved in the First wave of Pilots (01/03/2021-18/05/2021)

3. RISKS MANAGEMENT

This section includes a description of general risks management and measures applied for the pilots' activities and execution.
Besides the general approach adapted to all end user partners, this section describes also specific measures applied for the risk management in each Pilot.

4.1 Legal & ethical risk management in TeNDER pilots

The legal and ethical framework, applicable to TeNDER pilots, was described in D1.1 Fundamental Rights, Ethical and Legal Implications and Assessment (First Version), in more detail, and the impact of the pilots on fundamental rights will be issued in the First impact assessment (part of D1.4, which is due in M22). In this subsection, we will briefly repeat its main findings regarding two important aspects; the data protection challenges and biomedical ethics aspects of the first wave of pilots.

In the pilots, the data of patients and caregivers will be processed in order to develop an integrated care model. These data are considered personal data in the sense of the GDPR, insofar they fall under its scope of application.
The GDPR applies to processing of personal data. These notions are defined in Art. 4(1) and (2), respectively as: '**personal data**' means any information relating to an identified or identifiable natural person ('data subject'). '**Processing**' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.
In the TeNDER pilots, patients' health data will be processed. Due to their sensitivity and a higher impact on the data subject in case of a privacy breach, a stricter regime applies to processing of sensitive data. Their processing is not allowed unless restrictive criteria of art. 9 of the GDPR are met (such as processing with the explicit consent of the patient), and the regime may be further restricted by national legislation. '**Health data'** under the GDPR mean personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about their health status.
Various technologies, such as wearables and other sensorial devices and appliances, will be utilised in the pilots. The type of data that is currently intended to be collected includes identifying data (e.g.name, sex, age, place and date of birth, address, ID/social system number), geo-localisation data and data concerning health status. It is therefore safe to conclude that the data processed by the TeNDER project falls under the definition of personal data, and some under the definition of sensitive health data, and thereby will fall within the scope of the GDPR.
The partners involved in the pilots will be acting as either data controllers or data processors. **'Controller'** means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; **'processor'** is defined as a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.
The controller shoulders the burden of compliance with the obligations under the GDPR – it is responsible for and must be able to demonstrate compliance with data quality principles, as

specified in art. 5 of the GDPR, inter alia the purpose limitation, data minimisation and accuracy principles. Moreover, the controller is obliged to implement appropriate technical and organisational measures to ensure and to be able to demonstrate that processing is performed in accordance with the rules of the GDPR, according to its art. 24. The processor carries out the processing under the authority of the controller and is not allowed to deviate from the controller's instructions unless required to do so under national or European Union law.

In the pilot's context, the user partners are acting as controllers and the technical partners as processors; therefore, they have signed respective data sharing agreements, which in accordance with art. 28(3) of the GDPR, set out the subject-matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects and the obligations and rights of the controller.
Data processing must be based on valid legal grounds. As explained above, in case of processing sensitive data, explicit consent is required. The term explicit relates to the manner in which consent was expressed by the data subject and means that "the data subject must give an express statement of consent". Explicit consent may be obtained in writing as well as digitally and orally. However, like with consent, the controller has a duty to demonstrate consent was obtained. For that reason, documenting consent in writing holds clear benefits and TeNDER partners have obtained written consent from all the patients involved.

The right to data protection will be fully respected in trials. To this end, the consortium has taken steps to respect applicable legal and ethical frameworks, and several measures regarding the treatment of personal data have been adopted by the consortium partners. More specifically, our approach has been three-pronged:

1. **Definition of applicable framework in D1.1 Fundamental Rights, Ethical and Legal Implications and Assessment** (First Version): applicable legal and ethical frameworks, such as the GDPR, elemental principles of biomedical ethics, and regulation of medical devices. Based on our analysis, we defined the fundamental obligations of pilot partners vis-à-vis patients on protection of personal data, involvement of participants in pilots, ethical and social aspects, and safety requirements of medical devices deployed. Further, ethics compliance was demonstrated by our work in WP10.

2. **Support for pilot set-up and execution**: based on findings from step one, informed consent forms and information sheets for participants were drawn up. In this way, the consortium sought to fulfil the requirements of art. 13 and 14 of the GDPR and ensure the autonomy and informed consent as the fundamental principles of biomedical ethics. Data sharing agreements were circulated and signed by partners involved in specific trials, taking into account the roles of controllers and processors.

3. **Impact assessment and continuous legal and ethical monitoring:** in the impact assessment, we take into account the nature, scope, context and purposes of the processing in the TeNDER pilots in order to ascertain risks to the fundamental rights and freedoms of patients involved. The first impact assessment was carried out before the first wave of the pilots, and reflects the consortium's risk assessment and risk response based on the current technical

development. Our findings will be reported in the D1.4 First legal/ethical monitoring report, due in M22.

4.2 Technical support in the First wave of Pilots

The consortium defined a partner responsible for the technical support during the piloting in each pilot sites (table), in order to handle the technical aspects related to the first wave of pilots and to support the end-user partners during the piloting (especially during the installation, monitoring, configuration and integration of devices, and deinstallation phases).

PILOT	END-USER PARTNER	PARTNER RESPONSIBLE FOR TECHNICAL SUPPORT
1	SERMAS	UPM
2	APM	UPM
3	UNITOV	DW
4	SKBA	CERTH
5	SPO	ELG

Table 9 Technical responsibility for each Pilot site

In addition, in order to minimize the risk of failure during the installation and integration of devices procedure, the consortium elaborated a tool named “Issue Tracker”, available for all researchers in TeNDER sharing and coworking platform. Issue Tracker allows prompt notifications addressed to partner involved in specific tasks: this tool was created in order to optimize and speed-up communication and coworking between partners, especially between end users' partners and technical partners during the piloting. In particular, this tool allowed a quick resolution of issues raised during the piloting. Issue tracker notify all activities required to respective partners, classifying them based on priority. In addition, Issue tracker allows an overview of calendarization and planning of the activities.

An important aspect related to the piloting phase is the COVID-19 pandemic and the impact of restrictions and safety measures during the piloting. The protocol concerning the safety measures to reduce transmission of COVID-19 was already described in D6.1, but it will be implemented throughout the entire project. In fact, both European and national directives are subject to changes based on changes of circumstances regarding COVID-19 transmission in each country. The safety measures for COVID-19 are also subordinated to national governments and local rules, depending on the typologies of facility. Therefore, the COVID-19 impact and related safety measures are different and described in each pilot section.

4.3 Risk Management in Pilot 1

SERMAS leads the Pilot 1 and involves for the first wave the home scenario. During the design of the first wave, we encountered difficulties that we had to overcome. The main difficulties were to adapt our scenario and the characteristics of the internal organisation with the restrictions of covid 19 and the security measures for the development of the first wave.

4.3.1 Covid19 pandemic impact and safety measures

The internal organisation of SERMAS implies involving professionals from primary care offices. In this way, professionals will play a role as stakeholders and as collaborative researchers to recruit patients for the development of the project. With this in mind, the challenge at our site was to create a covid free distance training platform for professionals to gain knowledge of the project. Below you can find the Figure 2, image of the platform where professionals could access all the contents related to the project (bibliography on the use of technology and health, public access to the TeNDER website and twitter account, research book adapted to SERMAS, videos on the technology to be used). We also had several meetings by video call to present the training platform to all the professionals involved and we created a forum and an e-mail address to resolve any doubts and questions that might arise. Through this training platform as collaborative researchers, professionals get an accreditation that allows them to start recruiting patients and carers.

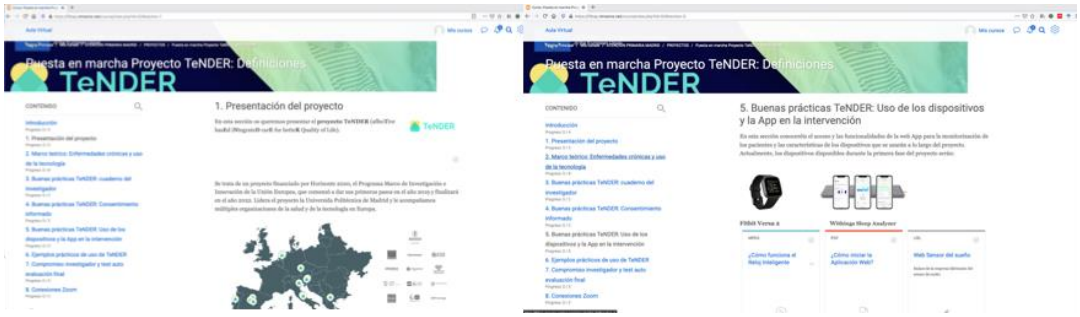

Figure 2 Image related to professionals training platform from SERMAS

For patient recruitment, potential users were selected from the primary care offices of the professionals involved and researchers contacted them by telephone.

The interview and device installation were conducted individually in the office and to avoid overcrowding of the room, technical colleagues were contacted by phone or video call during the device installation process. For access to the primary care centre, we created selected access routes to avoid unwanted contacts. We also offered patients the possibility to conduct the interview by phone call, but all preferred face-to-face (to avoid hearing loss and misunderstandings) and also the possibility to come to their home with all the security measures defined by our local and national government.

In all cases, safety measures such as the use of face masks and water-alcohol are mandatory. We also avoid and delay all visits in case the patient, caregivers or researchers have symptoms suggestive of coronavirus even if the test is negative or close contacts are positive.

4.4 Risk Management in Pilot 2

APM is leading Pilot 2 and during the first wave the most difficult challenge to overcome was to adapt our scenario to the health situation resulting from the Covid-19 pandemic.

4.4.1 Covid19 pandemic impact and safety measures

APM was initially planned to have three different settings in this first wave: day care centre, rehabilitation room and home.
The health measures imposed in Spain and specifically in the Autonomous Community of Madrid led to the closure of the day care centre. Although the association has tried to reopen it on two occasions in recent months, the fear of our users of the pandemic has made it unfeasible to reopen it. We hope to be able to count on it in future waves.
With regard to the home scenario, home visits have remained prohibited in the Community of Madrid until the end of the state of alarm on 9 May 2021, as a result of this circumstance, the recruitment of patients involved in this scenario has been shifted to the final weeks of the pilot.
In the rehabilitation room it has been necessary to adapt the recruitment because the maintenance of safety distances makes it impossible for the camera sensors to capture more than two patients in each session, which has been a great logistical challenge as we have had to increase the number of therapy groups involved in the test.
In addition to these organisational adjustments APM has developed a detailed protocol of prevention measures, including increasing the distances between patients in the rehabilitation rooms, as well as the capacity of the whole centre. Similarly, waiting areas have been severely limited and the use of hydrogel and masks have been implemented, among other preventive measures.
The home visit scenario has a careful protocol to ensure that deployment is carried out under the best safety conditions.

4.5 Risk Management in Pilot 3

UNITOV leads the Pilot 3 that involves home and hospital scenarios. The most critical challenge is obviously related to the COVID-19 pandemic and its impact on the daily living that influences the piloting execution. The pandemic impact and the safety measures applied are described below.
In addition, further measures applied in Pilot 3 concerns an insurance contract regarding the eventual and potential damages to stakeholders involved in the project, that covers eventual damages to the stakeholder and to the stakeholder's properties (for example eventual damages during the home installation phase etc.) throughout all phases of the project.

4.5.1 COVID-19 pandemic impact and safety measures

In hospital scenario the compliance with AntiCOVID-19 national regulations defined by The Italian Ministry of Health was guarantee during the execution of the Pilots.
Then, each patient and caregiver underwent a triage assessment in which there is a section regarding COVID-19.
Also, technicians of DW that performed the installation of devices in hospital scenario underwent a triage assessment. The impact of the COVID-19 spreading in this setting regards mainly the reduced access of the patients to not emergency services and, therefore, there was an impact on the recruitment of patients (and caregivers).

The major impact of COVID-19 spreading concerning TeNDER in home setting regards the installation and uninstallation of devices in home scenario: UNITOV elaborated Safety measures guidelines for TeNDER home installation and deinstallation procedures, in accordance to DW. In particular, in order to follow these necessary guidelines, the timing of installations was significantly affected.

Guidelines prepared for UNITOV full home set installation:
"DW employees, patients and caregivers will need to follow and share the following safety measures:
- During the sensor installation and deinstallation procedures, the environment must be ventilated and the windows must be open.
- The home environment must be cleaned and disinfected
- The patient and the caregiver must maintain a safety distance of at least 2 meters from the DW employees. In addition, the patient and caregiver must be in a different room from that of the DW employees during the sensor installation and uninstallation procedures.
- DW employees will carry out a molecular test (using a nose-pharyngeal swab) to detect the presence of Sars-Cov-2 in the 72 hours prior to the installation and deinstallation procedures of the sensors at the home of the participants in the TeNDER project.
- During the procedures, DW employees will wear suitable protective equipment during the installation and deinstallation procedures of the sensors at the home of the TeNDER project participants (FFP2 mask, disposable gloves, visor) and will sanitize their hands with disinfectant gel.
- The patient and the caregiver will also wear suitable protective equipment during the installation and deinstallation procedures (FFP2 mask, disposable gloves) and will sanitize their hands.
- Patient and Caregiver will provide a declaration in which they self-certify that:
1) They are not positive for Covid19
2) They're not in quarantine
3) Have no suspicious symptoms for Covid19 (e.g. fever, cough, shortness of breath, chills, muscle aches, headache, sore throat, loss of smell or taste)
4) They had no contact with people who then tested positive for Covid19 in the previous two weeks."

4.6 Risk Management in Pilot 4

SKBA leads the Pilot 4 involving health professionals, patients with AD, CVD, and PD and their caregivers in the hospital setting. The central restrictions were caused by the COVID-19 pandemic. Beyond the constantly adapted safety measurements we had to work with a significantly smaller patient population. The number of in-patients was significantly reduced at the SKBA hospital in order to be able to fulfil safety regulations. Furthermore, during the first COVID-19 wave for several weeks it was allowed to contact patients for medical treatment only. During the third COVID-19 wave we had many post-COVID patients in neurological rehabilitation and therefore lesser patients with CVD or PD. At SKBA's Alzheimer's Therapy Centre a reduced number of bookings were recognised. Persons with AD and their caregivers are elder and belong to the high-risk group suffering more often from a severe course of COVID-19. Therefore, this person group is still avoiding to stay in institutions with increased contacts to others.

4.6.1 Covid19 pandemic impact and safety measures

SKBA strictly followed the Covid-19 regulations by the Robert Koch Institute[4]. Regarding vaccinations the instructions of the Paul Ehrlich Institute[5] were implemented. Furthermore,

[4] www.rki.de
[5] www.pei.de

additional regulations considering the specific circumstances and factors at SKBA as a hospital with highly vulnerable patients and performing scientific work were developed in close cooperation by internal hygiene experts. At SKBA the general situation regarding Covid-19 is constantly being evaluated. Possible risks are detected in regular meetings and respective actions are taken immediately, if necessary. This includes restriction of visits to the clinic (completely or partly), wearing a specific face mask at all times, washing hands/using disinfectants when entering the hospital area or when engaging with patients, and keeping safe distances to others. Professional masks or FFP2 masks without a filter are used according to the current guidelines and the recommendations of the hygiene experts at SKBA. Also, if possible, employees work in home-office to keep the contacts at the lowest possible level. Furthermore, general Covid-19 tests are required in specified intervals from each employee, in order to be able to work at the facility. All measures are adapted to the current COVID-19 situation on a daily basis. Material used during the contact will be disinfected according to a procedure approved from the hygiene experts. In case disinfection is not possible the material will be discarded.

At any time, all employees involved in the TeNDER project will follow the recommendations and guidelines to protect the patients' rights, safety, and wellbeing. In case a participant of the TeNDER trial cannot follow the safety and hygiene regulations and the medical project leader detects a risk increase, actions putting the respective person at risk will be stopped immediately.

Vaccination is offered to all employees of SKBA. To date (17.05.2021), all members of the TeNDER team had been vaccinated at least once.

4.7 Risk Management in Pilot 5

SPO leads the Pilot 5 that involves people with dementia and their carers from home environments and also at day care centres together with professionals. For the first Wave we encountered difficulties regarding the restrictions because of COVID-19, temporary total lockdown of the Republic of Slovenia and also day care centres closure. We have overcome the difficulties with recruiting the people with dementia and their caregivers at their home environment (when possible) and adapted the security measures for the first Wave (regarding distance, presence in the close environments, using safety equipment according to NIJZ protocols, see below).

4.7.1 Covid19 pandemic impact and safety measures

SPO follows protocol "SARS-CoV-2 Infection Control Plan (COVID-19) - protocols for the operation of institutional care providers", defined by government of Slovenia. The general measurements are adapted according to the change of the COVID-19 situation. No participant was met face to face and all the communication about TeNDER was held online at the beginning of April, due to the general lockdown announced form the government. Moreover, as up to week 18 there was still restriction of gathering in closed space defined with distance and square meters, the meetings with the participants were performed only one-on-one (or more if people were from the same family). Due to COVID-19 restrictions, day-care centres have been closed, therefore, SPO is including full-time care residents in home for elderlies as in home scenarios with sets for home environment, according to the COVID-19 epidemiologic situation. Both institutions that are having contract with SPO to participate with their residents in TeNDER testing have own protocols and follow the general guidance from NIJZ (National Institute of Public Health) and Slovenian Ministry of Health provisions

and general and institutional rules for mitigation of COVID-19 risk spreading. All the rules and guidance form Slovenian government, Ministry of Health, NIJZ and institution, where the testing takes place, are followed by researchers form SPO and supporting technical partner ELG.

5. OUTCOMES

OBJECTIVES AND KPIs

In order to achieve TeNDER's main goal, we have broken it into Specific, Measurable, Achievable, Relevant and Timebound (S.M.A.R.T) Objectives (S.O.) which target specific innovation areas.
The SMART Objective 9 (S.O. 9) "Conduct large scale pilots" aims to develop large scale pilots that will be conducted by TeNDER user partners (APM, SERMAS, SKBA, SPO and UNITOV) including patients, their caregivers and families, health and social professionals.

The KPIs directly linked to S.O. 9 are the following:

- Number of diseases: at least 3
- Number of pilot sites: at least 5
- Number of pilot users: at least +1500, with at least 735 patients (1030 if including the control group), at least 85 health professionals (physicians mainly), at least 30 social workers, at least 570, caregivers (professional and relatives) and 60 others (clerks, Hospital IT support, etc.)

Referring to the number of users, TeNDER consortium agreed to involve in the First wave of Pilots at least 20% of the total amount of stakeholders.

Further SOs and KPIs are linked to the execution of the waves of Pilots and, particularly, several KPIs will be assess in WP7.
The outcomes of the KPIs directly linked to the Data analysis of the Quality of Life (QoL) indicators will be reported in D7.3/5 (First and Final report on QoL assessment).

PILOT 1 (Madrid region, Spain)

Scenario

Home scenario

SERMAS primary care services provide patients to participate in the project. Patients are informed and recruited by their own primary care professionals involved in the TeNDER project. Once patients accepted to enjoy the project, they sign informed consent and arrange a meeting for the interview and device installation.

Users involved in the First wave of Pilot 1 (01/03/2021-18/05/2021)

SERMAS has included a total of 4 patients (until 14/05/2021) in the home scenario. In the last week (10/5/2021), 25 professionals were recruited and included to the TeNDER project. Until the end of the first wave, by increasing the number of professionals we hope to increase rapidly the number of patients recruited. Patients included in the first wave will be mainly those with cardiovascular diseases.

Characteristics	Participants Involved				
Total N=36	Professionals (28)	Caregivers (4)	Patients (4)		
	Physician: 25(89%) Nurses: 3(2%)		AD (0)	CVD 4(100%)	PD (0
Age Mean (±SD)	46.2 (±12.2)	53,2 (±20.3)		70 (±2.2)	
Sex					
Male	6(2. 4%)	1(25%)	-	2 (50%)	-
Female	22(78.6%)	3(75%)	-	2 (50%)	-
Other	-		-	-	-
Stakeholders screened, but not included	-	3	-	3	-
Dropouts	-	-	-	-	-

Table 10 Participants involved in Pilot 1 (01/03/2021-18/05/2021)

Devices assigned and functionalities tested

SERMAS received support from UPM remotely.

The devices that are being tested in patients:

- Fitbit Versa + smartphone/tablet (in case of patient's personal smartphone was not compatible with TeNDER) for the patient;
- Smartphone/tablet for the caregiver (in case of caregiver's personal smartphone was not compatible with TeNDER)

The functionalities to be tested:

- Health state
- Nocturnal activities

Patients and caregivers are able to access to the information related to this functional through the TeNDER App and professionals through the TeNDER WebApp.

Next steps for the First wave (19/05/2021-31/07/2021)

- To include sleep sensor.
- To include a miniPC for data processing.

Discrepancies with planned protocols, mitigation and integration plans

Due to COVID-19 restrictions was decided to avoid using Position trackers as it was planned. The installation of this sensor involves the entry of multiple people into the patient's home that could generate rejection to the project development. Because of this the activity and room localization functionality will not be available.

PILOT 2 (Madrid city, Spain)

Scenarios

Rehabilitation Room

Rehabilitation Room scenario has been performed at APM Center (Poeta Esteban Villegas 12, Madrid) It was planned to include patients attending group physiotherapy.
In this scenario the Kinect camera and the fit bit bracelet were tested.
During the session the camera records the movement of the participating patients (in this first wave, the system recognises a total of 14 exercises) so that the degrees of movement, the number of repetitions and the time taken to perform the movements can be analysed. In addition, the bracelet is able to collect heart rate and step data during the session.

Home set

For the first wave, two types of home scenario are planned. The first involves the use of the fit bit bracelet and the mobile app, while the second type also includes the sleep tracker sensor.

Users involved in the First wave of Pilot 2 (01/03/2021-18/05/2021)

APM has included in this first wave a total of 27 patients in the rehabilitation room and by the end of this wave will have completed 5 home sets (two of which will include a sleep tracker). Also, APM has included 8 professionals.
APM has planned to include 27 caregivers

To date, all stakeholders included (with the exception of dropouts) are still in the monitoring phase.

Characteristics	**Participants Involved**		
Total N= 35	Professionals (8)	Caregivers (0)	Patients (27)
	Speech therapists: 1 (12.5%) Physiotherapists: 6 (75%) Psychologists: 1 (12.5%)		PD 27 (100%)
Age Mean (±SD)	35 (± 6,9)	-	69,77 (± 7,13)
Sex			
Male	3(37, 5 %)	-	17(63 %)
Female	5(62, 5%)	-	10(37%)
Other	-		-
Stakeholders screened, but not included	-	5	3
Dropouts	-	-	1

Table 11 Participants involved in Pilot 2 (01/03/2021-18/05/2021)

Devices assigned and functionalities tested

APM received technical support from UPM for the installation of the devices.

Rehabilitation room scenario

- Kinect 2 camera
- Fit bit Versa 2 + Smartphone
- High PC installed in APM rehabilitation room

Home set scenario

- Fit bit Versa 2 + Smartphone
- Sleep tracker

The functionalities to be tested:

- Health state
- Nocturnal activities

Next steps for the First wave (19/05/2021-31/07/2021)

- To include sleep sensor in 2 home sets.
- Recruitment of carers

Discrepancies with planned protocols, mitigation and integration plans

Due to the COVID-19 health crisis, APM has been forced to adapt its test scenarios. The lockdown initiated in March 2020 in Spain and the continuous restrictions to which we have been subjected up to now have led to the closure of the day care centre. There is still no date foreseen for its reopening, which is why in this first wave this scenario has been suppressed in Pilot 2.
Likewise, the Community of Madrid has maintained the ban on home visits, due to this situation, APM started the pilots exclusively in the rehabilitation room. On 9 May, with the lifting of the state of alarm, these visits were once again permitted, and it is from then on that this scenario is planned to be included.
In addition, as a consequence of the health measures for the prevention of COVID-19, the interpersonal distance must be at least 1.5 metres between people, for this reason the kinect camera is only able to collect a maximum of 2 patients per group, when under normal conditions it would include 3.
In addition, due to different situations, the sensors included in this first round of testing have been reduced, so that the scenarios have been simplified.

PILOT 3 (Rome, Italy)

Scenarios

Hospital and home scenarios
The hospital scenario has been performed at SLUCIA (Fondazione Santa Lucia IRCCS, Via Ardeatina 306-354, 00179, Rome, Italy) on the responsibility of UNITOV (University of Rome “Tor Vergata”).

Santa Lucia Foundation is a landmark institution in the field of highly specialized neurorehabilitation. Strong related health cares and research build its core activities. Neurorehabilitation programs affects patient with both, motor and cognitive deficits. Health services are provided under an agreement with the National Health Service (SSN) and also on a private patient basis[6].
The hospital setting that has been evaluated for the Pilot 3 is the neurological practice for non-hospitalized patients: day-hospital, neurological examinations, routinely evaluations according to clinical practice.
UNITOV team planned to involve patients and caregivers by providing a system that can be used and tested both in hospital scenario and in home scenario. Therefore, all users involved in the First wave of Pilot 3 tested the TeNDER system sets both in hospital scenario and in home scenario.

Users involved in the First wave of Pilot 3 (01/03/2021-18/05/2021)

UNITOV team included in the Pilot, for each patient, the respective caregiver (all informal).
We reported data from 10 Fitbit sets but we had 2 dropouts (1 patient and the respective caregiver) after only 1 week of monitoring.
Hence, we are collecting data from 9 Fitbit sets both in Hospital and in home scenarios, with an active involvement of 9 patients, 9 caregivers and 8 Health professionals.

Characteristics	**Participants Involved**			
	Professionals (8)	Caregivers (10)	Patients (10)	
Total N=28	Physicians: 4 (50%) Psychologists: 4 (50%)		AD 5 (50%)	PD 5 (50%)
Age Mean (±SD)	34 (± 5.2)	49.9 (± 15.2)	70.5 (± 7.2)	
Sex				
Male	2(25%)	2(20%)	7(70%)	
Female	6(75%)	8(80%)	3(30%)	
Other	-		-	
Stakeholders screened, but not included	-	5	5	
Dropouts	-	1	1	

Table 12 Participants involved in Pilot 3 (01/03/2021-18/05/2021)

Devices assigned and functionalities tested

The installation and deinstallation procedures were performed by UNITOV with the support of DW.

[6] https://www.hsantalucia.it/en/hospital

Fitbit set:

- Fitbit Versa 02 + smartphone/tablet (in case of patient's personal smartphone was not compatible with TeNDER) for the patient;
- Smartphone/tablet for the caregiver (in case of caregiver's personal smartphone was not compatible with TeNDER)
- Mini PC low-end installed at SLUCIA hospital

9 Fitbit delivered
5 Smartphones delivered
3 Tablets delivered
1 Mini PC low-end installed
9 Fitbit sets installed

The functionalities tested by using Fitbit sets are **Health tracking** and **Reminders** tested by 9 patients, 9 caregivers, 8 professionals.

Next steps for the First wave (19/05/2021-31/07/2021)

- 6 Fitbit sets will be installed on 19/05/2021

- From 1 to 4 UNITOV's home set will be installed in June 2021.

UNITOV's home set consists in:

- Fitbit Versa 02 + smartphone/tablet (in case of patient's personal smartphone was not compatible with TeNDER) for the patient;
- Smartphone/tablet for the caregiver (in case of caregiver's personal smartphone was not compatible with TeNDER)
- Microphone
- Withings Sleep Analyzer
- Mini PC low-end
- Position trackers

Discrepancies with planned protocols, mitigation and integration plans

As described above in Section 3, some sensors were not ready for the first wave of Pilots due to various issues. Therefore, according to the technologies assigned for UNITOV's First wave of Pilots in D6.1, binary sensors, environmental sensors, Aqara Hub, and Speaker are missing in the First wave of Pilot 3 due to technical readiness. In addition, the Real Sense cameras (purchased for the UNITOV's home set) were not ready for the integration in TeNDER system, as mentioned in the Section 3.
The Kinect Azure and the devices listed in this section will be installed and integrated in the Second wave of Pilot 3, according to technical developments.

PILOT 4 (Bavaria, Germany)

Scenario

Hospital scenario

The Schön Clinic hospital in Bad Aibling (Kolbermoorer Str. 72, 83043 Bad Aibling, Germany[7] and the Alzheimer's Therapy Center of the hospital were the settings of the SKBA pilot scenarios. The pilot has been conducted under the responsibility of SKBA.

Users involved in the First wave of Pilot 4 (01/03/2021-18/05/2021)

Users involved for the 1st wave of piloting at Pilot site 4 were patients hospitalised at Schön Clinic Bad Aibling, either in the main hospital or in the Alzheimer's Therapy Center. Patients with AD, CVD and PD were included, as well as informal caregivers (family members) of AD patients.

- 14 Patients (68.57 ± 10.34), (Male 42.86%, Female 57.14%), (AD 42.86%, PD 7.14%, CVD 50%)
- 6 Caregivers (69.5 ± 8.94), (Male 83.33%, Female 16.67%), (AD 100%, PD 0%, CVD 0%)
- 1 Professional (64 ± 0), (Male 100%, Female 0%), (AD 45.45%, PD 0%, CVD 54.55%)
- 36 stakeholders screened, but not included (Patients 61.11%, caregivers 38.89%)
- 0 dropouts

Characteristics	**Participants Involved**				
Total N= 19	Professionals (1)	Caregivers (6)	Patients (14)		
	Physician 1(100%)		AD 6 (42.86%)	CVD 7 (50%)	PD 1 (7.14%)
Age Mean (±SD)	64(±0)	71 (±12.8)	68.57 (±10.3)		
Sex					
Male	1(100%)	5 (83.33%)	6 (42.86%)		
Female	-	1 (6.67%)	8 (57.14%)		
Other	-	-	-		
Stakeholders screened, but not included	-	14	22		
Dropouts	-	-	-	-	-

7 patients and 2 caregivers finalized the testing due to dismissal of the clinic.

[7] www.schoen-klinik.de/bad-aibling-harthausen

Devices assigned and functionalities tested

Installation and deinstallation of devices have been performed by researchers of SKBA with the (virtual) support of CERTH. The following devices were installed at the hospital setting:

Hospital scenario for 1st wave of piloting:

- Fitbit versa 2
- Withings Sleep Analyzer
- Smartphone or Tablet
- App with reminders, notifications and reports

Data of all participants was gathered via a local Mini PC at SBKA pilot site. On average, patients and caregivers were using the TeNDER-system at the SKBA hospital and Alzheimer's Therapy Centre for two to three weeks.

The functionalities tested included Health tracking (e.g.heartbeat, steps) and monitoring of sleep quality (e.g duration and depth). Collected data was visualized via the TeNDER-App for patients and caregivers on provided smartphones and tablets. Professionals were able to access the collected data of respective patients via the TeNDER-Web-Application.

Next steps for the First wave (19/05/2021-31/07/2021)

Completion of recruitment of health professionals, patients and caregivers.

Discrepancies with planned protocols, mitigation and integration plans

According to the planned protocol in Deliverable 6.1, speaker functionality for virtual assistance was not tested. Furthermore, microphone and kinect azure were not tested, as it could not be ensured that only patient data was collected and not also data from other persons in the room.

PILOT 5 (Slovenia)

Scenario

Home environment and day care centres

During the 1st wave SPO is recruiting patients with dementia, their family members /or informal caregivers at their home environments. They are invited to test the wristband together with localization sensor, sleep-analyser, microphone for general emotional report in the environment and fall detection, and altogether processed locally on Mini-PC with the initial TeNDER system. SPO is also including professionals to express their views about the TeNDER system reports. SPO invites all participants to provide valuable feedbacks, their opinion, experience, suggestions, and also express their rights on how they want to use the system. Researchers from SPO and corresponding ELG technical partners are following the rules from National Institute of Public Health and Ministry of Health to ensure safety regarding COVID-19.

Users involved in the First wave of Pilot 5 (01/03/2021-18/05/2021)

Users involved for the 1st wave of piloting in Pilot 5 site are in home set environment: patients with dementia and their carers (family members or informal caregivers that are not in relation with a person with dementia, but are providing support and care, according to the inclusion criteria) or formal caregivers, and the professionals.

Characteristics	**Participants Involved**		
	Professionals (4)	Caregivers (5)	Patients (9)
Total N=18	Nurses: 2 (50%) Social worker: 2 (50%)		AD 9 (100%)
Age Mean (±SD)	35 (± 8)	54.2 (± 23)	77.9 (± 8.2)
Sex			
Male	-	2 (40%)	3(33%)
Female	4(100%)	3 (60%)	6(67%)
Other	-		-
Stakeholders screened, but not included	-	3	6
Dropouts	-	-	-

Table 13 Participants involved in Pilot 5 (01/03/2021-18/05/2021)

Devices assigned and functionalities tested

The installation and deinstallation procedures are performed by SPO and ELG members.

Home set scenario set for the 1st wave of piloting

- Mini-PC
- Xiaomi Mi Band (wristband)
- Localization sensors
- Smartphone and/or Tablet
- Withings sleep analyser
- ReSpeaker Mic Array v2.0 (microphone)
- TeNDER App for smartphone / tablet with reminders, reports, notifications
- TeNDER WebApp for professionals

Each primary user (participant as a patient) has its own set, data collected and summarised on the Mini-PC locally.

Devices assigned in the 1st Wave of piloting for Pilot 5 site are as reported in Deliverable 6.1 with exemption for the Speaker that is not used in the 1st Wave of piloting as described in Section "Devices installed and system Integration" of this document. The participants included in the Pilot 5 site are testing the following functions: calendar with notifications, quality of sleep reports, general emotional state recognition events/reports, room level localization and apartment level localization, apartment presence, physical activity.

Next steps for the First wave (19/05/2021-31/07/2021)

During the first Wave we are including patients with dementia with their caregivers in home environments, and plan to include participants also in day care centres environments when open. The next step is to include additional couples of patients with dementia and carers, and also more professionals from health and social care sector to provide feedback on the interfaces and TeNDER services in order to enhance the integrated care model development. The next step is also to continue with engagement of all participants in co-design with the emphasis on service development.

Discrepancies with planned protocols, mitigation and integration plans

According to the planned protocol in Deliverable 6.1, no participant has been included in day-care centres (due to COVID-19 and closure of the centres) so far and speaker functionality for virtual assistance was not tested. As a mitigation measure due to COVID-19 epidemic, shorter time of patient inclusion is foreseen for the 1st wave of the pilots according to set timeline. Moreover, functionality testing is performed as justified in Section "Devices installed and system Integration" of this document and will continue with testing of the proposed functionalities accordingly.

6. CONCLUSIONS

An overview of results obtained in the First wave of Pilots (until 18/05/21) is reported in Tab. 14. The KPI related to the number of diseases has been achieved. In fact, TeNDER system has been tested in three groups of diseases (AD, PD, CVD).
In addition, 5 Pilot sites have been involved in TeNDER testing phase, as described in this report.
The First wave of Pilots is still ongoing and the TeNDER consortium aims to reach the number of stakeholders expected for the First wave of Pilots (20% of the stakeholders involved in the entire project).
However, the technical issues that the consortium has experienced, influenced in particular the readiness of functionalities expected for caregivers (for example the delay in releasing of TeNDER App). Therefore, we foresee a reduction of the number of caregivers enrolled in the First wave of Pilots.
The final version of the Report on first wave of Pilots will be submitted in a second version of the Deliverable 6.2 after the conclusion of the First wave of Pilots, in M21.

KPI	Achievement	Comments
Number of diseases: at least 3	YES	TeNDER has been tested on AD, PD and CVD patients
Number of pilot sites: at least 5	YES	TeNDER has been tested in 5 pilot sites
Number of pilot users in the entire project: at least +1500	- 8.7% of patients expected in the entire project - 4.4% of caregivers expected in the entire project - 28% of professionals expected in the entire project	The foreseen number of stakeholders in the First wave of Pilots is 20%.

Table 14 KPI Gains in the First wave of Pilots - Intermediate Report (01/03/21-18/05/21)