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Acronyms and Abbreviations

Acronym/Abbreviatio	Description
n	
EC	European Commission
WHO	World Health Organization
WP	Work Package
EHR	Electronic Health Record
QoL	Quality of life
HR QoL	Health-Related Quality of Life





EMR

Electronic medical record



Tender D. 7.1 QoL Assessment Methodology

Contents

1 EXECUTIVE SUMMARY	0
2 INTRODUCTION	1
2.1 PURPOSE, CONTEXT, AND SCOPE OF THIS DELIVERABLE	1
2.3 HEALTH-RELATED QoL IN PATIENTS WITH CHRONIC DISEASES AND CAREGIVERS: STATE OF THE ART 1	2
2.4 INTEGRATED HEALTHCARE SOLUTIONS AND QOL: STATE OF THE ART	4
2.5 MEASUREMENT OF HR QoL: STATE OF THE ART1	5
2.6 USABILITY ASSESSMENT BACKGROUND1	7
2.6.1 INDICATORS OF USABILITY AND TECHNOLOGY ACCEPTANCE	8
3 OBJECTIVES AND KPIS ON QoL IN THE PROJECT	0
4 MEASUREMENT OF QoL	1
4.1 MEASUREMENT OF HR QoL IN PATIENTS AND CAREGIVERS AND OF WORKING CONDITIONS OF HEALTI AND SOCIAL PROFESSIONAL IN TENDER	H 1
4.2 SHORT FORM HEALTH SURVEY SF36	2
4.3 TENDER USER EXPERIENCE QUESTIONNAIRES	3
TENDER USER EXPERIENCE QUESTIONNAIRE: PATIENT VERSION	3
TeNDER USER EXPERIENCE QUESTIONNAIRES: CAREGIVER VERSION	3
TeNDER USER EXPERIENCE QUESTIONNAIRES: HEALTH AND SOCIAL PROFESSIONAL VERSION	4
4.4 HOW TO ASSESS KPIS ON QoL WITH QUESTIONNAIRES	5
PATIENTS	5
CAREGIVERS	5
HEALTH AND SOCIAL PROFESSIONALS	6
5 QoL ASSESSMENT PROTOCOL	7
5.1 PATIENTS	7
5.2 CAREGIVERS	7
5.3 HEALTH AND SOCIAL PROFESSIONALS	8
6 USABILITY ASSESSMENT METHODOLOGY IN THE FIRST WAVES OF PILOTS	9
REFERENCES	0
ANNEX 1: QUESTIONNAIRES FOR THE EVALUATION OF QoL	4
PATIENTS	4
POINT OF ENTRY QUESTIONNAIRE	4
FINAL QUESTIONNAIRE	0
CAREGIVERS	3
POINT OF ENTRY QUESTIONNAIRE	3
FINAL QUESTIONNAIRE	4



7

TeNDER D. 7.1 QoL Assessment Methodology

HEALTH AN	ID SOCIAL PROFESSIONALS	. 65
POINT OF	F ENTRY QUESTIONNAIRE	. 65
FINAL QU	JESTIONNAIRE	. 65
ANNEX 2: USA	ABILITY ASSESSMENT (FIRST WAVES OF PILOTS)	. 69
PRE-PILOTI	NG PHASE (FOR PATIENTS, CAREGIVERS, HEALTH AND SOCIAL PROFESSIONALS)	. 69
AFFINITY	FOR TECHNOLOGY	. 69
POST-PILOT	TING PHASE (FOR PATIENTS, CAREGIVERS, HEALTH AND SOCIAL PROFESSIONALS)	. 69
SUS QUE	STIONNAIRE	. 69
OPEN EN	IDED QUESTIONS	. 70





List of Figures:

Figure 1: Multidimensiona	l Character of Quality of Life	
---------------------------	--------------------------------	--

List of Tables:

Table 1: Components of HR QoL	
Table 2: Standardized questionnaires (generic questionnaires) for the i	measurement of HR QoL in a
population of elderly patients	Error! Bookmark not defined.5
Table 3: Standardized questionnaires (disease specific questionnaires) for	the measurement of HR QoL in
a population of older patients	Error! Bookmark not defined.5
Table 4: Common quantitative indicators of usability	Error! Bookmark not defined.
Table 5: KPIs on QoL in the project	
Table 6: Questionnaires for the assessment of QoL in TeNDER	
Table 7: How to assess KPIs on QoL with questionnaires in patients	
Table 8: How to assess KPIs on QoL with questionnaires in caregivers	
Table 9: How to assess KPIs on working conditions with questionnaires in Hea	Ith and social professionals 266
Table 10: QoL Assessment protocol (patients)	
Table 11: QoL assessment protocol (caregivers)	
Table 12: Working conditions assessment protocol (health/social professio	nals) 288
Table 13: Usability assessment methodology in the first waves of pilots of T	TeNDER 29





1 EXECUTIVE SUMMARY

TeNDER is a multi-sectoral project funded by Horizon 2020, the EU Framework Programme for Research and Innovation, developing an integrated care model to manage multi-morbidity in patients with neurodegenerative and cardiovascular diseases. TeNDER will create an integrated care ecosystem for assisting people with chronic diseases of Alzheimer's, Parkinson's, Cardiovascular Diseases, and – where present - comorbidities through the use of affect-based micro tools. These micro-tools will be able to recognize the mood of a person and thus adapt the system's probes to the person's needs via a multi-sensorial system, even in the most severe cases, and match with clinical (from EHRs) and clerical patient information, while preserving privacy, monitoring the ethical principles, providing data protection and security, with the result of increased quality of life. In addition to the QoL assessment for patients, this deliverable will contain caregivers' QoL assessments and health and social professionals' working conditions assessments since all of them are involved in an integrated care approach.

In order to achieve this general goal, TeNDER will perform five large-scale pilots in order to test services targeting patients, their caregivers, and care professionals. At each pilot setting (in Slovenia, Italy, Germany, and Spain), patients will be monitored according to the use cases and scenarios defined. TeNDER's technical, legal, and ethical experts ensure that all personal data is protected according to the General Data Protection Regulation (GDPR).

The deliverable covers the background of the TeNDER quality of life (QoL) assessments, including the methods, contents, aims, and objectives, and the significance of the QoL assessments in the project. It contains the QoL assessment questionnaires for patients with chronic diseases of Alzheimer's, Parkinson's and cardiovascular diseases and – where present – comorbidities. Moreover, it also contains caregivers' QoL assessments and health and social professionals' working conditions assessments. Furthermore, it will report the methodology for the usability assessment in the first waves of pilots in TeNDER project.

Section two describes the QoL and HR-QoL background, highlighting also the purpose, the context and the scope of the deliverable. Furthermore, it describes the state of the art of HR-QoL in patients with chronic diseases underlining its multidimensionality, also in relation to the integrated healthcare solutions. In addition, section two describes the state-of-art of usability assessment. In this section the most used standardized questionnaires in literature for the evaluation of HR-QoL and usability will be summarized.

Section three defines the objectives and key performance indicators (KPI) related to QoL in the TeNDER project (for patients, caregivers and health and social professionals involved) that guided the QoL indicators' creation.

Section four explains the measurement of HR-QoL in TeNDER, describing the questionnaires used in the project (questionnaires are reported in the annex): The standardized 36-Item Short Form Health Survey questionnaire will be used for the assessment of HR-QoL of patients involved in the project. Moreover, other aspects of QoL of the stakeholders and the working conditions of health/social professionals involved in the project will be assessed with TeNDER user experience questionnaires (a group of questionnaires created by the consortium).

Section five describes the HR-QoL assessment protocol in TeNDER, for patients, caregivers and health and social professionals involved in the project, describing the pre-piloting and the post-piloting assessment.



Section six describes the methodology of usability assessment in the first waves of pilots in TeNDER or patients, caregivers and health and social professionals involved in the project, describing the pre-piloting and the post-piloting assessment.

2 INTRODUCTION

2.1 PURPOSE, CONTEXT, AND SCOPE OF THIS DELIVERABLE

The TeNDER project will create an integrated care ecosystem for assisting people with chronic diseases of Alzheimer's, Parkinson's, and cardiovascular diseases and – where present- comorbidities through the use of affect-based micro tools. By combining user-friendly technologies and substantial research experience, our project aims to help improve the quality of life of patients and those who surround them. Moreover, it will test ways to ease communication between different health and care providers who treat patients with chronic diseases.

The user-centered approach of TeNDER calls for a core assessment that can be applied to all pilots. This assessment should measure the most relevant parameter, the patient's and caregivers' quality of life. Research has shown that patient-reported outcomes are highly relevant and suitable to show the impact of a system [1]. Due to the multiple diseases addressed in this project, the complex situations of patients, caregivers, and socio-health professional, the large number of influencing factors, and the multifactorial effects of the TeNDER system, and individualized performance measurement has to be applied to capture all facets of the system impact for all end users 'profiles.

2.2 QUALITY OF LIFE (QoL) BACKGROUND

Chronic diseases such as cognitive impairments and heart diseases are a major social and health issue. In fact, according to the WHO [2], dementia (including Alzheimer's disease) remains one of the biggest global public health challenges our society is facing nowadays. Cardiovascular disease (CVD) represented 31% of all global deaths in 2016, and it is considered as the leading cause of premature death (37% of all deaths under the age of 70) and disability worldwide [3]. The prevalence of Parkinson's disease is estimated to be approximately 6,2 million people worldwide, according to Global Burden of Disease Study (2015) [4]. In addition, patients with chronic diseases will increase in the next years: the number of people living with dementia worldwide today is estimated at 44 million, set to almost double by 2030, and is likely to rise to about 152 million by 2050. As regards Parkinson's disease, the Global Burden of Disease Study estimates that there may nearly 13 million people with Parkinson's by 2040 [4]. However, cognitive impairments are the major challenge for healthcare systems, and it is also frequent in people affected by other chronic diseases such as Parkinson's [5]. Common experience issues in people with these chronic diseases are 1) loss of judgment, 2) alterations in behaviour, 3) sudden mood changes, and 4) difficulties in planning and organizing. Finally, Alzheimer's, Parkinson's and Cardiovascular diseases have an estimated cost for the EU economy of





more than EUR 196 billion a year [6] and a trillion US dollars at the worldwide level with forecast estimation double by 2030.

The aforementioned concerns move public authorities (National Health Systems NHSs), policy makers, researchers, and private businesses to join forces to develop holistic solutions to extend the autonomy of affected people while maintaining, or even to improve their health-related Quality of Life (HR QoL): to face this challenge, TeNDER aims to create an integrated care ecosystem for assisting people with chronic diseases of Alzheimer's, Parkinson's and cardiovascular diseases, and – where present – comorbidities through the use of affect-based micro tools. Moreover, TeNDER aims to improve the efficiency and the working conditions of health and social professionals involved in the project, optimizing their time management and using high-quality data collected.

2.3 HEALTH-RELATED QOL IN PATIENTS WITH CHRONIC DISEASES AND CAREGIVERS: STATE OF THE ART

The term "Quality of Life" has been widely used since the second half of the 20th century. QoL is an important concept in medicine, sociology, and psychology. There is no universally accepted definition. The term suggests philosophical connotations about well-being and satisfaction in aspects related to personal judgment and social standards. The WHO defines QoL as an "individual's perception of his or her position in life in the context of the culture and value system where they live, and in relation to their goals, expectations, standards, and concerns" [7]. The concept QoL is: individual and subjective, self-controlled, variable with time, related to external personal factors, and multidimensional (Image 1). Moreover, QoL of is a dynamic concept that may vary between individuals and within individuals during the lifetime [8]so, it is mainly of interest to the Social Sciences.



Figure 1: Multidimensional Character of Quality of Life

In Figure 1, the presentation of factors that influence the individual QoL perception are presented.





When applied in healthcare, the concept of QoL refers mainly to Health-related QoL (HR QoL). HR QL is a component of global QoL. It integrates experiences and expectations related to health status, health care and health-related social support [9] [10].

HR QoL may be defined as "how well a person functions in their life and his or her perceived wellbeing in physical, mental, and social domains of health" [11]; furthermore, "health-related quality of life includes only those factors that are part of an individual's health" [12]. Based on the definitions made by several authors, HR QoL can be defined as "the assessment of the subjective influence of health status, health care, prevention, and health promotion activities on the individual's ability to achieve and maintain a level of functioning that allows for the achievement of vital goals and is reflected in general well-being. The fundamental dimensions are physical, psychological-cognitive and social functioning" [13].

Following these definitions, HR QoL is the fraction of the QoL associated with health and care, including physical, mental, social, and other components (Table 1).



Table 1: Components of HR QoL

It is important to underline that both health status and functional status influence HR QoL, but they are not exchangeable terms because the first does not comprise social aspects and the second refers only to mental and physical components.

Some factors may influence the HR QoL in older people with chronic diseases; in these patients, QoL is mainly influenced by physical independence, physical health, mental health, and physical and behavioral symptoms: the autonomy in performing daily activities has a fundamental effect on QoL of patients with chronic diseases; moreover, better general health status is associated with a higher QoL. [14,15].

Concepts of "aging in place" and HR QoL in patients with chronic diseases are strictly correlated [8]; the WHO defines "aging in place" as "Meeting the desire and ability of people, through the provision of appropriate services and assistance, to remain living relatively independently in the community in his or her current home or an appropriate level of housing" [16]: older persons with chronic diseases prefer not to move (in Europe, only a 3,3% of the population older than 65 years old live in an institutional center). HR QoL of patients seems to benefit from "aging in place," preserving their autonomy and social relationships; apart from this, "home" is the place where people spend most of their life. Therefore, this place binds them through deep and personal relations [8]. This clearly states that people want to live in their own homes, but people with chronic diseases (especially with dementia or Parkinson's disease) have several problems to manage alone and require care services.

Furthermore, many patients with chronic diseases depend on care from caregivers or relatives, owed to progressive impairments in functioning and/or cognition. The needs of patients may increase due to the





progression of disease severity and research studies have demonstrated that caregivers and relatives have an impairment of their HR QoL and a greater risk of [17-21]:

- Interruption of personal and/or professional roles
- Depression and psychological impairments
- Sleep disturbances
- Medical diseases
- Mortality

As regards caregiving, the burden is a key point to consider since a strict correlation between QoL and burden has been demonstrated [22-24], underlining that burden is an influential and a negative factor for the HR QoL of caregivers.

It's well-known the effectiveness of integrated healthcare interventions in order to improve the HR QoL in patients with chronic diseases, optimizing their well-being and leading to a positive impact on patient satisfaction as well [25][26]. Based on the above, TeNDER selected Alzheimer's, Parkinson's, and cardiovascular diseases, and – where present – comorbidities as the main focus of the integrated healthcare system proposed; one of the main objectives of the project is to improve the HR QoL of patients with these chronic conditions mentioned above and his/her family and caregivers as well, creating an integrated care ecosystem through the use of user-friendly technology.

2.4 INTEGRATED HEALTHCARE SOLUTIONS AND QOL: STATE OF THE ART

The number of elders, and consequently the number of patients with chronic diseases and comorbidities, has been increasing steadily across Europe and in the developed world, a trend that is expected to continue and which makes it imperative to develop care solutions specific to their needs [27].

The WHO has supported an integrated approach in the prevention and treatment of all chronic diseases for a long time. Key factors of this management are [28]:

- the existence of a valid system of care
- the development of the empowerment of patients and their caregivers.

Chronic diseases and multimorbidity are correlated with increased mortality and a lower health-related QoL [29]: HR QoL, though for a long time not a priority for physicians, has been found to significantly influence the efficiency of the care and/or treatment provided to patients: it has been shown that integrated healthcare solutions optimize the patient's care and treatment from the standpoint of time management, resources used and health-related QoL [28], involving multiple healthcare entities (hospitals, physicians, care facilities, patients 'associations etc.) and offering tools and techniques which find specific application in the area of care of elderly patients with chronic diseases, most notably:

- motion and location tracking systems that allow one to keep track of the patient remotely.
- Action recognition systems and cognitive sensor networks that can alert the attending to irregular and potentially dangerous activities by the patient.
- Emotion recognition and cognitive analysis tools have been successfully used to detect signs of depression, cognitive degeneration, and schizophrenia.
- Health and medication tracking devices, that monitor the patient's vitals and alert the attending in case abnormalities are detected. Devices such as smart bracelets are non-invasive technologies for a continuous transmission of health information [30]





- medication tracking devices, that monitor the medication adherence, a key point in the care of patients with chronic diseases [31].

TeNDER will bring together expertise from older European projects (e.g., ICT4Life, PATHWay, I-PROGNOSIS, PICASO, Sense4care and others) to reach our purposes. These methods may have preventive functions in that they can be used to continually monitor patients, take into consideration their particular circumstances, and identify indicators of diseases or otherwise undesired developments at their earliest onset, and alert the attending so that they may intervene in a timely manner, rather than wait until the symptoms to become visible to them. Constantly monitor patients with TeNDER sensors is a way to let patients stay in the own home longer, making more comfortable "aging in place" [32]. Our aim is to develop holistic solutions to extend the autonomy of people affected by these diseases living in their homes while improving their perceived HR QoL. Hence, TeNDER sensors may have a fundamental role in the perception of HR QoL (including the patient's perceived wellbeing in physical, mental, and social domains of health).

Furthermore, integrated healthcare systems aim to improve the working conditions of healthcare professionals: previous research has shown that there is a relationship between the working conditions of healthcare professionals and their HR QoL, and in particular, their well-being is closely related to stress, workload, work environment, and time management [33][34].

2.5 MEASUREMENT OF HR QoL: STATE OF THE ART

In the last 2-3 decades, the attention for the assessment of HR QoL has rapidly grown up with the development of several instruments suitable for this purpose; questionnaires are valid instruments designed to assess the different components of HR QoL in a population study [35][36].

As a subjective and multidimensional concept, HR QoL is studied as a PROM "Patient-Reported Outcomes Measures. The HR QoL study provides valuable patient-generated information that cannot be obtained by any clinical method [37]. The results obtained allow us to know the reality of the patients and, with it, to carry out an attention more adapted to their real needs and give an answer to their demands. [38]

In chronic diseases, improving or maintaining HR QoL is a goal of care, but at the same time, it is a challenge since the longevity of the population is often associated with chronicity, multi-morbidity, fragility, and disability, which makes it challenging to improve HR QoL. However, since it is a multi-dimensional concept, it is possible to focus on other dimensions related to it and improve it or at least maintain it [39].

In tables 2 and 3 are shown the most used questionnaires for the measurement of HR QoL in a population of older patients for research purposes: this assessment may be generic or disease-specific [40].

GENERIC QUESTIONNAIRE	DESCRIPTION
SF36	One of the most used questionnaires for the assessment of HR QoL in patients for research purposes. SF36 questionnaire includes 36 questions, measuring 8 domains of HR QoL [40] (description in the "SF-36" paragraph, please see below).

Table 2: Standardized questionnaires (generic questionnaires) for the measurement of HR QoL in a population of elderly patients





SF12	It includes 12 questions drawn from each of the 8 domains of SF-36 [41].
EuroQoL Five-Dimension	This questionnaire comprises 5 dimensions describing HR QoL:
Questionnaire (EQ-5D)	mobility, self-care, usual activity, pain, anxiety/depression. It is designed to be carried out in the context of primary health care [40].
Health Perception Questionnaire	This questionnaire evaluates 8 dimensions of HR QoL: current health, prior health, health outlook, disease resistance, health concerns, rejection of sick role, attitude toward going to the doctor and illness orientation. It was designed for the study of people's perception concerning their own health [42].
Sickness impact profile	A questionnaire designed in order to evaluate patients' dysfunction through his/her everyday behaviour [43].
CASP-19	A 19-item questionnaire including 4 domains of QoL (autonomy,
	pleasure, self-realization, control). It is based on models of needs satisfaction and self-actualization [40].
Older people quality of life (OPQOL) questionnaire	One of the most used questionnaires for QoL assessment, measuring 8 domains. It is a non-preference-based instrument for the measurement of QoL [44].
WHO Quality of Life-BREF (WHOQOL-BREF) questionnaire	This questionnaire assesses 4 domains of QoL: physical health, psychological health, social relationships, environment. It is derived from the WHOQOL-100 questionnaire, that it was designed to evaluate individuals' perception of their position in life in the context of value systems and culture in which they live [45]

Table 3: Standardized questionnaires (disease specific questionnaires) for the measurement of HR QoL in a population of older patients.

DISEASE SPECIFIC QUESTIONNAIRE	DESCRIPTION
Quality of Life Questionnaire for Dementia (QOL-D)	A questionnaire was used to evaluate QoL in patients with dementia, providing a profile of scores on subscales and no overall score [46].
Quality of Life in Alzheimer's Disease (QOL- AD) questionnaire	A 13-item questionnaire used for the evaluation of QoL in patients with Alzheimer's Disease [47].
The 39-Item Parkinson's Disease Questionnaire (PDQ-39)	A 39-item questionnaire which assess Parkinson's Disease specific health-related QoL, measuring 8 domains of daily living, including communication, social situation and relationships [40].
The 8-Item Parkinson's Disease Questionnaire (PDQ-8)	A 8-item questionnaire, derived from PDQ-39 questionnaire, which assess Parkinson's Disease specific health-related QoL [40].





Quality of Life Questionnaire in Severe	A highly acceptable instrument for the assessment of HR
Heart Failure	QoL in patients with heart failure [48].
The HeartQoL questionnaire	A highly acceptable instrument for assessing HR QoL in patients with cardiovascular disease validated in more than 30 languages [49].
Minnesota Living with Heart Failure Questionnaire (MLHFQ)	One of the most used questionnaires for the assessment of HR QoL in patients with heart failure [48].

2.6 USABILITY ASSESSMENT BACKGROUND

Sustainability for telehealth services can be defined as the use of telemedicine services that hold the promise of being absorbed into routine health care delivery. Indicators of telemedicine sustainability include continued use of tele-homecare systems with an increasing demand for those services, and acceptance of such services among home health care providers with a commitment to invest in them [50].

A recent systematic review focused on the sustainability of tele-homecare programs for chronic disease management, identified barriers and facilitators for sustainability of home tele-homecare programs, that included the perceptions of effectiveness, tailoring to patients, intra-users and intra-professionals' communication and collaboration, quality of tele-homecare technology, presenting the impact of usability and innovation of tele-homecare technology [50].

These aspects will be explored throughout the entire project, but one aim of this deliverable is to focus on the usability and technology acceptance in the first waves of Pilots, describing an initial feasible approach to measure the usability of TeNDER and the acceptance of technology. Our main purpose is to improve the QoL of elderly patients who live in their own home by using a holistic system aimed to increase their perceived autonomy and well-being. The interaction of stakeholders with technologies is crucial and, therefore, the usability of the system represents a fundamental factor in optimizing the use of sensors and the TeNDER app and devices in order to reach our purpose. An easy handling system may maximize the impact of TeNDER on daily living and long-term living of the stakeholders involved, including caregivers and relatives. Moreover, the usability of a system may influence the working conditions of professionals involved. In fact, according to an interesting paper [51], the quality of health professionals' working life is influenced by the habitual use of new technologies and the lack of support systems for learning and updating new systems and programs. Considering these scenarios, the usability of the system may influence the intended outcomes. In fact, users' acceptance of tele-homecare services was identified as a key factor of sustainability in a study on Australian telemedicine services [52], suggesting that users should be periodically oriented not only in the actual use of tele-homecare technology but also in the deployment of the system to achieve intended outcomes.

Moreover, because of the target of TeNDER consisting of older adults with chronic diseases, device usability must be specifically tailored to older adults' cognitive and physical capabilities. The majority of the literature concerning Electronic Medical Records (EMRs) and usability focused on physician use of EMRs and their task performance requirements [53].

Nevertheless, there are many other functions that EMRs support that can be used by the patient, caregivers or other professionals, including administrative staff, nurses, pharmacists, social workers. The most effective use of electronic medical records (EMRs) will result from wide-scale adoption and appropriate use of the technology-two factors that rely heavily on a system's usability. Hollin et al. identified eight aspects of usability relevant to EMR design. These aspects include the user–software interaction, learnability of software, cognition facilitation, degree of user control and software flexibility, degree of matching of system



17



structure and content to that of real-world tasks, design of graphics, system navigation, and editing capability and consistency among interfaces [54].

A recent review of EMR and EHR usability studies [53] revealed nine usability principles that should be considered:

- simple and natural dialogue,
- speaking the user's language,
- minimization of user's memory load,
- consistency in design,
- providing feedback,
- providing clearly marked exits,
- providing shortcuts,
- providing good error messages,
- error prevention.

A previous paper underscored the need to assess usability based on user feedback and to employ multiple methods to elicit information; this research revealed that asking questions in multiple ways yielded more complete feedback [54].

Qualitative evidence is generally exploratory, actionable, and hypothesis-generating. Quantitative evidence typically tests hypotheses or informs predictions. Either approach, individually or in combination, can be used to support formative data collection. Common examples of a survey instrument that produces quantitative preference evidence include discrete-choice experiments (DCE) or best-worst scaling (BWS). Quantitative preference studies may include other preference tasks or specific questions in order to personalize the patient experience.

On the other hand, qualitative data examples include in-depth and semi-structured interviews, focus groups, discussion groups (in person or online), direct observation, documentary analysis, and secondary analysis of existing qualitative data. It is increasingly accepted that qualitative evidence is central to developing any quantitative preference study protocol or instrument by promoting the value of people themselves as experts on their experience or living [55]. Self-written questionnaires are also commonly used for evaluation of usability.

2.6.1 INDICATORS OF USABILITY AND TECHNOLOGY ACCEPTANCE

Actually, several standardized quantitative questionnaires can be used to evaluate the usability of a technological system (Table 4).

Questionnaire	Description	Items
The IBM After-Scenario	In a scenario-based usability study,	3-item questionnaire (ease of task
Questionnaire (ASQ)	participants use a product, to do a series of practical tasks.	completion, time to complete a task, and

Table 42: Common quantitative indicators of usability





		adequacy of support information) with 7- point graphic scales [56]
Printer Scenario Questionnaire (PSQ)	Participants used the instructions and operator manuals to complete the	items are 5-point scales, anchored at the endpoints with the terms
	scenarios	"Acceptable as is" for 1 and "Needs a lot of improvement" for 5, and an "Unable to
		evaluate" rating outside the scale [56]
Post-Study System Usability Questionnaire (PSSUQ)	Participants need more time to complete the PSSUQ than the ASQ, but only complete it once, at the end of a usability study.	A 19-item questionnaire with 7-point graphic scales, anchored at the endpoints with the terms "Strongly agree" for 1, "Strongly disagree" for 7, and a "Not applicable" (N/A) point
		outside the scale [56]
The Computer System Usability Questionnaire (CSUQ)	The CSUQ is identical to the PSSUQ except for the wording	a 19-item questionnaire with 7-point graphic scales, anchored at the endpoints with the terms "Strongly agree" for 1, "Strongly disagree" for 7, and a "Not applicable" (N/A) point
		outside the scale [56]
System Usability Scale (SUS)	A valid, quick, and easy questionnaire	A 10-item questionnaire with 5-point scales, anchored at the endpoints with the terms "strongly disagree" to "strongly agree". The SUS does not require any license fee. The only prerequisite for its use is that any published report should acknowledge the source of the measure [57].
Telehealth Usability Questionnaire (TUQ)	A usability questionnaire that addresses the changes in telehealth service delivery and technology	A 21-item questionnaire in 5 categories [58]
Telemedicine Satisfaction and Usefulness Questionnaire (TSUQ)	Report telemedicine satisfaction and usefulness ratings of urban and rural participants	A 26-item questionnaire: 21 items focused on perceived satisfaction are 5-point scales, anchored at the endpoints with the terms "strongly disagree" to "strongly agree"; 5 items are 5-point scales, anchored at the endpoints with the terms "not at all useful" to "very useful"[59].
Telemedicine Satisfaction Questionnaire (TSQ)	TSQ is a questionnaire designed specifically for telemedicine systems.	A 14-item questionnaire [60].





	mHealth app	usability	Designed specifically to assess mHealth	The	first	version	is	а	18-item
	questionnaire (MAUQ)		app usability.	quest	tionnair	e; the seco	ond v	ersio	n is a 24-
				item	questio	nnaire [61]].		

The After-Scenario Questionnaire (ASQ) is a three-item questionnaire that IBM usability evaluators have used to assess participant satisfaction after completing each scenario.

The Printer Scenario Questionnaire (PSQ) was an early version of the ASQ. It differed from the ASQ in item format and number of scale steps per item. The ASQ and PSQ are both after-scenario questionnaires intended for use in a scenario-based usability testing situation. They contain virtually the same items, but the ASQ uses a 7-point scale and the PSQ uses a 5-point scale.

The Post-Study System Usability Questionnaire (PSSUQ) is currently a 19-item instrument for assessing user satisfaction with system usability.

The PSSUQ and The Computer System Usability Questionnaire (CSUQ) are both overall satisfaction questionnaires. CSUQ is similar to PSSUQ but except that the wording of the items does not refer to a usability testing situation but to a real-world scenario. The PSSUQ items are appropriate for a usability testing situation, and the CSUQ items are appropriate for a field testing situation. Otherwise, the questionnaires are identical [56].

The System Usability Scale (SUS), developed by Brooke in 1996, reflected a vital need in the usability community for a tool that could quickly and easily collect a user's subjective rating of a product's usability [57].

3 OBJECTIVES AND KPIS ON QOL IN THE PROJECT

The main objectives of the project are:

- to improve the HR QoL of patients with chronic diseases of Alzheimer's, Parkinson's, and cardiovascular diseases, and where present comorbidities and his/her family and caregivers as well, creating an integrated care ecosystem through the use of micro tools.
- to improve the efficiency and the working conditions of health and social providers and health professionals, optimizing their time management and using high-quality data collected by all stakeholder inputs, interactions and sensors.

As concerns these objectives mentioned above, TeNDER will measure its success through benchmarking with these typical key performance indicators (KPIs) improvements, described in Table 5.

Table 5: KPIs on QoL in the project

Patients	- 15% increase in perceived HR QoL.
	- KPIs improvements: Improvement physical well-being / QoL (measured by SF-36) 15%
	(~7-8 points); improved interaction paradigms (User Experience Questionnaire) >90%
	satisfaction rate.
	- HR quality of life measurement to patients of at least in 3 different conditions.
	- 10% increase autonomy.





Caregivers	- 15% increase in perceived HR QoL						
	- 10% increase satisfaction of relatives.						
	 Patient and care satisfaction of speed-up attention perception (>90% Questionnaires satisfaction). 						
Health and social professionals	 Improvement of health and social care providers and professionals' working conditions by at least 10% (measured with questionnaires). Reduction of average number of visits to the hospital of at least 12%. Improved interaction paradigms (User Experience Questionnaire) with >90% satisfaction rate 						

4 MEASUREMENT OF QoL

4.1 MEASUREMENT OF HR QOL IN PATIENTS AND CAREGIVERS AND OF WORKING CONDITIONS OF HEALTH AND SOCIAL PROFESSIONAL IN TENDER

The user-centered approach of TeNDER calls for a core assessment of HR QoL that will be applied at all pilots. This assessment should measure the most relevant parameter, the users' HR QoL. Therefore, the user-reported answers are highly relevant and suitable to describe the impact of TeNDER on their life. In order to allow a better harmonization of data from different conditions (Alzheimer's disease, Parkinson's disease, cardiovascular disease), a generic, standardized questionnaire was chosen by the consortium for the assessment of HR QoL in patients (SF-36). Moreover, several aspects of QoL of the stakeholders and the working conditions of health/social professionals involved in the project will be assessed with *TeNDER user experience questionnaires* (a group of questionnaires created by the consortium) (table 6): previous research has shown that there is a relationship between the work environment and HR QoL. In particular, professionals' well-being is closely related to stress, workload and time management [33][34].

Table 6: Questionnaires for the assessment of QoL in TeNDER





Tender D. 7.1 QoL Assessment Methodology

4.2 SHORT FORM HEALTH SURVEY SF36

The 36-Item Short Form Health Survey questionnaire (SF-36) is a one of the most used questionnaires for assessing HR QoL in patients for research purposes. SF36 includes 36 questions measuring 8 domains [62]:

- physical functioning
- role limitations due to physical health problems
- bodily pain
- general health
- energy/fatigue
- social functioning
- role limitations due to emotional problems
- emotional well-being

From these scales, two summaries are calculated:

- 1) the Physical Component Summary (PCS)
- 2) the Mental Component Summary (MCS)

The SF36 questionnaire has been translated into several languages. Furthermore, it is validated in people with Alzheimer's disease [63], Parkinson's disease [64], and cardiovascular disease [65].

RAND corporation grants permission to use SF36 questionnaire under the following conditions (https://www.rand.org/health-care/surveys tools/mos/36-item-short-form/terms.html):

- Changes to SF36 questionnaire may be made without the written permission of RAND. However, all such changes shall be clearly identified as having been made by the recipient.
- The user of SF36 accepts full responsibility and agrees to indemnify and hold RAND harmless, for the accuracy of any translations of the Health Survey into another language and for any errors, omissions, misinterpretations, or consequences thereof.
- The user of SF36 accepts full responsibility and agrees to indemnify and hold RAND harmless for any consequences resulting from the Health Survey's use.
- The user of SF36 will provide a credit line when printing and distributing the document acknowledging that it was developed at RAND as part of the Medical Outcomes Study.

Moreover, RAND corporation allows translations following their guidelines (<u>https://www.rand.org/health-care/surveys_tools/about_translations.html</u>).





4.3 TENDER USER EXPERIENCE QUESTIONNAIRES

TeNDER user experience questionnaires are a group of questionnaires created by the consortium, with which several aspects of QoL of the stakeholders involved in the project (patients, caregivers, health and social professionals) will be assessed. Our aim is the improvement of the assessed aspects, including the increase of perceived autonomy, the increase of the satisfaction rate, the reduction of number of visits (hospitals, day care centers, and/or rehabilitation rooms). Moreover, we aim to assess each device's impact on user's daily living and long-term living. Therefore, the modular set function questionnaires will assess the functionalities that are operable during the monitoring (and the ones that the patient has given consent to).

Due to the iterative nature of the required assessment and the fundamental role of the interaction between users and technologies, comparative early results may allow refining the questionnaires (by country, disease, profile of end user, gender, functionality and technology tested). Significantly, the questionnaires will be modified throughout the project according to the service development.

TENDER USER EXPERIENCE QUESTIONNAIRE: PATIENT VERSION

TeNDER user experience questionnaire for patients is composed by:

- An autonomy questionnaire, with which the percentage of autonomy of the patient will be measured before and after the pilot. The patient will be asked to answer 6 questions using a 5-point scale.
- a TeNDER satisfaction rate questionnaire will be performed at the end of the pilot to assess the satisfaction percentage of TeNDER. The patient will be asked to answer 4 questions using a 5-point scale.
- 2 questions regarding the number of visits (hospitals, day care centers, and/or rehabilitation rooms).
- Modular set function questionnaires: these questionnaires will assess the impact of each device used in the pilot on HR QoL of the patient.
- A question regarding events that could have affected QoL of the patient.

TENDER USER EXPERIENCE QUESTIONNAIRES: CAREGIVER VERSION

TeNDER user experience questionnaire for caregivers is composed by:

- a perceived QoL questionnaire, with which the percentage of perceived QoL of the caregiver will be measured before and after the pilot, evaluating his/her perceived well-being (physical, mental and social components of health related-QoL). The caregiver will be asked to answer 11 questions using a 5-point scale.
- A question regarding the satisfaction about the care of the patient. The caregiver will be asked to answer this question using a 5-point scale, before and after the pilot.
- a TeNDER satisfaction rate questionnaire that will be performed at the end of the pilot in order to assess the satisfaction percentage of TeNDER. The caregiver will be asked to answer 4 questions using a 5-point scale.
- 2 questions regarding the number of visits (hospitals, day care centers, and/or rehabilitation rooms) and the timesaving





- modular set function questionnaires: these questionnaires will assess the impact of each device used in the pilot on HR QoL of the caregiver.
- A question regarding events that could have affected QoL of the caregiver.

TENDER USER EXPERIENCE QUESTIONNAIRES: HEALTH AND SOCIAL PROFESSIONAL VERSION

TeNDER user experience questionnaire for health and social professionals is composed by:

- a working conditions questionnaire for the percentage evaluation of working conditions of health and social professionals involved in the project. Health and social professionals will be asked to answer 4 questions using a 5-point scale.
- 4 questions regarding the number of visits (hospitals, day care centers, and/or rehabilitation rooms) and timesaving
- a TeNDER satisfaction rate questionnaire will be performed at the end of the pilot to assess the satisfaction percentage of TeNDER. Health and social professionals will be asked to answer 2 questions using a 5-point scale.
- 4 questions regarding the usefulness of TeNDER.
- A question regarding events that could have affected QoL of health and social professionals.





4.4 HOW TO ASSESS KPIS ON QoL WITH QUESTIONNAIRES

The following tables show how the KPIs on QoL (Table 5) in the project will be assessed with questionnaires (Annex 1). The Tables describe how to assess KPIs on QoL with questionnaires in the patient (Table 7) and in caregivers (Table 8). Table 9 describes how to assess KPIs on working conditions with questionnaires in health and social professionals.

PATIENTS

Table 7: How to assess KPIs on QoL with questionnaires in patients

KPI: 15% increase in perceived health-related QoL.

HOW TO ASSESS: SF36 (pages 34 and 39)

KPI: Improvement physical well-being / QoL (measured by SF-36) 15% (~7-8 points)/ Improved interaction paradigms (User Experience Questionnaire) >90% satisfaction rate.

HOW TO ASSESS: SF36 (pages 34 and 39)/TENDER SATISFACTION RATE QUESTIONNAIRE (page 44)

KPI: Health-related quality of life measurement to patients of at least in 3 different conditions.

HOW TO ASSESS: MEASURING THE HEALTH-RELATED QoL IN ALL 3 PATIENT GROUPS (ALZHEIMER'S DISEASE, PARKINSON'S DISEASE, AND CARDIOVASCULAR DISEASE)

KPI: 10% increase autonomy

HOW TO ASSESS: AUTONOMY QUESTIONNAIRE (TENDER USER EXPERIENCE QUESTIONNAIRE, pages 38 and 43)

KPI: Patient and carer satisfaction of speed-up attention perception (>90% Questionnaires satisfaction)

HOW TO ASSESS: TENDER SATISFACTION RATE QUESTIONNAIRE (specific question "How satisfied are you with reports that lead to a Speed-up attention perception?", page 44)

CAREGIVERS

Table 8: How to assess KPIs on QoL with questionnaires in caregivers

KPI: 15% increase in perceived health-related QoL.



TENDER D. 7.1 QoL Assessment Methodology

HOW TO ASSESS: PERCEIVED QoL QUESTIONNAIRE (TENDER USER EXPERIENCE QUESTIONNAIRE, pages 50 and 51).

KPI: 10% increase satisfaction of relatives.

HOW TO ASSESS: QUESTION REGARDING THE SATISFACTION ABOUT THE CARE OF THE PATIENT (TENDER USER EXPERIENCE QUESTIONNAIRE, page 51 and 53).

KPI: Patient and care satisfaction of speed-up attention perception (>90% Questionnaires satisfaction).

HOW TO ASSESS: TENDER SATISFACTION RATE QUESTIONNAIRE (TENDER USER EXPERIENCE QUESTIONNAIRE, specific question "How satisfied are you with reports that lead to a Speed-up attention perception?" page 54).

KPI: Time saving for carers in waiting while patient is going to be attended (>10%)

HOW TO ASSESS: QUESTIONS REGARDING TIME-SAVING (TENDER USER EXPERIENCE QUESTIONNAIRE, page 53).

HEALTH AND SOCIAL PROFESSIONALS

Table 9: How to assess KPIs on working conditions with questionnaires in Health and social professionals

KPI: Improvement of working conditions of health and social care providers and professionals by at least 10% (measured with questionnaires).

HOW TO ASSESS: WORKING CONDITIONS QUESTIONNAIRE (TENDER USER EXPERIENCE QUESTIONNAIRE, page 60).

KPI: Reduction of average number of visits to the hospital at least 12%.

HOW TO ASSESS: QUESTIONS REGARDING THE NUMBER OF VISITS AND TIME-SAVING (TENDER USER EXPERIENCE QUESTIONNAIRE, page 61).

KPI: Reduction of time in access to clerical patient information at least 10%.

HOW TO ASSESS: QUESTIONS REGARDING THE NUMBER OF VISITS AND TIME-SAVING (TENDER USER EXPERIENCE QUESTIONNAIRE, page 61).

KPI: Improved interaction paradigms (User Experience Questionnaire) with >90% satisfaction rate.

HOW TO ASSESS: TENDER SATISFACTION RATE QUESTIONNAIRE (TENDER USER EXPERIENCE QUESTIONNAIRE, page 62).





5 QOL ASSESSMENT PROTOCOL

5.1 PATIENTS

An investigator contacts the eligible patients to provide oral information and present a detailed information document outlining the project and informed consent document to be understood and signed. Data collected and data procedures to be performed to evaluate the patients' QoL are described in the patient information sheet. Confirmation of willingness to participate is via a mutually signed consent document. Upon consenting, the patient undergoes a comprehensive point of entry questionnaire consisting of SF36 and TENDER User Experience Questionnaire. At the end of the pilot, the patient undergoes a Final Questionnaire consisting in SF36 adapted to consortium objectives and TENDER User Experience Questionnaire (Table 10).

In the control group both the pre-piloting and the post-piloting assessment will be performed by using SF36 (original form).

Point of entry questionnaire	 SF36 (original form) Autonomy Questionnaire of TeNDER USER EXPERIENCE QUESTIONNAIRE
Final questionnaire	 SF36 (contextualized to TeNDER) TeNDER USER EXPERIENCE QUESTIONNAIRE (Autonomy Questionnaire, questions regarding the number of visits, TeNDER Satisfaction Rate Questionnaire, Modular Set Function Questionnaire, a question regarding events that could have affected QoL of the patient).

Table 10: QoL Assessment protocol (patients)

5.2 CAREGIVERS

Upon consenting, the caregiver undergoes a comprehensive Point of Entry Questionnaire consisting in TeNDER User Experience Questionnaire. At the end of the pilot, the caregiver undergoes a Final Questionnaire consisting in the TeNDER User Experience questionnaire (Table 11).

Table 31: QoL assessment protocol (caregivers)

Point of entry questionnaire	 Perceived QoL Questionnaire, a question regarding the satisfaction about the care of the patient of TeNDER USER EXPERIENCE QUESTIONNAIRE.
Final questionnaire	 TENDER USER EXPERIENCE QUESTIONNAIRE (Perceived QoL Questionnaire, a question regarding the satisfaction about the care of the patient, questions regarding timesaving, TENDER Satisfaction Rate Questionnaire, Modular Set Function Questionnaire, question regarding events that could have affected QoL of the caregiver).





5.3 HEALTH AND SOCIAL PROFESSIONALS

Upon consenting, the health or social professional undergoes a comprehensive entry questionnaire consisting of a TeNDER User Experience Questionnaire. At the end of the pilot the patient undergoes a Final Questionnaire consisting in TeNDER User Experience questionnaire (Table 12).

Table 42: Working conditions assessment protocol (health/social professionals)

Point of entry questionnaire	 Working Conditions Questionnaire of TeNDER USER EXPERIENCE QUESTIONNAIRE.
Final questionnaire	 TENDER USER EXPERIENCE QUESTIONNAIRE (Working Conditions Questionnaire, questions regarding the number of visits and timesaving, TENDER Satisfaction Rate Questionnaire, questions regarding the usefulness of TENDER, question regarding events that could have affected QoL of health and social professionals.





6 USABILITY ASSESSMENT METHODOLOGY IN THE FIRST WAVES OF PILOTS

The first waves' usability assessment is an initial proposal that will be implemented throughout the entire project according to the early comparative results and the data collection from operable sensors and functionalities. This deliverable aims to select a quick and straightforward tool that will be implemented and tailored to the needs and characteristics of the stakeholders involved (including age, gender, country, cognitive capability, etc).

The usability assessment methodology in the first waves of pilots of TeNDER could be resumed in the following table (table 13).

Table 5: Usability assessment methodology in the first waves of pilots of TeNDER

PRE-PILOTING PHASE	POST-PILOTING PHASE
 Affinity for technology (pre-piloting phase): patients, caregivers, and health and social professionals will be asked to answer 1 question using a 5-point scale. 	 Quantitative assessment (post-piloting phase), using SUS questionnaire (patients, caregivers, and health and social professionals will be asked to answer a 10-item questionnaire with 5-point scales). Qualitative assessment (post-piloting phase), patients, caregivers, and health and social professionals will be asked to answer 3 open-ended questions.

All questions and SUS questionnaire are reported in the Annex 2.

The usability as mentioned earlier 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 elaborated in Task 6.2 and reported in D6.3.





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ANNEX 1: QUESTIONNAIRES FOR THE EVALUATION OF QoL

PATIENTS

POINT OF ENTRY QUESTIONNAIRE

SF 36 (ORIGINAL FORM)

GENERAL HEALTH:

	Excellent	Very Good	Good	Fair	Poor
In general, would					
health is:					

	Much better now	Somewhat better	About the same	Somewhat worse	Much worse than
	than one year ago	now than one year		now than one year	one year ago
		ago		ago	
Compared to one year ago, how would you rate your health in general now?					

LIMITATIONS OF ACTIVITIES:

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited a lot	Yes, Limited a Little	No, Not Limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.			
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			
Lifting or carrying groceries			
Climbing several flights of stairs			





Climbing one flight of stairs		
Bending, kneeling, or stooping		
Walking more than a mile		
Walking several blocks		
Walking one block		
Bathing or dressing yourself		

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Cut down the amount of time you spent on work or other activities		
Accomplished less than you would like		
Were limited in the kind of work or other activities		
Had difficulty performing the work or other activities (for example, it took extra effort)		

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
Cut down the amount of time you spent on work or other activities		
Accomplished less than you would like		
Didn't do work or other activities as carefully as usual		

SOCIAL ACTIVITIES:

	Not at all	Slightly	Moderately	Severe	Very Severe
Emotional problems interfered with					
your normal social					



activities with			
family, friends,			
neighbours, or			
groups?			

PAIN:

	None	Very Mild	Mild	Moderate	Severe	Very Severe
How much bodily pain have you had during the past 4 weeks?						

	Not at all	A little bit	Moderately	Quite a bit	Extremely
During the past 4					
did pain interfere					
with your normal					
work (including					
both work outside the					
home and housework)?					

ENERGY AND EMOTIONS:

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling.

	All of the time	Most of the time	A good Bit of the Time	Some of the time	A little bit of the time	None of the Time
Did you feel full of pep?						
Have you been a very nervous person?						
Have you felt so down in the dumps that nothing could cheer you up?						





Have you felt calm and peaceful?			
Did you have a lot of energy?			
Have you felt downhearted and blue?			
Did you feel worn out?			
Have you been a happy person?			
Did you feel tired?			

SOCIAL ACTIVITIES:

	All of the time	Most of the time	Some of the time	A little bit of the time	A little bit of the time
During the past four weeks, how much of the time has your physical health or emotional problems interfered with					
your social activities (like visiting with friends, relatives, etc.)?					

GENERAL HEALTH:

How true or false is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people					
I am as healthy as anybody I know					





I expect my health to get worse			
My health is excellent			

TENDER USER EXPERIENCE QUESTIONNAIRE

AUTONOMY QUESTIONNAIRE

1) How often do you require help from other persons in your daily activities? Please circle one number

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

2) How often do you postpone doing things as you don't feel confident? Please circle one number

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

3) How often do you confidently go out of your apartment/house? Please circle one number

Never	Rarely	Sometimes	Often	Always
(1)	(2)	(3)	(4)	(5)

4) How often do you feel lost? Please circle one number

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

5)How often do you call services to help you? Please circle one number

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)





6)How often do you feel safe at home? Please circle one number

Never	Rarely	Sometimes	Often	Always
(1)	(2)	(3)	(4)	(5)





FINAL QUESTIONNAIRE

SF36 (CONTEXTUALIZED TO TENDER)

GENERAL HEALTH:

	Excellent	Very Good	Good	Fair	Poor
In general, would					
you say your					
health is:					

	Much better now	Somewhat better	About the same	Somewhat worse	Much worse than
	than one year ago	now than one year		now than one year	one year ago
		ago		ago	
Compared to one year ago, how would you rate your health in general now?					

LIMITATIONS OF ACTIVITIES:

Even if your health status remains the same, using the TeNDER tool, quantify the limitation you have in each of the following activities:

	Yes, Limited a lot	Yes, Limited a Little	No, Not Limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.			
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			
Lifting or carrying groceries			
Climbing several flights of stairs			
Climbing one flight of stairs			
Bending, kneeling, or stooping			
Walking more than a mile			
Walking several blocks			





Walking one block		
Bathing or dressing yourself		

PHYSICAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Cut down the amount of time you spent on work or other activities		
Accomplished less than you would like		
Were limited in the kind of work or other activities		
Had difficulty performing the work or other activities (for example, it took extra effort)		

EMOTIONAL HEALTH PROBLEMS:

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities resulting from any emotional problems (such as feeling depressed or anxious)?

	Yes	No
Cut down the amount of time you spent on work or other activities		
Accomplished less than you would like		
Did not do work or other activities as carefully as usual		

SOCIAL ACTIVITIES

During the time you were using the TeNDER tool:

	Not at all	Slightly	Moderately	Severe	Very Severe
Emotional problems interfered with your normal social					





activities with			
family, friends,			
neighbours, or			
groups?			

PAIN

During the time you were using the TeNDER tool:

	None	Very Mild	Mild	Moderate	Severe	Very Severe
How much bodily pain have you had during the past 4 weeks?						

	Not at all	A little bit	Moderately	Quite a bit	Extremely
During the past 4					
weeks, how much					
did pain interfere					
with your normal					
work (including					
both work outside					
the					
home and housework)?					

ENERGY AND EMOTIONS:

During the time you were using the TeNDER tool:

	All of the time	Most of the	A good Bit of	Some of the	A little bit of	None of the
		time	the lime	time	the time	lime
Did you feel full						
of pep?						
Have you been						
a very nervous						
person?						
Have you felt						
so down in the						
dumps that						





nothing could cheer you up?			
Have you felt calm and peaceful?			
Did you have a lot of energy?			
Have you felt downhearted and blue?			
Did you feel worn out?			
Have you been a happy person?			
Did you feel tired?			

SOCIAL ACTIVITIES:

During the time you were using the TeNDER tool:

	All of the time	Most of the time	Some of the time	A little bit of the time	A little bit of the time
During the past					
four weeks, how					
much of the time					
has your physical					
health or					
emotional					
problems					
interfered with					
your social					
activities (like					
visiting with					
friends, relatives,					
etc.)?					

GENERAL HEALTH:

How true or false is each of the following statements for you?

Definitely t	true Mostly true	Don't know	Mostly false	Definitely false
--------------	------------------	------------	--------------	------------------





I seem to get sick a little easier than other people			
I am as healthy as anybody I know			
I expect my health to get worse			
My health is excellent			

TENDER USER EXPERICENCE QUESTIONNAIRE

AUTONOMY QUESTIONNAIRE

During the time you were using TeNDER tool:

1) How often did you require help from other persons in your daily activities? Please circle one number

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

2) How often did you postpone doing things as you don't feel confident? Please circle one number

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

3) How often did you confidently go out of your apartment/house? Please circle one number

Never	Rarely	Sometimes	Often	Always
(1)	(2)	(3)	(4)	(5)

4) How often did you feel lost? Please circle one number





Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

5)How often did you call services to help you? Please circle one number

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

6)How often do you feel safe at home? Please circle one number

Never	Rarely	Sometimes	Often	Always
(1)	(2)	(3)	(4)	(5)

NUMBER OF VISITS

Using TeNDER system:

	Yes	l don't know	No
Do you think that			
TeNDER system leads			
to a potential			
decrease of number			
of visits?			

	No reduction (0%)	Small (10%)	reduction	Moderate reduction (20-40%)	High (>50%)	reduction
How much do you think the number of visits has decreased?						



45



TENDER SATISFACTION RATE QUESTIONNAIRE

1)How satisfied are you with Tender system? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

2)Rate your experience with the Tender system. Please circle one number

Bad	Fairly bad	Normal	Great	Excellent
(1)	(2)	(3)	(4)	(5)

3) How satisfied are you with reports about your activities and progress? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

4) How satisfied are you with the overview of your health status and events from TeNDER? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

MODULAR SET FUNCTION QUESTIONNAIRE

FUNCTION: ENTRANCE DOOR AND/OR WINDOWS STATUS (safety and wellbeing)

	Yes	I don't know	No	I don't want to answer
Does the information about the door and/or windows open/closed status increase your perceived quality of life?				





Here we are going to ask you a question about the perception of usefulness of "Entrance door and/or windows status": think if this sensor has had an influence on your daily life

	Less	About the same	More	I don't know	I don't want to answer
Do you worry about having left the door open?					

How satisfied are you with "Entrance door and/or windows status" function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: INDOOR ENVIRONMENTAL MONITORING (safety and wellbeing)

	Yes	I don't know	No	I do not want to answer
Does the				
information on the				
Indoor air quality				
increase your				
perceived quality of				
life?				

Here we are going to ask you a question about the perception of usefulness of "Indoor environmental monitoring": think if this sensor has had an influence on your daily life

	Less	About the same	More	l don't know	I don't want to answer
Do you feel comfortable with knowing the temperature and air quality?					

How satisfied are you with "Indoor environmental monitoring" function? Please circle one number





Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: ADHERENCE TO DRUG TREATMENT (The person is notified to take the medication on a predefined schedule.)

	Yes	I don't know	No	I don't want to answer
Does the reminder of medication increase your perceived quality of life?				

Here we are going to ask you a question about the perception of usefulness of adherence to drug treatment (reminder for medication intake): think if this function has had an influence on your daily life

	Less	About the same	More	l don't know	I don't want to answer
Do you forget to take your medication?					

How satisfied are you with "Adherence to drug treatment" (reminder for medication intake) function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: MEDICAL EXAMINATIONS (CALENDAR FOR, Reminders of medical therapies and exercises, appointments to MD)

	Yes	I don't know	No	I don't want to
				answer
Does the calendar				
for medical				
examinations				
increase your				
perceived quality of				
life?				





Do the reminders on		
important events		
and appointments		
help you in your		
daily living?		

How satisfied are you with the calendar for medical examinations? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: ROOM-LEVEL LOCALIZATION (in which room, for how long)

	Yes	l don't know	No	I don't want to
				answer
Does the localization information (for instance wristband/bracelet that determines the				
room-level position) increase your perceived quality of life?				

How satisfied are you with "Room-level localization" function (sensors for localization)? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: EMOTIONAL STATE DETECTION

	Yes	l do not know	No	I don't want to answer
Does the emotional state detection increase your perceived quality of life?				
Do you feel that early detection of unwanted emotions				





by the system helps		
you to prevent		
them?		

How satisfied are you with emotional state detection? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: QUALITY OF SLEEP

	Yes	l don't know	No	l don't want to answer
Does the information on your quality of sleep increase your perceived quality of life?				
Are you more comfortable during the day with your activities, emotions and events as you have the information about your sleep quality for the night before?				

How satisfied are you with sensors for quality of sleep? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)





FUNCTION: WELLBEING (for instance: sensors for health status, calendar, communication services, applications to use games)

	Yes	I don't know	No	I don't want to answer
Do these TeNDER sensors increase your perceived quality of life?				
Do you feel more autonomous by using these sensors?				

How satisfied are you with sensors for safety and wellbeing? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: FALL DETECTION (safety)

	Yes	I don't know	No	I don't want to answer
Does the information on falls increase your perceived quality of life?				
Do you feel safer due to the monitoring of your health?				

How satisfied are you with sensors for fall detection? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)





QUESTION REGARDING EVENTS THAT COULD HAVE AFFECTED QoL

In the last two months, have you faced some of the following issues?

Financial difficulties	Family problems	Have overcome virus infection	Work problems of your own or someone close to you	Others	No





CAREGIVERS

POINT OF ENTRY QUESTIONNAIRE

TENDER USER EXPERIENCE QUESTIONNAIRE

PERCEIVED QOL QUESTIONNAIRE

1)How would you rate your quality of life? Please circle one number

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)

2)How often do you feel calm and relaxed?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

3) How do you feel when you are not with the person who you are caring for?

Very insecure	Insecure	A little insecure	Safe	Very safe
(1)	(2)	(3)	(4)	(5)

4) How often do you need to check for his/her needs in a day?

Always	Quite frequently	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

5) How often do you need to visit/to attend the person who you are caring for?

Always	Quite frequently	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

6) How would you rate your physical status?

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)





7) Do you feel the person you are caring for is dependent on you?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

8) Do you feel stressed between caring for the person you take care for and trying to meet other responsibilities for your family or work?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

9) Do you feel your health has suffered because of your involvement with the person you are caring for?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

10) Do you feel you could do better in taking care of the person you care?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

11) How often do you feel your cared person is safe at home when you leave it? Please circle one number

Never	Rarely	Sometimes	Often	Always
(1)	(2)	(3)	(4)	(5)

QUESTION REGARDING THE SATISFACTION ABOUT THE CARE OF THE PATIENT

How do you feel about his/her care?

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FINAL QUESTIONNAIRE





TENDER USER EXPERIENCE QUESTIONNAIRE

PERCEIVED QOL QUESTIONNAIRE

1)How would you rate your quality of life? Please circle one number

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)

2)How often do you feel calm and relaxed with the app and the sensors?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

3) How do you feel when you are not with the person who you are caring for with the app and the sensors?

Very insecure	Insecure	A little insecure	Safe	Very safe
(1)	(2)	(3)	(4)	(5)

4) How often do you need to check for his/her needs in a day with the app and the sensors?

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

5) How often do you need to visit/to attend to the person you are caring for with the app and the sensors?

Always	Often	Sometimes	Rarely	Never
(1)	(2)	(3)	(4)	(5)

6) How would you rate your physical status?

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)

7) Using the app and the sensors, do you feel the person you are caring for is dependent on you?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)





8) Using the app and the sensors, do you feel stressed between caring for the person you take care of and trying to meet other responsibilities for your family or work?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

9) Using the app and the sensors, do you feel your health has suffered because of your involvement with the person you are caring for?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

10) Using the app and the sensors, do you feel you could do better in taking care of the person you care?

Never	Rarely	Sometimes	Quite frequently	Always
(1)	(2)	(3)	(4)	(5)

11)Using the app and the sensors, how often do you feel your cared person is safe at home when you leave it? Please circle one number

Never	Rarely	Sometimes	Often	Always
(1)	(2)	(3)	(4)	(5)

QUESTION REGARDING THE SATISFACTION ABOUT THE CARE OF THE PATIENT

How do you feel about his/her care, using the app and the sensors?

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

QUESTIONS REGARDING TIME-SAVING

	Yes	I don't know	No





Do you think that TeNDER system leads		
to a decrease of waiting time while patient is going to be attended?		

	No reduction (0%)	Small Reduction (10%)	Moderate (20-40%)	reduction	High reduction (>50%)
Can you quantify the reduction of waiting time?					

TENDER SATISFACTION RATE QUESTIONNAIRE

1) How satisfied are you with Tender system? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

2)Rate your experience with Tender system. Please circle one number

Bad	Fairly bad	Normal	Great	Excellent
(1)	(2)	(3)	(4)	(5)

3) How satisfied are you with the reports about activities and progress of the patient? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

4) How satisfied are you with the overview of the patient's health status and events from TeNDER? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)





MODULAR SET FUNCTION QUESTIONNAIRE

FUNCTION: ENTRANCE DOOR AND/OR WINDOWS STATUS (safety and wellbeing)

	Yes	I don't know	No	I don't want to answer
Does the sensor on the door and/or the windows increase your perceived quality of life?				

Here we are going to ask you a question about the perception of usefulness of "Entrance door/and or windows status", think if this function has had any influence on your care work.

	Less	About the same	More	I don't know	l don't want to answer
How often does he/she forget to close the (entrance) door and/or the windows?					

How satisfied are you with "Entrance door and/or windows status" ? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: INDOOR ENVIRONMENTAL MONITORING (safety and wellbeing)

	Yes	I don't know	No	I don't want to
				answer
Does the				
information on the				
Indoor air quality				
increase your				
perceived quality of				
life?				

Here we are going to ask you a question about the perception of usefulness of Indoor environmental monitoring: think if this sensor has had an influence on your care work.





	Less	About the same	More	l don't know	I don't want to answer
Do you feel comfortable with knowing the temperature and air quality of the place where the person you are caring for is?					

How satisfied are you with Indoor environmental monitoring function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: ADHERENCE TO DRUG TREATMENT (The person is notified to take the medication on a predefined schedule.)

	Yes	I don't know	No	I don't want to answer
Does the reminder for medication increase your perceived quality of life?				
Do the reminders on medical examination and other important events help you in your care work?				
Do the reminders on Adherence to drug treatment increase your perceived quality of life?				
Do the Adherence to drug treatment in form of reminder for medications and/or pill dispenser help you in your care work?				





Here we are going to ask you a question about the perception of usefulness of Adherence to drug treatment (reminder for medication intake), think if this function has had any influence on your care work.

	Less	About the same	More	I don't know	I don't want to answer
How often does he/she forget to take his/her medication?					

How satisfied are you with "Adherence to drug treatment" function (reminder for his/her medication and/or pill dispenser)? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: MEDICAL EXAMINATIONS (CALENDAR FOR, Reminders of medical therapies and exercises, appointments to MD)

	Yes	I don't know	No	I don't want to
				answer
Does the calendar				
examination				
schedule help you in				
your care work?				
Do the reminders on				
important events				
and appointments				
help you in your				
he/she can act more				
confident?				
Does the calendar				
for medical				
examinations				
increase your				
perceived quality of				
life?				

How satisfied are you with Calendar for medical examinations? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)





FUNCTION: ROOM LOCALIZATION MONITORING (sensors for localization inside the house, which room and for how long)

	Yes	I don't know	No	I don't want to answer
Does room localization help you in your care work?				
Do you feel safer with room localization functionality the person is using?				
Do you have more freedom due to room localization functionality the person is using?				
Does this function increase your perceived quality of life?				
Does it help monitoring activity recognition and path-tracking?				

How satisfied are you with "Room localization monitoring" function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: EMOTIONAL STATE DETECTION

	Yes	I don't know	No	l don't want to answer
Do you feel that early detection of unwanted emotions by the systems helps you to prevent them?				
Does the emotional state detection of a person you are caring for help you in your care work?				





Does the emotional		
state detection		
increase your		
perceived quality of		
life?		

How satisfied are you with emotional state detection? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: QUALITY OF SLEEP

	Yes	I don't know	No	I don't want to answer
Are you more comfortable during the day with your activities, emotions and events as you have the information about his/her sleep quality for the night before?				
Does having the information about sleep quality increase your perceived quality of life?				

How satisfied are you with quality of sleep monitoring? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(0)	(1)	(2)	(3)	(4)

FUNCTION: WELLBEING (for instance: sensors for health status, calendar, communication services, applications to use games)

Yes	I don't know	No	I don't want to
			answer



Does monitoring of the health and wellbeing of a person you are caring for help you in in your care work?		
Do the reports on wellbeing help you in your care work?		
Do these reports increase your perceived quality of life?		

How satisfied are you with the reports about wellbeing (for instance: sensors for health status, calendar, communication services...)? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: FALL DETECTION (safety)

	Yes	I don't know	No	I don't want to answer
Does these TeNDER alerts/reports increase your perceived quality of life?				
Do you feel more peace due to the monitoring of possible falls of a person you are caring?				

How satisfied are you with sensors for fall detection? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)





QUESTION REGARDING EVENTS THAT COULD HAVE AFFECTED QoL

In the last two months, have you faced some of the following issues?

Financial	Family	Have	Work problems	Others	No
difficulties	problems	overcome virus	of your own or		
		infection	someone close		
			to you		





HEALTH AND SOCIAL PROFESSIONALS

POINT OF ENTRY QUESTIONNAIRE

TENDER USER EXPERIENCE QUESTIONNAIRE

WORKING CONDITIONS QUESTIONNAIRE

1)	How would	you rate	your working	conditions?
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Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)

2) As regards your working activities, how would you rate your time management?

. –	. –			-
Very poorly optimized	Poorly optimized	Normally optimized	Well-optimized	Very well- optimized
(1)	(2)	(3)	(4)	(5)

3) How would you rate your quality of life during your work?

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)

4) How would you rate the communication between you and the patient or the carer?

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)

FINAL QUESTIONNAIRE

TENDER USER EXPERIENCE QUESTIONNAIRE

WORKING CONDITIONS QUESTIONNAIRE

1) How would you rate your working conditions using TeNDER?

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)





2) As regards your working activities, how would you rate your time management using TeNDER?

Very poorly optimized	Poorly optimized	Normally optimized	Well-optimized	Very well- optimized
(1)	(2)	(3)	(4)	(5)

3) How would you rate your quality of life during your work using TeNDER?

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)

4) How would you rate the communication between you and the patient or the carer using TeNDER?

Very poor	Poor	Normal	Good	Excellent
(1)	(2)	(3)	(4)	(5)

NUMBER OF VISITS AND TIME-SAVING

Using TeNDER system:

	Yes	l don't know	No
Do you think that			
TeNDER system leads			
to a potential			
decrease of number			
of visits?			

	No reduction (0%)	Small Reduction (10%)	Moderate (20-40%)	reduction	High reduction (>50%)
How much do you think the number of visits has decreased?					

Yes	l don't know	No
-----	--------------	----





Do you think that TeNDER system leads		
to a potential		
decrease of time in		
access to patient		
clerical information?		

	No reduction (0%)	Small Reduction (10%)	Moderate reduction (20-40%)	High reduction (>50%)
How much do you think the time in access to patient clerical information has decreased?				

TENDER SATISFACTION RATE QUESTIONNAIRE

1)How satisfied are you with Tender system? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

2)Rate your experience with Tender system. Please circle one number

Bad	Fairly bad	Normal	Great	Excellent
(1)	(2)	(3)	(4)	(5)

INFORMATION ABOUT THE USEFULNESS OF TENDER

1) Do you get more information about him/her and find this useful?

Yes	I don't know	No

2) Does TeNDER system improve your approach to the patient?

Yes	l don't know	No





3) Have you found something new that improves your knowledge of him/her using TeNDER system?

Yes	I don't know	No

4) Do you feel that you can apply better or more specific therapies to the patient because of the system?

	Yes	I don't know	No
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QUESTION REGARDING EVENTS THAT COULD HAVE AFFECTED QoL

In the last two months, have you faced some of the following issues?

Financial	Family	Have	Work problems	Others	No
difficulties	problems	overcome virus	of your own or		
		infection	someone close		
			to you		





ANNEX 2: USABILITY ASSESSMENT (FIRST WAVES OF PILOTS)

PRE-PILOTING PHASE (FOR PATIENTS, CAREGIVERS, HEALTH AND SOCIAL PROFESSIONALS)

AFFINITY FOR TECHNOLOGY

I like testing the functions of new technical systems.

Completely disagree	Largely disagree	Slightly disagree	Slightly agree	Largely agree	Completely agree

POST-PILOTING PHASE (FOR PATIENTS, CAREGIVERS, HEALTH AND SOCIAL PROFESSIONALS) SUS QUESTIONNAIRE

1)I think that I would like to use this system frequently.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

2)I found the system unnecessarily complex.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

3)I thought the system was easy to use.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

4)I think that I would need the support of a technical person to be able to use this system.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

5)I found the various functions in this system were well integrated.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
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I	(1)	(2)	(2)	(4)	(_)
	(1)	(Z)	(3)	(4)	(5)

6)I thought there was too much inconsistency in this system.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

7)I would imagine that most people would learn to use this system very quickly.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

8)I found the system very cumbersome to use.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

9)I felt very confident using the system.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

10)I needed to learn a lot of things before I could get going with this system.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

OPEN ENDED QUESTIONS

- 1) How do you feel with TeNDER sensors?
- 2) What do you like less about TeNDER sensors?
- 3) What do you like more about TeNDER sensors?

