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


# Deliverable 1.3
# Evaluation Strategy and Protocols

Work Package 1: Data Protection, Ethical Impact and Interoperability

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

**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 personalised & outcome based integrated care

**Funding Scheme:** IA - Innovation action

# Disclaimer



The TeNDER consortium consists of the following Partners.

*Table 1 - Consortium Partners List*

| 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 |

# Document Information

| | |
|---|---|
| **Project short name and Grant Agreement ID** | TeNDER (875325) |
| **Work package** | WP 1 |
| **Deliverable number** | D1.3 |
| **Deliverable title** | evaluation Strategy and Protocols |
| **Responsible beneficiary** | SPO |
| **Involved beneficiaries** | ELG, VUB, SKBA, APM, UNITOV, SERMAS |
| **Type**[1] | R |
| **Dissemination level**[2] | PU |
| **Contractual date of delivery** | 31 January 2021 |
| **Last update** | 7 January 2021 |

[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).

# Document History

| Version | Date | Status | Authors, Reviewers | Description |
|---|---|---|---|---|
| v 0.1 | 01/12/2020 | Draft | SPO (Špela Glišović Krivec) | Table of Contents |
| V 0.2 | 14/12/2020 | Draft | SPO (Špela Glišović Krivec, David Krivec) | Input in Sections |
| V0.3 | 30/12/2020 | Draft | SPO (Špela Glišović Krivec, David Krivec) | Input in Sections incorporating TeNDER partners` comments, and elaboration on section 2.2 for pilot evaluation |
| V0.4 | 4/01/2021 | Draft | SPO (Špela Glišović Krivec, David Krivec) | Inputs in Evaluation for piloting, Methods, Indicators in Annexes A-E |
| V0.5 | 5/01/2021 | Draft | SPO (Špela Glišović Krivec) | Incorporating partners comments and changes |
| V0.6 | 5/01/2021 | Draft | SKBA (Barbara Schäpers, Martina Steinböck) | Comments, inputs in text and suggestions |
| V0.7 | 7/01/2021 | Draft | SERMAS (Cristina Maria Lozano Hernández) | Comments |
| V0.8 | 7/01/2021 | Draft | SPO (Špela Glišović Krivec, David Krivec) | Incorporating partners comments and changes |
| V0.9 | 8/01/2021 | Draft | APM (Laura Carrasco) | Comments and annexes |
| V10.0 | 9/01/2021 | Draft | SPO (Špela Glišović Krivec, David Krivec)) | Incorporating changes, Inputs and comments, and preparation for the final version |
| V11.0 | 15/01/2021 | Draft for peer review | SPO (Špela Glišović Krivec) | General review and incorporating changes from all partners |
| V12.0 | 27/01/2021 | First peer review | VUB (Paul Quinn) | Peer review |
| V13.0 | 29/01/2021 | Second peer review | UPM (Annelore Hermann) | Comments on organisation, language and content |
| V14.0 | 29/01/2021 | Final version | SPO (Špela Glišović Krivec, David Krivec) | General review |

# Acronyms and Abbreviations

| Acronym/Abbreviation | Description |
|---|---|
| EC | European Commission |
| EU | European Union |
| TeNDER | affecTive basEd iNtegrateD carE for betteR Quality of Life |
| WPx | Work Package |
| Tx.x | Task |
| QoL | Quality of Life |
| AD | Alzheimer's Disease |
| PD | Parkinson's Disease |
| CVD | Cardiovascular Disease |
| WHO | World Health Organization |

# Contents

# List of Figures



# List of Tables

# Executive Summary

TeNDER is a multi-sectoral project funded by Horizon 2020, the EU Framework Programme for Research and Innovation. We will develop an integrated care model to manage patients with chronic diseases as Alzheimer's, Parkinson's, Cardiovascular Diseases, and, where present, comorbidities, and other people that surround them. TeNDER aims also to help patient`s family and others in their care pathway by addressing difficulties experienced in independent living and their care arrangements. We will be able to recognize the affective state of a person by using affective based micro tools, and by this adapt the system's probes to the person's needs via a multi-sensorial system. Further on, by matching clinical and clerical patient information, while preserving privacy, monitoring the ethical principles, providing data protection and security, we expect the result of an increased QoL.

The tasks under WP1 of the TeNDER project will ensure that the TeNDER ecosystem is developed in line with the relevant rules and regulations in terms of data privacy, security, integrity and interoperability.

Herein we describe how TeNDER will address the user-oriented and professional-driven approach, and the protocols that are accepted to assess and reach the goal of the project. Following project Objective 2, continuous ethical monitoring will influence project results over the course of the various activities in order to guarantee access, privacy and security. To address this topic properly, a plan for user selections procedure, piloting scenarios, methods, time plan, risks planning and mitigation described in this Deliverable will allow to link all developments with the project objectives. In each of the countries involved, partners perform face-to-face interviews with a representative sample of users for the targeted diseases and the professionals. The measures that will be taken to monitor the evolvement of the tools are presented in Section 2 and strategies for protocols are provided in Annexes of the document. Evaluation of specific areas will be performed and described within dedicated Work packages. Findings on user-oriented and professional-driven evaluation are summarised in three internal Reports.

# 1. INTRODUCTION

## 1.1 PURPOSE AND SCOPE

EU is facing the healthcare challenges due to rising of chronic diseases. Integrated care approach has been shown to optimize the patient's treatment, time management, resources used and QoL [1] by approaching patient's care as a continuous process with multiple interconnected components. This approach can significantly alleviate the load to the care system and produce improved results with regard to the patient's welfare [2].

The TeNDER project creates solution for people with chronic diseases of Alzheimer's, Parkinson's and cardiovascular diseases, and – where present – comorbidities, through the use of affective based micro tools and with creating an integrated care ecosystem.

Partners of the TeNDER consortium have started identifying and validating the users' requirements with regard to the technology acceptance and different functionalities that are being developed and integrated, allowing data from different devices to be merged into the TeNDER ICT system. The selected devices are off the shelve, already on the EU market. Functionalities that will be provided for testing over the second and third years of TeNDER implementation are described in Deliverable 2.3, WP02.

The user centred approach and professional driven approach, together with the co-design methods put in place by TeNDER multidisciplinary teams will further on be reached by gathering additional feedbacks on usability, satisfaction and efficiency of TeNDER system. The interviews that being held for the first phase of piloting were assessed in Report 1 *Evaluation Strategy and Protocols,* WP01. The second report under this task will focus on the interviews in the second phase (first wave of piloting), and the last report will summarize the findings in the second wave of piloting. In that way, we will collect overall user feedback of all phases of the development of TeNDER.

The purpose of the evaluation described in this Document is to analyse the partners' detailed planning where evaluation strategy and protocols are made explicit. The goal is to describe the methodology adopted by TeNDER consortium required to assess how well the strategies are able to achieve the goals of the TeNDER Project, always taking into account the user needs. The evaluation of the users' needs is assessed in co-design process and interviews performed with all stakeholders that are reported and summarized findings presented in Report 1 *Evaluation Strategy and Protocols* will be assessed further on during the project. The impact of the system will be assessed by surveys and interviews, but also from an ethical perspective and evaluated in Report 2 and 3 *Evaluation Strategy and Protocols*.

## 1.2 CONTRIBUTION TO OTHER DELIVERABLES

The present deliverable will contribute to the upcoming Deliverables under several WPs: WP01 (D1.4 First version Legal/Ethical Monitoring and Review), WP02 (D2.4 and D2.5 User Requirements and Data Model), WP04 (D4.4 Personalised interactions and safety perception), WP05 (D5.4 First version of TeNDER Platform and D5.5 Final version of TeNDER Services), WP06 (D6.2 Report on First wave of Pilot, D6.3 Report on Iterative testing and Results gathering, D6.4 Report on second wave of Pilots and D6.5 Final Report on large scale Pilots), WP07 (D7.3 and D7.5 Report on QoL Assessment), WP08 (D8.11 report on Communication and Standardization Activities, D8.12 Report on Business Modelling).

Moreover, through these measures, an important contribution to other first and intermediate technical deliverables will follow and will be used for the TeNDER system development.

## 1.3 STRUCTURE OF THE DOCUMENT

The Deliverable 1.3 is structured into six main sections: the presentation of the document (introduction), TeNDER evaluation section, section with describing the plan of user selection and recruitment, methods, time plan and risk and mitigation. The document also contains annexes, that will help partners to evaluate the ethical approach, provide the researchers the main topics to address when interviewing the participants and also the main points that shall be taken into account for the independent assessment.

# 2. TeNDER EVALUATION

The evaluation of the system usability and impact has two main dimensions: a user-oriented approach and a professional-driven approach. Partners prepared the ethical and legal frameworks for piloting, developed use cases (stories) and prepared the frameworks for the results gathering in the pre-piloting phase of the project. The technical architecture was defined, functionalities were recognized and devices for testing integrated into the first version of the system. Throughout the process, the monitoring the impact on the society through an ethical lens was performed and partners involved participants to be engaged in the development of the tools and system. The first evaluation occurred with the User Requirement surveys and interviews with future users (patients, caregivers and different professionals) were reported in the Report 1 *Evaluation Strategy and Protocols,* WP01.

In the 1st piloting wave, the working TeNDER prototype with main tools will be tested in real-life experiments. The integration of functionalities that have been defined together in co-creation phase of the project will be tested, data will be gathered and analysed. Data obtained will be used and also updated with user requirements and advantages and shortcomings discovered will be Reported.

In the 2nd piloting wave, as the validation phase will demonstrate more realistic operating conditions, the efficiency together with usability and satisfaction will be closely assessed and Report will contain evaluation on improvements.

The evaluation will assess TeNDER services from the respective stakeholders' perspective and identify areas that might need to be adapted or specifically developed during the TeNDER development. Broader TeNDER evaluation covers a combination of objective indicators and subjective perceptions of the stakeholders, therefore the whole consortia will assess the project throughout different WPs in different dimensions: detailing the needs of target population for TeNDER; technology acceptance evaluation (WP06 and WP02); QoL evaluation (pre- and post-testing questionnaire) (WP07); usability evaluation at the end of each wave (WP06); efficiency evaluation at the end of each wave, particularly from a professional driven approach (time saving and knowledge provided) (WP06 and WP07); satisfaction evaluation at the end of each wave (WP06 and WP07); continuous ethic evaluation (WP01) and technical validation (WP05).

The TeNDER evaluation and protocols (Task 1.4, WP01) will be reflected in 3 internal Reports:

1. *Report 1 Evaluation Strategy and Protocols* on ethical challenges on performing research with people with dementia and Parkinson's disease, with repot on strengths and barriers recognized in pre-piloting phase;
2. *Report 2 Evaluation Strategy and Protocols* on ethical evaluation of working with vulnerable group of patients and advantages and shortcomings discovered in 1st piloting wave with first evaluation on usability;

3. *Report 3 Evaluation Strategy and Protocols* on evaluation of usability, satisfaction and efficiency and with improvements and assessment of reaching the main TeNDER goal up to the end of 2nd piloting wave.

Therefore, partners have firstly defined guidance that shall be followed in the project form an ethical perspective, and evaluated the proposed tools. Report 1 Evaluation Strategy and Protocols of this task contains the general recommendations and specific aspects for the researchers to perform the research with people with dementia and Parkinson`s disease, report on the interviews with patients (AD, PD, CVD), their caregivers and professionals, main common barriers and strengths recognized.

Further, the continuous evaluation and feedback of all the relevant stakeholders will ensure efficient resource utilization and coordination of care over the whole TeNDER development period. All piloting partners will evaluate the 1st piloting wave with involved stakeholders and together with the development in other WPs, particularly WP06, provide the next Report (Report 2 Evaluation Strategy and Protocols) on user-oriented approach: ethics, efficiency and satisfaction and professional-driven approach: usability and satisfaction. As partners will include patients from vulnerable groups, ethical challenges will be assessed, advantages and shortcomings of the tools tested will be investigated.

Finally, after the 2nd piloting wave, the Report 3 Evaluation Strategy and Protocols will provide insights in usability, satisfaction, efficiency and ethics form involved stakeholders` point of view in different countries and for the diseases covered in piloting. During the final evaluation, the focus will be on the improvements, achievement of the indicators set in this deliverable and on the real impact and potential impact of the project. The final report will also evaluate what we have done well, how we can improve and what did we learn and provide recommendations for the full TeNDER system piloting in the 3rd piloting wave.

## 2.1 EVALUATION IN PRE-PILOTING

Opinion from patients, caregivers and professionals has been collected for their met and unmet needs, as well as opinion on usefulness of the TeNDER functionalities were done in the pre-piloting phase.

The main tool for feedback gathering form the participants in pre-piloting were interviews and surveys (developed under WP02, co-creation process, templates were finalized in Deliverable 2.2 and time plan was set in Deliverable 2.3).

Feedback on the qualitative questions from all stakeholders is being used to further improve TeNDER approach. Before the implementation of the 1st piloting wave, partners have reported the findings in Report 1 Evaluation Strategy and Protocols. The Report 1 in Task 1.4, WP01, is structured into nine main sections:

1. introduction with main purpose and scope of the Report;
2. general recommendations for the researchers that perform research and interviews with people with dementia and how the protection of participant confidentiality and anonymity in the TeNDER project is handled;
3. communication guidance for the interviews with people with Alzheimer's disease and other forms of dementia, and for Parkinson's disease;
4. general recommendations and protocols for the recruitment of the participants;
5. protocol regarding safety, mainly focused on covid-19 related concerns;
6. report on interviews with the users from the first phase of the project; pre-piloting;
7. conclusions on the first phase interviews with patients, caregivers and professionals.

The main barriers that were recognized were:

- ⇨ **awareness**: proposed types of sensors and services are usually not yet a part of care management; the usefulness of these functions is not well recognized by patients; a more positive attitude was sensed from caregivers and professionals,
- ⇨ **trust**: concerns about ethics, privacy and concerns on devices capability to assist the personal autonomy were recognized; the concerns in regard to potential impact on the care process and impact on personal relationships were expressed,
- ⇨ **empowerment**: mainly patients don't feel comfortable and up-to the use of new technologies alone; caregivers have the perception that they would need to do more - will need to help caretakers a lot with using technology; professionals commented that the system should be simple to use.

On the other hand, strengths were recognized:

- ⇨ **care facilitation:** the potential to reduced load of caregiving as the system would allow the patients being more independent and autonomous, moreover, some technologies offer functions that were recognized to be useful to support the daily routine of a patient,
- ⇨ **motivation:** digital solutions could provide support for performance tracking in certain tasks and activities, which may increase motivation,
- ⇨ **improved communication**: between patients, professionals and carers via digital communication tools and system-based reports, moreover, technologies could help professionals in bridging communication with patients and other professionals, in time and data management,
- ⇨ **accuracy and insightfulness**: these services may enable more precise measurement and the collection of more data, which also enables better and easier comparisons in time and may allow more insights into the evolvement of the disease.

**Relation to TeNDER KPIs:**

The pre-piloting phase interviews covered a sample of representative patients with AD, PD, and CVD (n= 19), caregivers (n=24) and professionals (n=18). The patient participants were representative of people with Alzheimer's disease or other form of dementia (n=13, 68%), Parkinson's disease (n= 4, 21%), and cardiovascular disease (n=2, 11%). The progress according to the KPIs to involve at least 20 end-users during the TeNDER co-design process (related to WP02) is thus covered for pre-piloting co-design process and results are covered in the Report 1 Evaluation Strategy and Protocols. By this, we also set the base to fulfil the KPI to Include over 3 different types of stakeholders and service users across the various co-design phases (related to WP02), as patients, caregivers and professionals were included as stakeholders in the pre-piloting interviews in order to analyses their needs and opinions.

As the end user requirements will be partly assessed in qualitative analysis in pilot testing by interviews reported in Task 1.4, also the KPI for 100% coverage of end-user requirements through functional validation during TeNDER test phases (related to WP06) will be evaluated.

Partners have found the following indicators that will be chosen to address the topic in the piloting evaluation, besides the indicators that have been already set for the Project (objective indicators and KPI):

- trust on technology;
- accuracy of the system;
- impact on communication and care relationship;
- motivation to use technology.

## 2.2 EVALUATION IN PILOTING

The evaluation will assess TeNDER services from the perspective of each stakeholders group. It is twofold: On the one hand, the user-oriented approach: ethics, efficiency and satisfaction are the priorities here and on the other hand, the professional-driven approach: usability and satisfaction count here.

To conduct the evaluation, we have chosen to consider a combination of objective indicators and subjective perceptions of the stakeholders, therefore the whole consortia will assess the project throughout different WPs: technology acceptance evaluation (WP06 and WP02); QoL evaluation (WP07); usability evaluation at the end of each pilot wave (WP06); efficiency evaluation (WP06 and WP07); satisfaction evaluation (WP06 and WP07); and technical validation (WP05).

The main method used in Task 1.4, WP01, will be the interview. From the participants' perspective, the reporting will include in-depth analysis and included in the WP06 and WP07 Tasks outcomes, while the main findings and the independent assessment will be reported in Task 1.4 Reports. The indicators that were defined in pre-piloting (see Section 2.1) phase will be evaluated through the observations and opinions gathered from the researchers that will perform the piloting and interviews with all users, and with independent assessment of the summarized findings from the interviews. Evaluation procedure in piloting will include:

a. Ethical aspects assessment (Annex A);
b. Evaluation of usability, satisfaction, efficiency and usefulness based on the defined questionnaires (Annex B);
c. Performance indicators: number of participants by profile (patient, caregiver, professional; will be assessed monthly, Annex C);
d. Quality control: each partner will include in the interviews (or focus group) in each wave at least 3 patients, 3 caregivers and 3 professionals, selected respecting the expected distribution of the respective samples;
e. Researchers participating in the field work will write observations based on the interactions with participants and will follow-up the indicators of impact of the trust on technology, communication and care relationship and motivation to use technology (Annex E);
f. Independent assessment of the summarized findings from the interviews / focus groups (Annex D) by a person that was not included in the interviews.

The evaluation procedure described (as defined in WP06) will be assessed in a way that will include people that were not participating in the interviews. Main findings will be represented in reports by piloting partners and will be gathered in order to evaluate the outcomes from an integrated, comparative perspective.

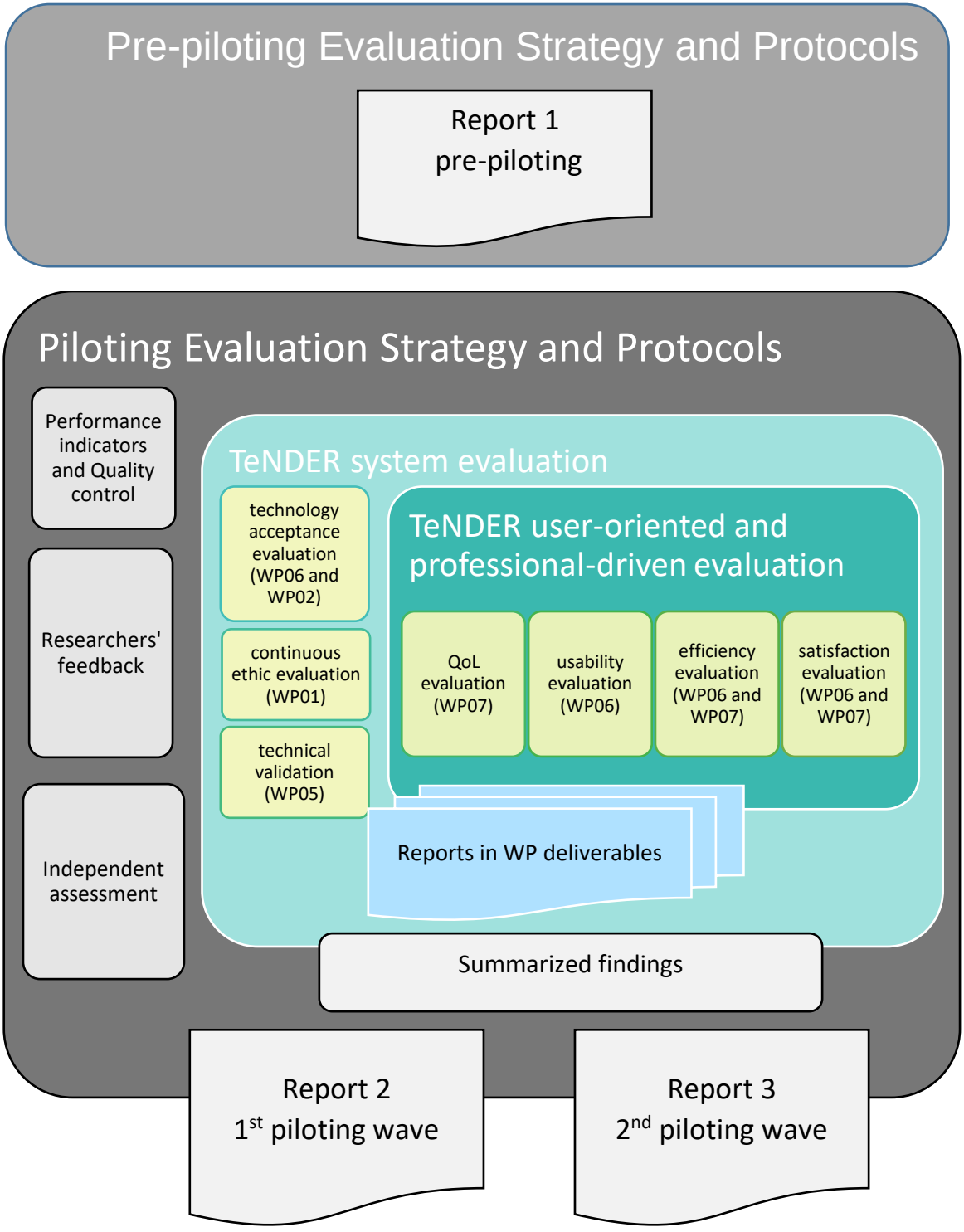



*Figure 1: Evaluation strategy and Protocols and references to other WPs*

# 3. PLAN FOR USER SELECTION PROCEDURES AND ETHICAL CHALLENGES

Five different pilots will run simultaneously according to the validation strategy defined for the co-design process as set in the description of work of TeNDER. Before testing, partners also passed ethical committee approval.

## 3.1 PLAN FOR THE RECRUITMENT

Participants are being recruited in two phases of the project:

a. the first phase, when user requirements are gathered;

b. the second phase, where participants are involved in testing and validation of TeNDER.

The co-design process (assessing User Requirements and in later phases User feedback) will also take place later, in the piloting phase. The participants that will be recruited in piloting will be invited to collaborate in the co-creation with interviews. This way, we will gather users' feedback about the TeNDER project, so that partners can improve the solutions provided and contribute to the development of a final TeNDER system.

The first phase includes participants that will represent a rather minor sample from different countries (Spain, Italy, Germany and Slovenia) according to the inclusion criteria set in WP06. TeNDER partners performed surveys and interviews with the participants from different groups, and draw conclusions based on partners` previous knowledge about the insights from the field. In this phase, all the analysis was done in an anonymous way and it is not possible to relink the answers or results with the participants.

In the second phase, the participants that fulfil the inclusion criteria (described in Deliverable 6.1), will be included in piloting and we will have their signed consents for piloting. At least 20 participants will be included during co-design process to participate both in the piloting phase and in the validation phase. The interviews will be summarized and documented in Reports of this Task.

Each organization leading a pilot will check every month that the respect for the protocols for recruiting users and also of the profile of the participants involved in the pilots suits the inclusion and exclusion criteria, reporting SPO of eventual deviations from the agreed criteria. Reasons for eventual errors in the recruitment process will be gathered and contingency measures (such as including more precise guidelines for researchers working in the field work, for instance) will be adopted.

### 3.1.1 RECRUITING USERS FOR USER REQUIREMENT GATHERING AND PROTOCOL

For the first phase, participants were recruited by the researchers of TeNDER consortium members representing the User group in each of the 4 participating countries that will carry out TeNDER piloting. The researcher explained the participation is voluntarily to all people that meet the selection criteria until the agreed sample size was reached. The details of the approach are described in Deliverable 2.1 and Deliverable 2.2, WP02 and is being further developed in the Research Book under WP02 and WP06.

Regarding the COVID-19 situation, partners provided interviews by telematics (web videoconferencing tools) and if restrictions allowed, in some countries, also F2F (face-to-face). Partners have described the ways of contacting the participants in the Deliverable 2.2, WP02, and foreseen the first option to call the potential participants by phone, when a brief explanation of the project was given.

Afterwards, researchers explained to participants the purpose of the interview, voluntary participation and that their data will be anonymously treated and used only for the purpose of TeNDER. Researchers also explained to the participants that there is a small risk of re-identification despite the fact that the interviews will be treated anonymously (especially in the interviews, as a sample population was small for each country, due to COVID-19 situation). In cases when the partners recorded the interview for the purpose of the transcript, the researcher also explained to the participant that the recording is on voluntary base, the purpose of recording and that the record will be destroyed immediately after the transcript is done.

If the participant consented to do the interview, the interview was carried out by phone or the candidates were offered access to the link and, upon agreement, were interviewed by web-call. The notes of the statements were taken for the purpose of the analysis.

In case of the F2F interviews, researchers adopted the following protocol for the interaction with the participants:

- *He / She will have the appointment with the researcher and first of all will be welcomed and thanked for participating. The researcher introduces him or herself including their role in the project.*
- *Afterwards, the participant will be given all the appropriate explanations about the development of the interview and her / his rights to withdraw, stop at any time and the right not to answer the questions.*
- *The participant will be informed that if agreed, the interview will be recorded to facilitate the transcription of the data obtained and its subsequent analysis; immediately after the transcription the recordings will be destroyed.*

- *Once everything is clear, the participant explicitly confirms that he or she has no more questions and if the participant consents to be included in the interview, the interview will begin.*

The interview in pre-piloting was divided into general topics as described in Deliverable 2.2 and Deliverable 2.3, WP02:

- *Opening: giving a brief introduction of TeNDER and explanation of the goals and scopes of the project and the importance of the obtained data.*
- *Warming-up: participants introduce themselves, answering some questions about themselves.*
- *Focused questions: a transition between the previous very general exchanges and increasingly specific questions and discussion of the issues to be covered.*
- *Closing: researcher summarizes and eventually clarifies remaining issues. The last action is to thank the participant for supporting the research activities.*

### 3.1.2 RECRUITING USERS FOR THE PILOTING

In the second phase, researchers from piloting partners will include participants from all groups (patients, caregivers, professionals) in the testing and validating of TeNDER, according to the inclusion criteria set in WP06. The protocol of recruiting and inclusion criteria, as well as the interaction with the participants, is described in Deliverable 6.1, WP06:

1. order of the interaction;
2. protocol of interaction with the technology with main guidelines for the researchers.

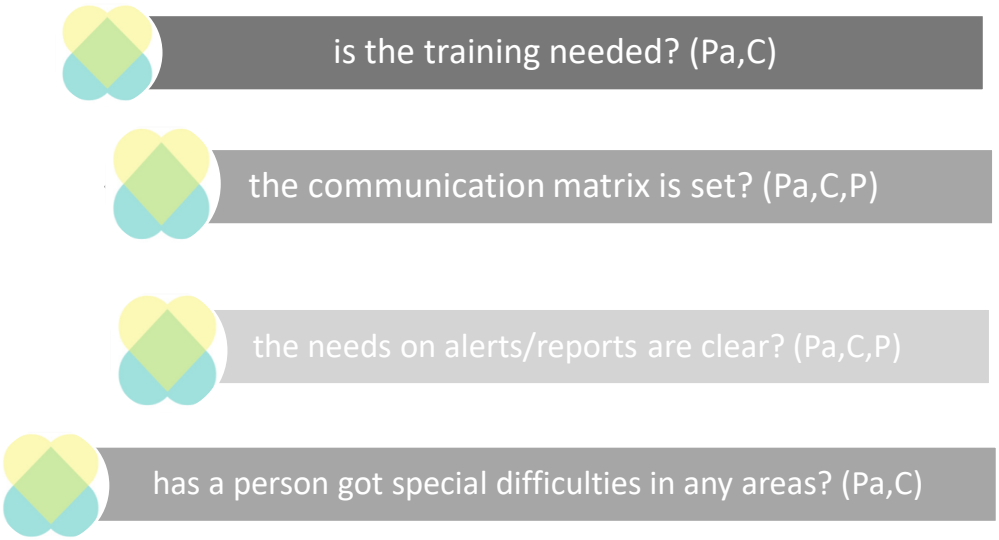
***Order of interaction with participants***

- *Information sheet and explanation of Informed consents for data and/or image recording (signed).*
- *Entry interviews to determine individual baseline for both intervening and control group.*
- *Quality of life surveys.*
- *Interaction with TeNDER functionalities/devices by disease and scenario.*
- *Exposure to the lab with sensors (if applies).*
- *Assessment of technology and functions by participants.*

*Protocol of interaction with technology*

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

The recruitment will follow the general inclusion and exclusion criteria, as set in Deliverable 6.1, WP06. For each scenario (home setting, day-care centres, rehabilitation rooms and hospital setting), inclusion and exclusion criteria for patients for each disease are described in Deliverable 6.1, WP06. Before the testing, the researchers will also identify the following (Pa=patient, C=caregiver, P=professional):



## 3.2 ETHICAL CHALLENGES

TeNDER research is being evaluated by Ethical Committees, as described in Deliverable 1.1, (Section 2.8, Table 3), WP01.

Partners have developed several recommendations in Report 1 Evaluation Strategy and Protocols, WP01, that will be used as guideline for the contacting and interacting with the patients. General recommendations include provisions from Alzheimer Europe Report "Overcoming ethical challenges affecting the involvement of people with dementia in research: recognising diversity and promoting inclusive research" that was developed together with the European Working Group of People with Dementia (EWGPWD) with including several guidance for the researchers and main potentially negative consequence/experience that shall be taken into account (Table 2) [3].

As described in the Deliverable 1.1, WP01, several societal and ethical concerns have to be taken into account concerning participation of vulnerable groups in scientific research. In Section 2 of the Deliverable 1.1 several conditions related to the engagement of human participants were presented and partners will follow relevant frameworks and ethical principles already mentioned. Partners will therefore also follow the provisions from Deliverable 2.1, WP02, that describe the proper language usage and other aspects.

As the words used in speech and in writing can influence others' mood, self-esteem and create feelings of happiness or being uncomfortable (like: sad, disappointed, frustrated). A casual misuse of words or the use of words with negative connotations in conversations can have a profound impact on the person. The usage of appropriate language was emphasised already in Deliverable 2.1. and usage of the dementia language guidelines, developed by Dementia Australia [4], is proposed.

Moreover, as partners are strongly aware that the communication is how we understand and how we are understood by others, tips are proposed to communicate properly with some groups of patients, that are often very reflective on other person's moods. Alzheimer Association has published useful tips [4] for communicating with people suffering from dementia in different stages of the disease. As TeNDER intends to include people with dementia in different stages of the disease, partners shall adopt the guidelines according to each person involved (according to Dementia Australia guideline [4]). Partners have also prepared general communication tips for people with dementia and Parkinson's disease that include special attention to non-verbal communication and other aspects.

Partners also recognize that it is highly recommended that there is adequate space for interaction – the interviewer should be able to comfortably face the person he/she is speaking to and have adequate and appropriate lighting at the interview. The distractions shall be

reduced to lowest possible. For example, a person can become overwhelmed with what is going on around them, as persons with dementia can have troubles to filter out unwanted stimuli.

In case of some dementia and occurrence of visual hallucinations, fluctuating attention, time shifts (may interpret what is happening in the present by drawing on memories of the past) or other difficult behaviour, the interviewer shall stay calm and seek the way to make the interviewed person comfortable. Sometimes, switching on/off the lights for a moment can be beneficial to normalise the situation, having a drink, having a conversation on another topic and other tips are described in Report 1 Evaluation Strategy and Protocols, WP01.

*Table 2: Promoting wellbeing and preventing potential harm and negative consequences (adapted from Dementia in Europe Ethic report 2019, pg. 78)*

| Action | Potentially negative consequences/experience of the participant |
|---|---|
| being interviewed | • feeling intimidated by highly educated researchers<br>• concerns about performance in relation to other people who were interviewed<br>• concerns that other people will find out what was said<br>• revival of memories of unpleasant things from the past<br>• unease linked to the discussion of sensitive topics |
| being monitored | • concerns about who has access to the information<br>• concerns about doing or saying something embarrassing<br>• feeling exhausted – no break from observation, no privacy |
| participating in the survey | • difficulty in understanding some questions<br>• fear of making mistakes, letting researchers down or not responding in a way that will bring the answer researchers are looking for<br>• arousal of unpleasant emotions, feelings (anger, frustration, inadequacy) |
| being involved in a focus group discussion | • feeling of not having sufficiently contributed<br>• feeling of not having been equally valued in research<br>• feeling of not being sufficiently knowledgeable or eloquent<br>• concerns about having disappointed the researchers |

Moreover, it's well-known that Parkinson's disease is often associated with [6]:

- motor speech disorders (for instance hypokinetic dysarthria);
- language deficits (comprehension and production) related to cognitive impairment.

Furthermore, particular aspects need to be taken into account in the communication with patients with PD [7]:

- occurrence of depression,
- need for emotional support,
- negative impression that may be given by a person with PD during the interaction.

Verbal and non-verbal communication guidance for people with dementia and people with PD are provided in Report 1 Evaluation Strategy and Protocols, WP01.

# 4. METHODS

For piloting, the Deliverable 6.1, Section 5, describes the Methods used (Section 5, Figure 4 and 5).

*Three waves of pilots will follow a first phase of initial definition. As mentioned in Deliverable 2.3, the first two waves of pilots will implement the TeNDER system with a revision of the proposed solutions based on users´ evaluations. The third wave will allow the final TeNDER system evaluation. The project will measure its success with patients through benchmarking with Improvement physical well-being / QoL (measured by SF-36) and Improved interaction paradigms (User Experience Questionnaire). The patient management based on electronic information sharing and/or monitoring by technological devices will be applied for a period between 45 days - 2 months for each patient (with their respective caregiver and professionals) in home setting. The project will measure its success through benchmarking with Improvement perceived QoL and Improved interaction paradigms (User Experience Questionnaire) in caregivers. The project will measure its success with professionals through benchmarking with Improved interaction paradigms (User Experience Questionnaire) during the entire period of the project. Particularly, User Experience Questionnaire measurements (UEQ professional) will be performed during each wave in all professionals involved.*

The main method in this Task is an interview. Interviews can be defined as a qualitative research technique that involves "conducting intensive individual interviews with a small number of respondents to explore their perspectives on a particular idea, program or situation [8].

The advantages of interviews include the possibility of collecting detailed information about research questions. Moreover, in this type of primary data collection researcher has direct control over the flow of process and also has a chance to clarify certain issues during the process if needed. Disadvantages, on the other hand, include longer time requirements and difficulties associated with arranging an appropriate time with perspective sample group members to conduct interviews.

There is a risk of interviewee bias during the primary data collection process and the researcher shall be trained to perform the interview in a way, that his reactions do not interfere with peoples' views.

In the second phase of the project, during the piloting, the method will be gathering the opinion and observations of the researchers (Annex E), and independent assessment of the interview /focus group findings (Annex D).

## 4.1 INTERVIEWS

### 4.1.1 USER REQUIREMENT INTERVIEWS

User requirement interviews (first phase, co-creation process) are developed in WP02 and divided into sections:

- *basic information about the participant [socio-demographic data; characteristic of living environment (patient); Characteristics of care received (patient); characteristics of the care provided (caregiver); occupation (professionals)].*
- *General questions with regard to health status (patients, caregivers).*
- *General questions about the technology acceptance.*
- *Sections for the technology-based needs*
    - *Location and activity monitoring,*
    - *Monitoring of vital signs,*
    - *Sleep quality monitoring,*
    - *Personal Calendar,*
    - *Smart Pillbox and drug intake,*
    - *Safety and wellbeing at home,*
    - *Emotions and detection of the states.*
- *Questions in regard to access and sharing the information with other stakeholders (patient-caregiver, patient-professional).*

Moreover, some partners will involve some of the patients throughout all the project in the co-creation process and all waves of the Piloting. Further questions and sections for interviews are being developed in WP02 and will be included in next Reports Evaluation strategy and Protocols in Task 1.4, WP01.

### 4.1.2 INTERVIEWS IN THE PILOTING

In the piloting phase of TeNDER, partners will conduct user experience interviews to evaluate usability, satisfaction and efficiency. TeNDER user experience will also be evaluated through the questionnaire, included in QoL assessment, as described in Deliverable 7.1, WP07 and used for quantitative analysis.

The assessment background and the indicators of usability and technology acceptance are described and evaluated in Deliverable 7.1, WP07. An approach for the first wave of piloting is also provided and the usability assessment methodology is being resumed in Table 2 (table 13, Deliverable 7.1). The aforementioned usability assessment will be performed in all the users involved in the first wave. However, the usability assessment will be implemented during the second and third waves of pilots. The Iterative Testing and Results Gathering will be further elaborated in WP06.

*Table 3: Usability assessment methodology in the first wave of pilots of TeNDER (Table 13, Deliverable 7.1)*

In the table the main approach is represented, a question to assess the affinity for technology, 10 questions for quantitative assessment (SUS) and 3 open questions for qualitative assessment for the 1st wave of piloting are provided in Annex of the Deliverable 7.1.

| PRE-TESTING | POST-TESTING |
|---|---|
| Affinity for technology | SUS questionnaire<br>open-ended questions |

The qualitative assessment through open questions and interviews will be reported after the piloting wave. Partners have described the aspects that shall be taken into account in Deliverable 7.1:

*TeNDER partners are aware of the importance of tailoring device usability to the cognitive and physical capabilities of older adults, as the target group of TeNDER users consists of older adults with chronic diseases. The aspects of the user–software interaction, learnability of software, cognition facilitation, degree of user control and software flexibility, degree of matching of system structure and content to real-world tasks, design of graphics, system navigation and editing capability and consistency among interfaces will be taken into account.*

*Partners will follow nine usability principles:*

1) *simple and natural dialogue,*
2) *speaking the user's language,*
3) *minimization of user's memory load,*
4) *consistency in design,*
5) *providing feedback,*
6) *providing clearly marked exits,*
7) *providing shortcuts,*
8) *providing comprehensive reports on errors,*
9) *error prevention.*

*Partners have described the importance of complementing studies of telemedicine effectiveness with studies that examine perceptions of satisfaction and usefulness as well as actual utilization of various telemedicine services. In Deliverable 7.1 there are several indicators described and partners consider to use the indicators of usability, that would include also acceptance and satisfaction in order not to burden patients with the long-lasting interviews.*

# 5. TIME PLAN

The interviews for pre-piloting (User requirement, first phase) took place according to the Time Plan in Deliverable 2.3 and were a part of reaching the Milestone 1 in the Project.

The interviews for efficiency, satisfaction and usability will be performed after the testing in each wave of piloting according to Time Plans in deliverables in WP06. As stated in deliverable 6.1, the expected timeline of the first wave was M13-M18. Nevertheless, due to several conditions presented during the pandemic caused by Covid-19 (activity of health care centre, patients' homes and hospital limited or interrupted, leaving non-urgent check-ups for later, restriction of patients/professionals allowed to access to hospital, rehabilitation centres and day care centres, etc.) the timeline of the first wave will be delayed.

The interviews will begin when the first testing of TeNDER will end, as proposed in M17 for the 1st piloting wave, and according to the time plan of the Project evolvement further on, extended into the 2nd wave of piloting. The report on interviews will be established after the collecting of the main findings and the summarization of the observations. The independent assessment will follow and the report will also include the opinion and possible proposals for the next steps.

| okt.20 | nov.20 | dec.20 | jan.21 | feb.21 | mar.21 | apr.21 | maj.21 | jun.21 | jul.21 | avg.21 | sep.21 | okt.21 | nov.21 | dec.21 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| M12 | M13 | M14 | M15 | M16 | M17 | M18 | M19 | M20 | M21 | M22 | M23 | M24 | M25 | M26 |
| Pre-piloting interviews | | | | | First wave piloting interviews | | | | | | | Second wave piloting interviews | | |
| | | **Report 1** | | | | | | **Report 2** | | | | | | **Report 3** |

*Figure 2: Time plan for the interviews and evaluation in different phases of the project*

In the figure the proposed time plan for the interviews is presented. It is informative and will rely on the work and time plan in WP02 and WP06.

# 6. RISK PLANNING AND MITIGATION

## 6.1 GENERAL MEASURES

During the TeNDER project the Covid-19 situation requires measures to be taken to guarantee the safety of the TeNDER project participants. A series of measures will be taken based on the recommendations of the European Commission[1].

These measures will be:

- Conversion of physical visits into phone calls or video visits. Only the strictly necessary visits will be made to the sites.
- If necessary, recruitment of new participants will be slowed down to ensure security measures.
- If necessary, the duration of the intervention will be extended to ensure safety measures.
- Closure of the sites. If it is not feasible for a site to remain open, other scenarios should be considered to ensure security.
- In all face-to-face situations the official protocol of each institution will be followed, in accordance with the regulations of each country and the European Union to guarantee the safety of participants and researchers.

## 6.2 SPECIAL CONCERNS REGARDING COVID –19

The protocol concerning the safety measures to reduce transmission of COVID-19 will be described and implemented throughout the entire project. The section 6, Deliverable 6.1 provides necessary safety measures for COVID-19 in TeNDER project will be integrated and updated.

**Possible situations to take into account:**

1. Participants who contracts Covid-19 during the project;
2. Participant who is in close contact with a Covid-19 positive person;
3. A Covid-19 positive person was in the residence or in the same environment where TeNDER testing is happening;
4. Researcher of TeNDER contracts Covid-19 or was in close contact with a Covid-19 positive person.

If not generally disabled, the participant (patients, caregiver, professional) or the researcher of TeNDER, who contracts Covid-19, may continue the participation/conducting the study by remote participation for the duration that is prescribed in each Member State or the

institution. Thus, if possible, the web-based or phone-based conversations may continue. The same applies to the persons that were in close contact with a Covid-19 positive person.

As the information gathering, recruitment phase and the piloting will probably take place during the Covid-19 pandemic, partners need to develop protocols regarding the safety of the participants that will be interviewed. If possible, the F2F interviews can be done in open space, otherwise, the partners shall use the general procedures prescribed from Member States to minimize the risk of spreading the infection. The Table 3 in Report 1 Evaluation Strategy and Protocols summarizes the Guidance that will be followed at each piloting site in different countries.

*Table 4: Guidance that will be followed at each Piloting Site for Covid-19 from Report 1 Evaluation Strategy and Protocols, Table3*

| | Guidance followed at each Piloting Site |
|---|---|
| APM (Spain) | During field work to collect information, researchers must follow a series of guidelines in order to avoid contamination by the COVID-19 virus.<br>• At the entrance to the association all TeNDER professionals will disinfect their hands with hydro alcohol and also the soles of their shoes on the mats at the entrance with virucidal.<br>• The professional will wash his hands and if he has to handle anything, he will put on his gloves.<br>• The greeting will be cordial, but without touching or kissing the partner or the relative, neither when arriving nor when leaving.<br>• Maintain the security distance (2 meters).<br>• As a general rule he will avoid touching his/her face.<br>• At the end of the visit to the rehabilitation room, the gloves will be removed and/or hands washed with soap and water or hydro alcoholic solution.<br>• Used gloves and mask used during the day will be discarded and hands washed with soap and water before leaving the centre.<br>• Surgical masks should be worn by both professionals and patients.<br>• The pens used must be sanitized before and after each use. |
| SERMAS (Spain) | During the personal relationships that are established F2F will follow the recommendations collected by the Ministry of Health, Consumption and Social Welfare, Government of Spain (https://www.mscbs.gob.es/). Such as: |

| | |
|---|---|
| | • individual protection with a mask and a minimum distance of 2 meters during the entire F2F.<br>• hand hygiene before and after the F2F;<br>• preferably in an open space, if it is an enclosed location, a ventilation of the place before and after the F2F, but during the F2F air currents should be avoided |
| SKBA (Germany) | In Germany, partners will perform F2F interviews only if countrywide Covid-19 regulations, as well as specific regulations at SKBA, allow it. The regulations of the responsible authorities, mainly the Robert Koch Institute (www.rki.de), will be followed. At SKBA the general situation regarding Covid-19 and resulting possible risks is constantly evaluated and respective actions will be taken immediately, if necessary. This includes restriction of visits to the clinic (completely or partly), wearing a 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 will be used according to the current guidelines and the recommendations of the hygiene experts at SKBA.<br>Also, if possible, employees work in home-office to keep the contacts at the lowest possible level. Furthermore, general Covid-19 tests are required weekly from each employee, in order to be able to work at the facility. The frequency of the testing may be adapted to the current COVID-19 situation. In case an employee had contact to a person, who was tested positive for Covid-19 or was in a high-risk region, he/she has to immediately follow quarantine regulations and cannot enter the facility unless tested negative twice for Covid-19. The second test can hereby not be taken earlier than 5 days after re-entering the country or the exposition date. Furthermore, constantly wearing a FFP2 mask, without a filter, in the facility until day 14 is required. Similar actions are taking place, if the employee him/herself is being tested positive. In addition, all first-contact persons of the last 2 weeks have to be contacted.<br>Also, according to the risk level, the clinic can close the Alzheimer's Therapy Center or minimize the admission of non-Covid-19 and non-emergency patients to the hospital.<br>At any time, all employees involved in the TeNDER project will follow the effective and to the current situation adapted recommendations and guidelines to protect the patients' rights, safety, and wellbeing.<br><br>According to these guidelines, interviews will take place in ventilated environments. Researchers will contact participants |

| | |
|---|---|
| | only when having a current negative test result for Covid-19, as mandated by the responsible authorities and the SKBA hygiene experts. Furthermore, researchers will wear protective equipment, such as a face mask and follow hygiene guidelines on washing hands and using disinfectants. Also, a safe distance (min. 1.5m) will be kept to the participants at all times.<br>Moreover, participants, as well as researchers will declare that:<br>• they have not been tested positive for Covid-19<br>• they have no suspicious symptoms for Covid-19 (fever, cough, tiredness, aches and pains, sore throat, headache, loss of taste and smell etc.).<br>• they have not had contact to persons tested positive for Covid-19 in the last 2 weeks<br>• they are not under quarantine.<br>Material used during the interviews will be disinfected. In case disinfection is not possible the material will be discarded. |
| SPO (Slovenia) | In Slovenia, partners will try to perform F2F interview in open space under the treetops in front of the Spominčica centre, otherwise will follow general guidance form NIJZ (National Institute of Public Health, https://www.nijz.si/). Personal Protective Equipment (PPE) will be worn by the investigator and the potential stakeholders involved (patients, caregivers), keeping a safe distance (min 1.5 meters). At least the following guidance from NIJZ will be followed:<br>• prevention of infection with virus SARS-COV_19<br>• instructions for ventilation of premises outside medical institutions at the time of spread of the infection<br>• Covid-19 dementia and recommendations |
| UNITOV (Italy) | In Italy, partners will perform F2F interviews in ventilated environments, following the general guidance of ISS (Istituto Superiore di Sanità, https://www.iss.it). Personal Protective Equipment (PPE) will be worn by the investigator and the potential stakeholders involved (patients, caregivers), keeping a safe distance (min 1 meter). Moreover, the potential stakeholders involved will declare that:<br>• they have not an ascertained positivity to COVID19.<br>• they have not suspicious symptoms for COVID19 (fewer, dry cough, tiredness, aches and pains, sore throat, headache, loss of taste and small etc.).<br>• they are not under quarantine. |

# 7. CONCLUSIONS

The present deliverable reports on planning and evaluation strategy for the TeNDER solution. It sets the core basis for the recruitment of the participants, user approach, risk planning and mitigation, and topics for evaluation protocols.

Broader TeNDER evaluation covers a combination of objective indicators and subjective perceptions of the stakeholders; therefore, the whole consortia will assess the project throughout different WPs. TeNDER evaluation and protocols are reflected in 3 internal Reports: one in pre-piloting phase and two in piloting phase. Based on the work performed in Task 1.4, partners have initially defined guidance that shall be followed in the project from an ethical perspective and evaluated the proposed tools for interviewing patients with different diseases, caregivers and professionals.

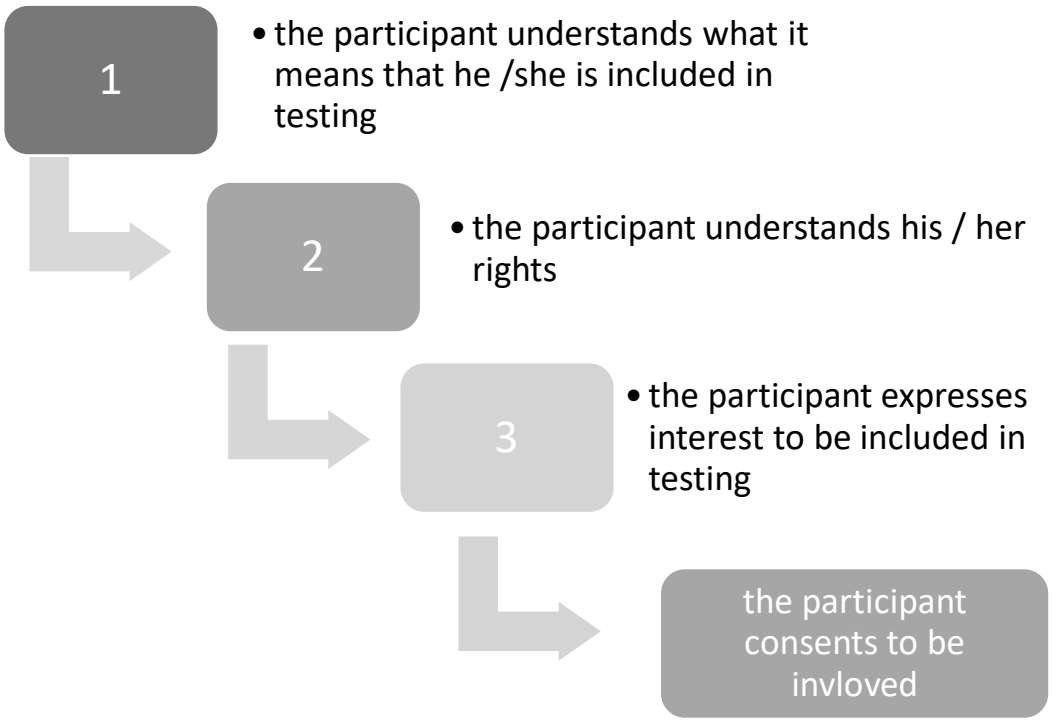
According to the main barriers and strengths recognized (Report 1 Evaluation strategy and protocols), the indicators to be followed during the TeNDER testing are set in this Deliverable. Further, the continuous evaluation and feedback of all the relevant stakeholders will ensure efficient resource utilization and coordination of care over the whole TeNDER development period. Evaluation procedure includes: feedbacks of user requirements; ethical assessment; usability, satisfaction, efficiency and usefulness evaluation; quality control; observational report on indicators set in pre-piloting and independent assessment of summarized findings.

The Deliverable was developed according to the work performed in WP01, WP02, WP06 and WP07 so far. The evaluation can be further developed and updated in regard to the development of several WPs and feedback from the fieldwork.

Moreover, through set measures in this Deliverable, an important contribution to other first and intermediate technical deliverables will follow and will be used for the TeNDER system development.

# ANNEXES

## A. ETHICAL EVALUATION




As described in Section 2.2 of the Report 1 Evaluation Strategy and Protocols, Informed consent for data processing, is described in Deliverable 10.8 and the detailed procedure for Obtaining Informed Consent for Participation of Humans in Research is described in Deliverable 10.2.

The procedure and criteria for identifying and recruiting participants for the TeNDER pilots to ensure that this process takes into account the relevant ethical considerations is therefore described in Deliverable 10.1, where the Criteria for recruitment and Procedure for recruitment are described. Moreover, the detailed criteria are set in Deliverable 6.1.

The technical and organizational measures to protect data subjects in regard to data security are described in Deliverable 10.5, where the Data Processing Agreement Template is set. In accordance with the GDPR, that requires data controllers (and processors) to put in place appropriate technical and organisational measures to ensure a level of security that is appropriate to the risks that are presented by processing, in particular from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted, stored or otherwise processed, partners define technical and organizational measures in work in WP10.

Description of the Security Measures Preventing Unauthorised Access to Personal Data is set in Deliverable 10.6, including Security Measures at Pilot Location. The consortium will also undertake a data protection impact assessment in line with Article 35 of the GDPR as part of Task 1.3 in WP01, which will map, in more detail, the possible risks associated with the processing of personal data in the context of the TeNDER project and identify any additional organisational measures to be taken.

Moreover, Deliverable 10.7 describes the Pseudonymisation and anonymization procedures that are defined in the project TeNDER. Finally, Risk Evaluation of Data Processing Activities in TeNDER is described in Deliverable 10.9.

## B. CHECKLIST FOR THE PILOT EVALUATION

1. patient

| | |
|---|---|
| Point of entry questionnaire | SF36 (original form)<br>Autonomy Questionnaire of TeNDER<br>USER EXPERIENCE QUESTIONNAIRE<br>Affinity for technology (pre-piloting phase) |
| Final questionnaire | SF36 (contextualized to TeNDER)<br>TeNDER USER EXPERIENCE QUESTIONNAIRE (Autonomy Questionnaire,<br>questions regarding the number of visits,<br>TeNDER Satisfaction Rate Questionnaire,<br>Modular Set Function Questionnaire,<br>question regarding events that could have affected QoL of the patient)<br><br>SUS questionnaire<br>open-ended questions for usability<br>efficiency questions<br>motivation questions<br>user requirements<br>technical validation |

2. caregiver

| | |
|---|---|
| Point of entry questionnaire | Perceived QoL Questionnaire, a question regarding the satisfaction about the care of the patient of TeNDER USER EXPERIENCE QUESTIONNAIRE.<br><br>Affinity for technology (pre-piloting phase) |

| | |
|---|---|
| Final questionnaire | TeNDER USER EXPERIENCE QUESTIONNAIRE (Perceived QoL Questionnaire, a question regarding the satisfaction about the care of the patient,<br>questions regarding time-saving,<br>TeNDER Satisfaction Rate Questionnaire,<br>Modular Set Function Questionnaire,<br>question regarding events that could have affected QoL of the caregiver).<br>SUS questionnaire<br>open-ended questions for usability<br>efficiency questions<br>motivation questions<br>user requirements<br>technical validation |

3. professional

| | |
|---|---|
| Point of entry questionnaire | Working Conditions Questionnaire of TeNDER<br>USER EXPERIENCE QUESTIONNAIRE.<br>Affinity for technology (pre-piloting phase) |
| Final questionnaire | TeNDER USER EXPERIENCE QUESTIONNAIRE (Working Conditions Questionnaire,<br>questions regarding the number of visits and time-saving,<br>TeNDER Satisfaction Rate Questionnaire,<br>questions regarding the usefulness of TeNDER,<br>question regarding events that could have affected QoL of health and social professionals)<br>SUS questionnaire<br>open-ended questions for usability<br>efficiency questions<br>motivation questions<br>user requirements<br>technical validation |

## C. PROPOSAL FOR THE EVALUATION AS MONTHLY REPORTS

Partners will follow the progress in piloting through the common database on a monthly basis according to the plan in WP06 Large Scale Piloting and Validation planning and mitigation. The proposal for monthly reports covers:

**Patient AD**
**Patient PD**
**Patient CVD**

| Data Input at screening | |
|---|---|
| Date of Screening | [date] |
| Inclusion | [yes/no] |
| Close out due to exclusion criteria | drop down menu with exclusion criteria |
| Reason in case of refusal | |

| Data input at inclusion | |
|---|---|
| Date of inclusion | [date] |
| Patient ID | [ID; ID; ID; ...] |
| Caregiver ID | [ID; ID; ID; ...] |
| Professional ID | [ID; ID; ID; ...] |
| Gender | [m/f/d] |
| Age | [years] |
| Setting | [hospital/home/day-care/rehab] |
| Comorbidity | [ICD Category; ICD Category; ...] |

| Data input after termination of participation | |
|---|---|
| Date of termination | [date] |
| Reason in case of premature termination | |
| Fitbit Used | [yes/no] |
| Duration Fitbit | [days] |
| Sleep Sensor Used | [yes/no] |
| Duration Sleep Sensor | [days] |
| Kinect Used | [yes/no] |
| Duration Kinect | [days] |
| RealSense Used | [yes/no] |
| Duration RealSense | [days] |
| Xiaomi band Used | [yes/no] |
| Duration Xiaomi band | [days] |
| Environmental sensor Used | [yes/no] |
| Duration Environmental sensor | [days] |
| Binary sensor Used | [yes/no] |
| Duration Binary sensor | [days] |
| Microphone Used | [yes/no] |
| Duration Microphone | [days] |
| Speaker Used | [yes/no] |
| Duration Speaker | [days] |
| Position tracker Used | [yes/no] |
| Duration Position tracker | [days] |

**Caregiver**

| Data Input at screening | |
|---|---|
| Date of Screening | [date] |
| Inclusion | [yes/no] |
| Reason in case of refusal | |

| Data input at inclusion | |
|---|---|
| Date of inclusion | [date] |
| Caregiver ID | [ID; ID; ID; ...] |
| Patient ID | [ID; ID; ID; ...] |
| Professional ID | [ID; ID; ID; ...] |
| Gender | [m/f/d] |
| Age | [years] |
| Disease of caretaker | [hospital/home/day-care/rehab] |

| Data input after termination of participation | |
|---|---|
| Date of termination | [date] |
| Reason in case of premature termination | |

## Professional

| Data Input at screening | |
|---|---|
| Date of Screening | [date] |
| Inclusion | [yes/no] |
| Reason in case of refusal | |

| Data input at inclusion | |
|---|---|
| Date of inclusion | [date] |
| Professional ID | [ID; ID; ID; ...] |
| Caregiver ID | [ID; ID; ID; ...] |
| Patient ID | [ID; ID; ID; ...] |
| Occupation | [Physician/Neurologist/ ...] |
| Gender | [m/f/d] |
| Age | [years] |

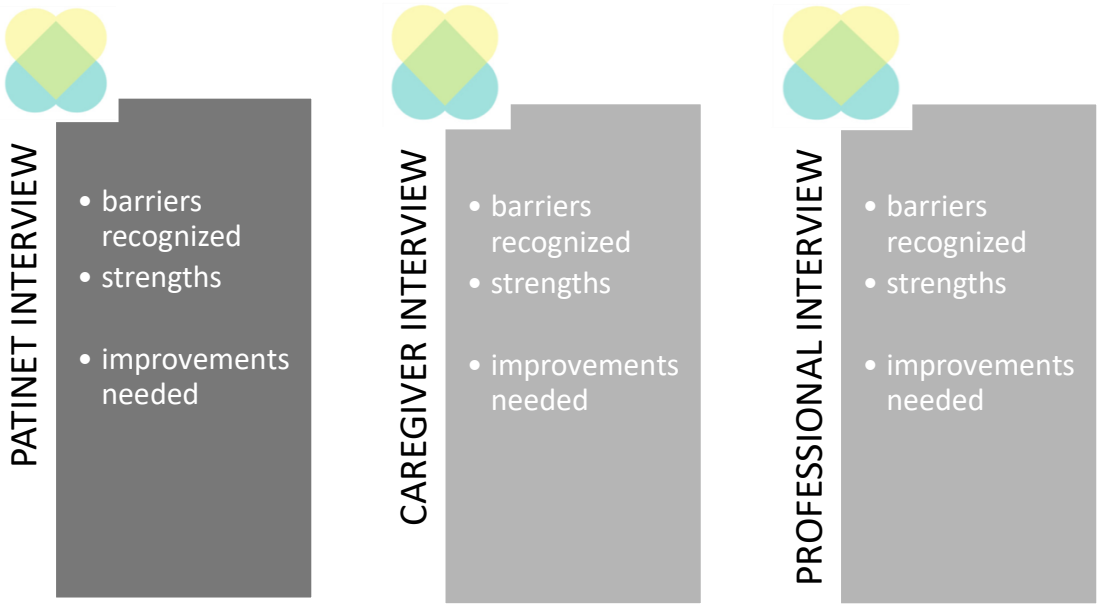
| Data input after termination of participation | |
|---|---|
| Date of termination | [date] |
| Reason in case of premature termination | |

## Researcher Experience

| Researcher Experience | |
|---|---|
| Participant ID | [ID; ID; ID; ...] |
| Researcher name | |
| Date of inclusion | [date] |
| First reaction of the user | 1st day |
| First observations | [date] |
| First barriers | within a few days |
| Intermediate observations | [date] |
| Barriers of the usage | 2 weeks+ |
| Special feedbacks | |
| Complaints | |
| Final observations | [date] |
| Observation at the end of testing | |

## D. INDEPENDENT ASSESSMENT SECTIONS

To assess how well the strategies have allowed us to achieve our goals, an independent assessment will follow the indicators that have been identified by TeNDER consortium in pre-piloting phase and reported in the Report 1 Evaluation Strategy and Protocols. Assessor will identify if the following findings are addressed properly and the improvement and/or will recommend the pathway to address it.




The main barriers that were recognized were:

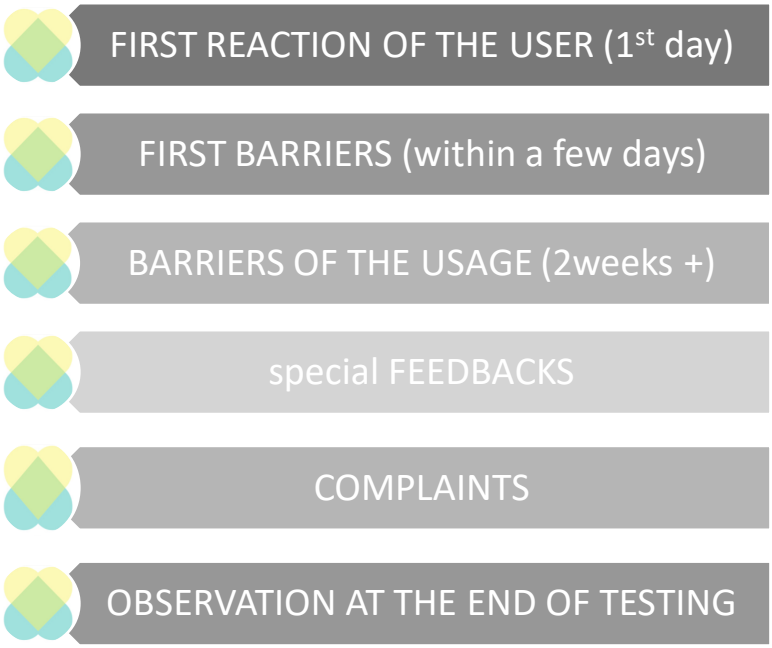
- **awareness**: proposed types of sensors and services are usually not yet a part of care management; the usefulness of these functions is not well recognized by patients; a more positive attitude was sensed from caregivers and professionals,
- **trust**: concerns about ethics, privacy and concerns on devices capability to assist the personal autonomy were recognized; the concerns in regard to potential impact on the care process and impact on personal relationships were expressed,
- **empowerment**: mainly patients don't feel comfortable and up-to the use of new technologies alone; caregivers have the perception that they would need to do more - will need to help caretakers a lot with using technology; professionals commented that the system should be simple to use.

On the other hand, strengths were recognized:

- **care facilitation:** the potential to reduced load of caregiving as the system would allow the patients being more independent and autonomous, moreover, some technologies offer functions that were recognized to be useful to support the daily routine of a patient,
- **motivation:** digital solutions could provide support for performance tracking in certain tasks and activities, which may increase motivation,
- **improved communication**: between patients, professionals and carers via digital communication tools and system-based reports, moreover, technologies could help professionals in bridging communication with patients and other professionals, in time and data management,
- **accuracy and insightfulness**: these services may enable more precise measurement and the collection of more data, which also enables better and easier comparisons in time and may allow more insights into the evolvement of the disease.

## E. PARTICIPATING RESEARCHER'S SECTION

Sections for the observational report of the researchers will cover at least the following topics:



## F. Interview guidelines

Guidelines for the interviews in the co-design process were set in D2.1 (Section 4) and include:

- the definition of end-users and other participants;
- common methodological background with the variables that will be followed, different scenarios in living setups that will be covered and thus the representative sample of these groups shall be included in the interviews;
- user involvement with the protocol (Figure 3, Section 4, Deliverable2.1);
- ethical considerations;
- the way users will be contacted with the steps of the interview (page 25, Deliverable2.1).

During the evolution of the project the specificities for the Interviews are further detailed in Section 4.2, Deliverable 2.2: contacting the participants in the covid-19 situation, division of the interviews, data collection and proposed Interviews templates (Annex 2, Deliverable 2.2).

Partners have described general recommendations and communication guidelines in the Report 1 Evaluation Strategy and Protocols (Section 2, 3), with updated section 4 including a description for the recruitment of the participants due to covid-19 situation.

All guidelines, especially guidelines for the patients (Section 2, 3) that are a part of Report 1 Evaluation Strategy and Protocols shall be followed in the piloting interviews.

## G. Proposed Organisation of the interviews for the partners

Partners will follow the table provided as a guide for organizing interviews. This ensures that all profiles, scenarios and different diseases are interviewed. All partners will take care to cover the proposed sampling in the piloting phase: to include in the interviews the participants from similar/comparable scenarios, age and disease covered in the piloting phase according to the covid-19 situation in each country.

| | | | SPAIN | | | | | ITALY | | SLOVENIA | | GERMANY |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | SERMAS | | | APM | | UNITOV | | SPO | | SKBA |
| PROFILE | disease | INTERV. (number) | Day Centre | Home | Primary Care | Home | Rehab. Room | Home | Hospital | Day Centre | Home | Hospital |
| | AD | | | | | | | | | | | |
| PATIENTS | PD | | | | | | | | | | | |
| | CVD | | | | | | | | | | | |
| | AD | | | | | | | | | | | |
| CARERS | PD | | | | | | | | | | | |
| | CVD | | | | | | | | | | | |
| PROFESSIONAL | social | | | | | | | | | | | |
| | health | | | | | | | | | | | |
| TOTAL INTERV. | | | | | | | | | | | | |
| TOTAL COUNTRY | | | | | | | | | | | | |

# REFERENCES


1. O. Capelli, B. Quattrini, F. Abate, B. Casalgrandi and I. Cacciapuoti (May 11th 2016). Integrated Care for Chronic Diseases – State of the Art, Primary Care in Practice - Integration is Needed, Oreste Capelli, IntechOpen, DOI: 10.5772/63362. Available from: https://www.intechopen.com/books/primary-care-in- practice-integration-is-needed/integrated-care-for-chronic-diseases-state-of-the-art
2. Savage E, Hegarty J, Weathers E, Mulligan L, Bradley C, Condon C, et al. Transforming Chronic Illness Management through Integrated Care: A Systematic Review of What Works Best and Why. International Journal of Integrated Care. 2016;16(6): A394. DOI: http://doi.org/10.5334/ijic.2942
3. https://www.alzheimer-europe.org/Publications/Alzheimer-Europe-Reports, accessed on 30.8.2020
4. https://www.dementia.org.au/sites/default/files/resources/dementia-languageguidelines.pdf
5. https://www.alz.org/help-support/caregiving/daily-care/communications
6. *Saldert C, Bauer M. Multifaceted Communication Problems in Everyday Conversations Involving People with Parkinson's Disease. Brain Sci. 2017 Oct; 7(10): 123.*
7. *https://www.nice.org.uk/guidance/ng71/evidence/full-guideline-pdf-4538466253*
8. Boyce, C. & Neale, P. (2006) "Conducting in-depth Interviews: A Guide for Designing and Conducting In-Depth Interviews", Pathfinder International Tool Series