Project Title:	**Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions**
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Topic:	PHC-21-2015: Advancing active and healthy ageing with ICT: Early risk detection and intervention
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Assessment protocol (final)

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Change History

Ver.	Date	Status	Author (Beneficiary)	Description
7.2.1	03.01.2018	Draft	Materia	Executive summary, introduction
7.2.2	14.02.2018	Draft	Materia	Revisions, additions, corrections
7.2.3	21.02.2018	Draft	Materia	1st draft completed. Submitted for review, comments, input
7.2.4	22.02.2018	Draft	SIGLA	Input
7.2.5	23.02.2018	Draft	AGE	Input
7.2.6	24.02.2018	Draft	UoP	Input
7.2.7	26.02.2018	Draft	Brainstorm	Review
7.2.8	27.02.2018	Draft	SIGLA	Review
7.2.9	28.02.2018	Final	Materia	Final version

1 EXECUTIVE SUMMARY

This is the first deliverable of WP7, “Testing and Evaluation”, whose main objective is to test the FrailSafe integrated system in validation scenarios, while placing emphasis on ethics standards. This is a public report of the outcomes of the work completed so far in T7.1 (Pilot planning and assessment protocol). The task is in progress (ending in M26, when the final version of this Assessment protocol will be delivered).

This deliverable aims to describe the assessment protocol to be used to demonstrate and validate the FrailSafe system. The protocol includes a detailed description of the procedure to carry out the validation process, which includes among others: the evaluation pilot studies, inclusion/exclusion criteria, experimental conditions, data collection instruments, and outcome measures. The work completed in T1.2 and reported in D1.2 are a basis for this process.

Parameters to be taken into account for method of validation include: identity, selectivity/specificity, limits of detection/quantification, linear and working range, precision (repeatability, intra and inter-laboratory reproducibility), trueness, robustness, accuracy of the measurement test, uncertainty.

The structure and format of the evaluation pilot studies will be based on the work performed in D1.3 (Architecture and technical specifications) and the principles of D1.2 (UCD methodology). In addition, the clinical methodology of the evaluation studies will be based on the rationale and methodology of the clinical trials held throughout the project, which is presented in analysis in D2.1-revised.

2 DOCUMENT INFORMATION

Contract Number:	H2020-PHC–690140	**Acronym:**	FRAILSAFE
Full title	Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions		
Project URL	http://frailsafe-project.eu/		
EU Project officer	Mr. Jan Komarek		

Deliverable number:	7.2	**Title:**	Assessment Protocol (Final)
Work package number:	7	**Title:**	Pilot planning and assessment protocol

Date of Contractual delivery	**28/02/2018 (M26)**	**Actual**	
Status	Draft ☐	Final ☒	
Nature	Report ☒ Demonstrator ☐ Other ☐		
Dissemination Level	Public ☒ Consortium ☐		
Abstract (for dissemination)	This deliverable describes the way the evaluation of the developed system will be organized, supported and managed throughout the duration of the project. This Deliverable benefits of and refers to elements coming from D1.2, and D1.3 and D2.1.		
Keywords	Pilot studies, assessment protocol, final, system validation, validation method		

Contributing authors (beneficiaries)	Stella Nicolaou (Materia) Marina Polycarpou (Materia) Kimon Volikas (Materia)			
Responsible author(s)	Elena Aristodemou		**Email**	elena@cnti.org.cy
	Beneficiary	Materia	**Phone**	+357 22 573 577

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2.4 List of abbreviations and acronyms

(in alphabetical order)

AR (Glasses)	Augmented Reality
BP	Blood Pressure
DSS	Decision Support System
FORA (BP monitor)	Blood Glucose Plus Blood Pressure Monitoring System
FS	FrailSafe
IMUs	Inertial Measurement Units
MO	Medical Objectives
PDA	Personal Digital Assistant
SUS	System Usage Questionnaire
TO	Technical Objectives
UCD	User Centred Design
UoP	University of Patras
VPM	Virtual Patient Model
WBAN	Wireless Body Area Network
WWBS	Wearable WBAN System
WWS	Wearable Wellness System

3 INTRODUCTION

System Testing and Evaluation (T&E) is an extremely important component of a system's development and it refers to the process by which a system is tested against its requirements and specifications (MITRE, 2014). T&E is further divided into two different processes, namely the Developmental Test and Evaluation (DT&E) and the Operational Test and Evaluation (OT&E). The Developmental Test and Evaluation (DT&E) is an iterative process of testing, taking place during the development of a system while Operational Test and Evaluation (OT&E) refers to testing and evaluation utilizing real users in simulated or pragmatic conditions (MITRE, 2014). Similarly, WP7 aims at testing the FrailSafe integrated system in validation scenarios, using real users. In order to achieve that, WP7 comprises of a pilot planning and assessment protocol task, through which D7.1 and D7.2 are being prepared.

Specifically, Task 7.1 (Pilot planning and assessment protocol) lays the ground for the pilot evaluation studies. It consists of designing and planning the way the pilot studies will be organized, supported and managed throughout the duration of the project. A basis for this task derives from the results of T1.4.

Therefore, D7.1, Assessment Protocol (version a) was developed to:

- Describe the upcoming pilot evaluation studies in terms of design, planning and management throughout FRAILSAFE project,
- Attempt a first version of the overall assessment protocol for the integrated FRAILSAFE system.

D7.2 focuses on refining and finalizing the Assessment Protocol developed in D7.1, outlining in detail the testing and evaluation activities of the FrailSafe project.

The project validation activities will consist of the evaluation the FrailSafe system, through a longitudinal demonstration involving a sample of 75 seniors of all stages of frailty who will be monitored for six months (plus three months follow-up). The specific goal of the latter is to evaluate whether FrailSafe effectively encourages self-care support for frailty.

In this deliverable, which is the result of the work completed so far in WP7, it will be presented in detail:

- The FrailSafe Assessment Protocol in the wider context of the projects' objectives
- The design and planning of the way the pilot studies will be organized, supported and managed during the project's lifecycle (A basis for this task lays on the results of T1.4-D1.3)

3.1 D7.2 in the context of the project's objectives

3.1.1 Overview

The ageing population is rapidly increasing worldwide and the 60+ age group is estimated to reach 2.1 billion by 2050 (UN, 2017). Actions aiming to increase the combination of increased life expectancy with quality of life and to improve the healthy life indicator (number of years without disability), are necessary.

Frailty is a biological syndrome of decreased reserve and resistance to stressors, resulting from cumulative declines across multiple physiologic systems and causing vulnerability to adverse outcomes (Buckinx, 2015). Susceptibility to stressors is influenced by biological,

behavioural, environmental, and social risk factors, with the main consequence being an increased risk for multiple adverse health outcomes, including disability, morbidity, falls, hospitalization, institutionalization, and death (Buckinx, 2015). Frailty causes older adults to become more vulnerable to stressors and this has major health care implications, such as increased risk of incidence of falls, delirium, worsening of mobility, disability, hospitalization, institutionalization, and mortality. All these have an impact on planning and providing health and social services, as it increases both the burden and the cost of care for the older adult, their family and society (Buckinx, 2015).

Frailty is considered as a condition at which the symptoms develop during a large period of time and affect directly the everyday life of the older persons. Providing means to them in order to self-monitor their medical, physical, social, psychological, cognitive and functional aspects would allow them and their caregivers to monitor, handle and prevent the symptoms of frailty. Frailty could be delayed by developing a set of measures and tools and health evidence-based recommendations.

In that respect, the FrailSafe project aims to create new measures of qualitative and quantitative assessments leading to a model which will be able to better understand, detect and predict frailty and its relation with other health conditions. Additionally, it purports to develop a real-life sensing and intervention platform for older persons and to achieve all these through a safe and acceptable system for the ageing population while reducing the health care system costs.

3.1.2 Medical and technological objectives

Testing and Evaluation is directly linked to the Medical and Technological Objectives of the project, as in order for each one of them to be successfully achieved, it is imperative that the system and/or processes are evaluated and assessed. Table 1 analyzes the relation of Testing and Evaluation to the each one of the project's Medical Objectives.

Table 1: Relation of Testing & Evaluation to FrailSafe's Medical Objectives

M01	***Objective***	Better understand frailty and its relation to co-morbidities
	Relation with T&E Tasks	The evaluation pilot study results will largely contribute to this objective, as the chosen metrics and co-morbidities will be tested on whether they do indeed relate to frailty prediction.
M02	***Objective***	Develop quantitative and qualitative measures to define frailty
	Relation with T&E Tasks	The FrailSafe system assessment aims to establish whether this objective has been achieved and to which degree, as well as to suggest further steps for improvement in order to increase measurement validity and reliability
M03	***Objective***	Use these measures to predict short and long-term outcome
	Relation with T&E Tasks	The FrailSafe system assessment procedures will test the reliability and the functionality of the system, not only as a diagnostic, but also as a prognostic tool
M04	***Objective***	Develop real life tools for the assessment of physiological reserve and external challenges
	Relation with T&E Tasks	System usability and acceptability are integral components of the evaluation, which will be addressed thoroughly through the assessment process
M05	***Objective***	Provide a model sensitive to change in order that pharmaceutical and non-pharmaceutical interventions which will be designed to delay, arrest or even reverse the transition to frailty, can be tested.

	Relation with T&E Tasks	The assessment process will test the effectiveness of the system taking into consideration the reported serious adverse events and outcomes during the evaluation phase, as well as the transition to the next frailty level.
M06	***Objective***	Create "prevent-frailty" evidence based recommendations for older people regarding activities of daily living, lifestyle, nutrition, etc. to strengthen the motor, cognitive, and other "anti-frailty" activities through the delivery of personalized treatment programs, monitoring alerts, guidance and education and estimate the influence of these interventions
	Relation with T&E Tasks	Comparing the effect of FRAILSAFE-generated individualized lifestyle recommendations vs. general, existing practice recommendations, and their short term and potential impact, is part of the assessment process.
M07	***Objective***	Achieve all with a safe and acceptable to older people system.
	Relation with T&E Tasks	This is a main objective of WP7, and largely determines the usefulness of FRAILSAFE. Safety refers both to objective and perceived safety, and acceptability determines usability.

Similarly, Table 2 analyzes the relation of Testing and Evaluation tasks with the Technological Objectives of the project.

Table 2: Relation of Testing & Evaluation to FrailSafe's Technological Objectives

T01	***Objective***	Design and development of hardware components (ambient and wearable sensors, body node coordinator (e.g., smart phone) optimised in terms of ergonomics, user-friendliness compactness, unobtrusiveness and energy consumption that can be used indoors and outdoors providing functionalities for effective yet simple and economical personalized monitoring of the individual patient's condition for purposes of detecting/alerting/averting of frailty events, merged to an integrated system, explicitly taking into account security and privacy issues.
	Relation with T&E Tasks	All of the abovementioned parameters, of the developed integrated system, are the main components under testing and evaluation in WP7. The main aim is to validate that the system meets all of these requirements.
T02	***Objective***	Design and development of efficient signal processing algorithms for low level processing including signal enhancement, activity classification, energy expenditure, and behavioural monitoring.
	Relation with T&E Tasks	The effectiveness of the system in these aspects affects its validity.
T03	***Objective***	Development of a self-adaptive Virtual Patient Model offering optimal services for managing frailty ranging from critical situation management, facilitating social integration to day-to-day self-management and health preservation based on a personalized patient profile.
	Relation with T&E Tasks	The feedback of health care professionals on the Virtual Patient Model is important, in order to ensure that the included parameters are useful and targeted
TO4	***Objective***	Development of a generic monitoring and management infrastructure on which modular services and patient-specific applications will be built.
	Relation with T&E Tasks	The modules are added into the system throughout the project. Assessment will evaluate how they co-function as a whole.

TO5	***Objective***	Development of novel methods for the offline management, fusion and analysis of multimodal and advanced technology data from social, behavioural, cognitive and physical activities of frail older people and application of these methods to manage and analyze the large amounts of data collected leading to integrative interpretation and better understanding of frailty, introduction of new quantitative frailty biomarkers as well as frailty metrics, correlation of co-morbidities and frailty, advanced decision making capabilities (DSS) assisting diagnosis by medical professionals
	Relation with T&E Tasks	Health care and IT professionals are among the end user groups which will evaluate FrailSafe as part of the assessment protocol
TO6	***Objective***	Development of real-time data management and data mining methods effectively making decision assessing frailty levels, detecting frailty risks and triggering alarms in case of emergency situations (e.g., fall, loss of orientation, incoherent utterances or suicidal manifestations in written text) based on minimal processing of real-time multi-parametric streaming data and economical personalized monitoring guided by a minimal number of sensors and parameters (FrailSafe prediction engine and Risk Factor Evaluation).
	Relation with T&E Tasks	Evaluation of clinical studies data analysis will determine whether this objective has been achieved and what can be done for further improvement.
TO7	***Objective***	Investigation of processing time, storage and communication trade-offs for real-time analysis at the WBAN or the phone/PDA and use of data reduction and summarization techniques for reducing raw streaming data to secondary or tertiary parameters. Effectively use Virtual Patient Models and results from the offline data mining of multi-parametric data to make real-time analysis more efficient and targeted.
	Relation with T&E Tasks	Virtual Patient Model is an important part of the integrated system for health care professionals, and will be addressed using the procedures laid out in this protocol.
TO8	***Objective***	Development of dynamically synthesized, personalized and highly innovative AR games consisting of different scenarios that measures parameters of behavioural, cognitive and physical domain while implementing various intervention strategies.
	Relation with T&E Tasks	AR games are part of the integrated FS system and will be assessed along with all other components in the testing and evaluation tasks.
T09	***Objective***	Extensive testing of the FrailSafe integrated system in several validation scenarios while ensuring compliance with ethics standards.
	Relation with T&E Tasks	This refers to the main objective of WP7 along with its Milestones MS11 “definition of evaluation scenarios and applications and MS14 “FrailSafe outcomes evaluation”.

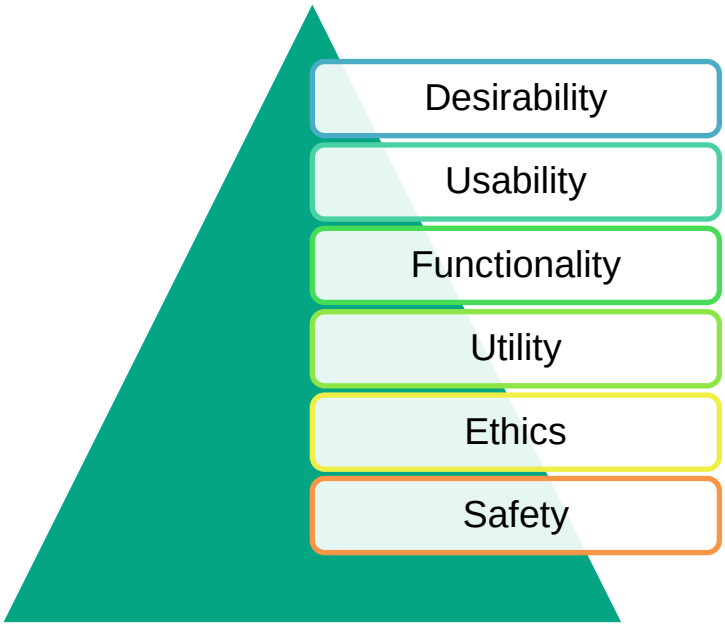
3.2 Rationale behind the chosen assessment procedures

The assessment protocol of FrailSafe aims to evaluate the integrated system’s test results against the following general criteria:

- Effectiveness of the FS system against goals stated in the project’s description
- Range of Impact of the FS system
- Allocated resources and how they relate to the effectiveness/ impact
- Time required for the FS system to be effective
- Key stakeholder’s satisfaction

In the UCD methodology (described in detail in D1.2), which is implemented throughout the project, including the pilot evaluation studies, the evaluation process and goals is built along with the development of the system. For example, in the beginning, when only few parts of the system were available, the evaluation focused on validating the concept and certain interaction paradigms. In contrast, with the more integrated functional prototype, the research team wishes to measure a variety of aspects of the system, which appear in the following diagram:

Figure 1: Evaluation of User Requirement Types to be Addressed



4 UCD METHODOLOGY IN THE PILOT EVALUATION STUDIES

Deliverable 1.2 (User requirements, use cases, UCD methodology and final protocols of evaluation studies, M12) identified end-user needs and how this knowledge has led to the definition of the use-case scenarios on which the system design was based. The UCD methodology is applied throughout the project, including the FrailSafe assessment.

More specifically, the assessment procedure can be summarized as follows:

- Identification of user groups (see Table 3)
- Design of the assessment campaign
- Administration of evaluation tools (data collected from the usage of the system, Questionnaires, interviews, surveys and focus groups)
- Analysis of the collected data
- Results of the FrailSafe system assessment

Questionnaires, interviews, surveys and focus groups with different user groups will be conducted in order to evaluate the integrated FrailSafe system and validate the chosen metrics. Thus, at the end of the evaluation studies, it will be possible to determine whether

the metrics chosen to investigate do indeed create a matrix which can act as a comprehensive tool to diagnose, predict and even reverse frailty.

The priorities and user needs extracted from the user requirements reported in D1.2, and whose satisfaction needs to be evaluated, are:

Table 3: Identification of user groups

User requirement	Older adults	Families	Health care professionals	Researchers	Commercial organisations	IT developers
Need for improved understanding of frailty, its causes and ways to prevent it.	☑	☑	☑	☑	☑	☑
Need for individualized help from the healthcare professionals.	☑	☑				
Need for participation by the older people and sending feedback to the healthcare personnel.			☑		☑	
Need for enjoyable frailty-preventing activities that require physical and cognitive effort.	☑	☑				
Need for clinical assessment methods that are easy to perform.	☑		☑			
Need for predictive treatment functionalities in order to reduce the risk of frailty.	☑	☑	☑		☑	
Need for real-time monitoring and alerts in order to reduce the anxiety of family members.	☑	☑	☑		☑	☑
Need for sensory and measurement components that are safe to use by the older people.			☑			☑
Need for sensory and measurement components that are easy and comfortable to use.	☑	☑	☑			
Need for acceptable wearable components that are not obtrusive.	☑	☑	☑			
Need for frailty-related software components and games that are easy to use and learn.	☑		☑		☑	☑
Need for hardware interaction devices that are easy to use.	☑	☑	☑			☑
Need for extensive data collection for research.			☑	☑		☑

A more detailed description of the procedure and steps carried out to specify the abovementioned user needs and priorities can be found in deliverable 1.2.

4.1 Evaluation - Seniors

As part of the Testing and Evaluation tasks, and building on the continuous involvement of users in the development process, 150 seniors from all three clinical centres will be recruited to participate in the Evaluation Phase of the project (described in detail in the next section). The Evaluation Group will be active from Month 31 to Month 36 of the project, and all data

collected will be used to assess the FrailSafe system in all the above mentioned parameters. Seniors, will be asked right before the completion of their participation to respond to some questionnaires, providing their own assessment on the usability, usefulness, satisfaction and acceptance of the FrailSafe system.

4.2 Evaluation - Other Target Groups

In addition to the seniors, the main end users of the FrailSafe system, people from all other identified target groups will be engaged in the evaluation of the FrailSafe system. The targeted users as well as the areas of feedback they will provide are:

Table 4: Targeted User Groups

User Group	Areas of feedback
Older adults	Recorded data, acceptance, usefulness, usability, safety, ethics, ease of learning, desirability, suggestions for improvement
Families	usefulness, usability, safety, ethics, performance, ease of installation, ease of learning, etc.
Health care professionals	usefulness, usability, safety, ethics, performance, ease of installation, ease of learning, etc.
Commercial organisations	Usefulness, commercialisation potential, marketability, acceptance and exploitation of the integrated system in similar or different applications, costing.
Researchers	usefulness, usability, performance, ease of learning, ethics etc.
IT developers	Functionality, innovation, possible technological advancements, etc.

5 PILOT EVALUATIONS

Clinical studies through the vast duration of the study (M4-M30), aim to gather experimental data in order to feed computational models for the quantification of the FrailSafe system while at the same time guide its technical development. During M31-M36, the clinical evaluation studies will focus on evaluating and validating the FrailSafe integrated developments.

5.1 Small-Scale Evaluation

Following the launching of the first version of the developed system, there will be a small-scale evaluation in order to firstly test the ability of the signal analysis algorithms to automatically categorize the signals on the basis of older people's activities and characteristics and to secondly test the sensitivity of the sensors with respect to different environmental conditions.

The small-scale evaluation will be conducted in all three clinical centres (France, Greece and Cyprus), where a selection of ten (10) seniors per country will test the first integrated version of the FrailSafe system. The participants will be randomly selected, as they will be the ones that at the time of the small-scale evaluation have a planned FrailSafe system session scheduled.

The evaluation will utilize a predefined protocol, which will be followed by the participants at their house with the guidance of a trained clinician. The protocol is described in detail below:

5.1.1 Protocol for signal testing

Equipment needed:

- WWBS
- Independent IMU'S
  - ✓ Right Wrist
  - ✓ Left Wrist
  - ✓ Left Ankle
  - ✓ Right Ankle
  - ✓ Low waist
- Beacon set
- Smartphone
- Chronometer
- Tension meter

Start the chronometer at the same moment as the WWBS

And at the same time note down the local time displayed on the

ID :	**Date :**	**Start time (Smartphone) : __ :__**	
LAPS	**Actions**	**Time (Chronometer)**	**Remarks**
-	Instructions: The participant is asked to cross the hands in front of his/her chest and not use them. If he/she needs to use hands to sit and stand, the clinician notes it in the remarks. The lap changes at the 6th sit.		
Lap 1	**5 times sit and stand**		
Lap 2	Instructions: The participant is asked to reach an item the clinician is holding. The distance should seem reachable but it shouldn't be.		(Dead time)
Reaching forward:			
Lap 3	• Sitting position		
Lap 4	Instructions: The participant is asked to lean forward and try to rich the wall. He/she is placed at a position that is not to close, but also not too far from the wall.		(Dead time)
Lap 5	• Standing position		

Lap 6	Instructions: The participant is asked to lift each leg and stay there for as long as he/she can.		(Dead time)
Standing on one single foot:			
Lap 7	• On right leg (5-10 sec)		
Lap 8	• On left leg (5- 10 sec)		
Lap 9	Instructions: The participant is asked to stand with legs levelled to the opening of the shoulders.		(Dead time)
Standing with normal pace width:			
Lap 10	• With open eyes (10 sec)		
Lap 11	• With closed eyes (10 sec)		
Lap 12	Instructions: The participant is asked to stand with the legs closed.		(Dead time)
Standing with joined pace width:			
Lap 13	• With open eyes (10 sec)		
Lap 14	• With closed eyes (10 sec)		
Lap 15	Instructions: The participant is asked to walk up to the sticker on the floor (3m away) and return. The lap changes when he/she sits.		(Dead time)
Lap 16	**Time get up and go**		
Lap 17	Instructions: The participant is asked to walk for 30 seconds up and down in the room.		(Dead time)
Lap 18	**Gait speed (30 sec walking up and down)**		
Lap 19	Instructions: The participant is asked to pick up an object from the floor, in any way they can.		(Dead time)
Lap 20	**Pick an object up from the floor**		
Lap 21	Instructions: The participant is asked to take 5 short breaths quickly.		(Dead time)
Lap 22	**5 breaths quickly**		
Lap 23	Instructions: The participant is asked to walk to another room and return. The lap starts when the participant starts walking and changes when he/she is back next to the clinician.		(Dead time)
Lap 24	**In and out of the room**		

Lap 25	Preparation for blood pressure taking. The lap starts when the start button of the BP is pressed and stops when the screen shows the heart rate.		(Dead time)
Lap 26	**Blood pressure measurement (note down the Heart Rate only)**		
		End time (Smartphone): __ : __	

5.1.2 Calendar of Outdoor Activities

Further to the timed protocol, participants of the small-scale evaluation will be asked to note down their outdoor activities, as much as they can, within the duration of their active FrailSafe system session. Specifically, **IF** they go out on their own initiative, they will be asked to note down the time of departure and return, the activity they endorsed into, the method of travel (on foot or by car) and the approximate distance covered.

EXAMPLE:

ACTIVITY	TIME	TRAVEL WAY	DISTANCE
Got out to buy bread	11.20-11.45am	On foot	200m or two blocks
Went to gym- aerobic	17.00-17.45pm	By car	about 700m from home

5.1.3 Calendar of symptoms

Last, participants will be asked to note down if they experienced any unusual event, feeling or symptom while wearing the devices, specifying on the time this has happened. A list (shown right below) of predefined symptoms will be provided to them for easy completion.

SYMPTOM TIME

1. malaise/sickness undetermined
2. instability without fall
3. palpations
4. vertigo/dizziness
5. headache
6. pain (except headache)
7. fall
8. faintness without loss of consciousness
9. loss of consciousness
10. other, please specify.....

5.2 Field Trials (Evaluation Group)

The evaluation study will be performed in the 3 Clinical Centres which have run all clinical trials for the project: University of Patras (UoP), Greece; INSERM-Nancy, France; and MATERIA-Nicosia, Cyprus. Each centre will recruit 25 individuals for the evaluation group C and 25 individuals for the control group D. By this way a total of 150 community living subjects aged 70 years and older will be recruited.

Group C (evaluation group) will receive interventions: an application of the FrailSafe system (just like Groups A and B) in order to monitor frailty-related parameters. In addition, for evaluation purposes a subgroup will receive individualised interaction/feedback and personalized guidance in the form of consultation recommendations and assistance to its accomplishment. In the sections below the detailed protocol of the pilot evaluation studies is described.

5.2.1 Participant Characteristics

For the clinical evaluation trials, older participants are of the same profile as described in detailed participant profiling in D2.1. The inclusion and non-inclusion criteria are demonstrated in table 5.3 (derived from D2.1)

Table 5: Inclusion criteria

Inclusion criteria
Age ≥70 years
Informed consent provided
Exclusion criteria
Lack of wish to participate
Consent withheld
Inability to give consent because of incapacity
Inability to walk
Inability to speak Greek or French (see clinical centres)
Diagnosis of clinically significant cognitive impairment or score less than 24 on the Mini–Mental State Examination
Diagnosis of advanced malignancy, other terminal illness or an estimated life expectancy of less than 12 months
Active psychiatric disorder based on medical records or clinical opinion at the time of recruitment, current substance users, or excessive alcohol drinkers.

5.2.2 Sample size

Pilot studies are implemented on a small scale, aiming to show whether FRAILSAFE has potential to succeed on a larger scale or not.

The evaluation Group (Group C) and Control Group (group D) is comprised of 25 participants per group in each of the three centres. The sample size is considered adequate for the evaluation phase and has been determined based on feasible numbers according to financial and human resources.

Group (C) will be further divided in two sub-groups: participants of each centre with numbers 121-140 will belong to the “Standard” Evaluation Group; while those with numbers 141-145 will belong to the “Long Term” Evaluation Group.

Table 6: Clinical Evaluation study Groups

Group	**4-digit Participant serial number**
	Prefix of 1= Greece 2= Cyprus 3= France,
C- Evaluation	121-145
Ci- Standard Evaluation	121-140
Cii- Long term Evaluation	141-145

5.2.3 Randomisation

Group C, which is the Evaluation group, will be randomly selected. Group C and Group D (control group) are the only samples in the study which are randomly selected, due to practical difficulties in randomising Group A (start-up) and Group B (main). For this reason, recruitment efforts for Group C should occur early on, in order to gather a sufficient pool size for randomisation to occur. In this way, we will avoid any selection bias (even if with minimal effect) which was acknowledged in the selection method of the previous groups. Recruitment will take place individually by each clinical centre (Greece, France and Cyprus).

5.2.4 Design

Group C will be further randomised into two sub-groups.

Group Ci, standard evaluation group

Group Cii, long-term evaluation group

From this point onward in the study (M20-M30), recruitment campaigns will start again in order to create the pool of eligible subjects from which participants for group C and D will be randomly selected.

In addition, the participants of the evaluation group C will be further randomized (1:1) into two categories either to receive a tailored set of lifestyle, nutrition and exercise recommendations (predetermined recommendation and “intervention” proposals based on the monitoring performed using the FrailSafe system) or to receive general life style recommendations

(standard care). The technical personnel responsible for the extraction and analysis of data will be blind on the randomization procedure.

5.2.5 Evaluation Testing Protocol

Group C (evaluation) and Group D (control) are the groups which will be compared against each other. For consistency purposes, all Groups (Group A, Group B, Group C, and Group D) tested in the clinical trials follow the same steps 1-5 below (except step 2 is followed only in Groups C and D) then from step 6 onwards, each group has a different procedure according to its purpose.

Predictions on outcome events and on transition of frailty rates will be evaluated, together with rehabilitation effect of "FrailSafe". Compliance rates and user satisfaction will be also tested. Long term continuous monitoring data will be available to test compliance and feasibility. Shorter periods of monitoring will be compared with longer periods of monitoring to identify cost effective approaches. Part of this work could be considered a pilot randomized single blinded study for evaluating interventions and building a test model for pharmaceutical and non-pharmaceutical interventions.

Group Ci (Standard Evaluation Group) testing procedure (as described in D2.1, Clinical Study Methodology Revised)

1. Quick first verification of inclusion and exclusion criteria
2. Randomization to groups
3. Informed consent and attribution of a unique ID number
4. First part of clinical evaluation session: questionnaires to verify inclusion and not inclusion criteria, Fried's criteria of frailty, medical history and cognitive assessment will be administered (Annexes 1,2, 3,4,5)
5. Second verification of the inclusion/exclusion criteria according to the first part of the clinical evaluation's results. If exclusion, replacement of the participant and repetition of steps 1-5 for the next candidate1-5. As described above for all groups
6. Complete clinical evaluation session (M31) (Annexes2, 6, 7, 8, 9, 10, 11).
7. First FrailSafe system home visit (M31):
8. Blood sampling for telomeres
9. Fill in the evaluation form regarding the participant's housing (Annex 12)
10. Collect any questionnaires filled in by the participant since the last visit: written texts, social media and big five questionnaires
11. Complete any missing information of the clinical evaluation (i.e. scanning of a forgotten prescription, scanning of an older written text provided by the participant, write down dictated text)
12. Installation of the currently available FrailSafe system and explication of the use, the purposes and the technical issues of the FrailSafe material. Verification of its correct function
13. Provide contact details and instructions in case of any help needed
14. Set the next appointment to retrieve the FrailSafe material (5th day)
15. Maintenance of the FrailSafe system at home during 5 days
16. Short satisfaction interview in the day of FrailSafe system retrieval
17. FrailSafe system home visit (M33)
18. Administration of follow up questionnaire (Annex 13)

19. Installation of the currently available FrailSafe system and reminding of the use, the purposes and the technical issues of the FrailSafe material (Session 3.8). Verification of its correct function
20. Provide contact details and instructions in case of any help needed
21. Set the next appointment to retrieve the FrailSafe material (5th day)
22. Maintenance of the FrailSafe system at home during 5 days
23. User satisfaction interview in the day of FrailSafe system retrieval
24. Last FrailSafe system home visit (M35). Repetition of steps 12-15.
25. [Only for Patras]: Second blood sampling (M35)
26. Last clinical evaluation (M36) (Annexes 2-11)
27. Data collection of written text after the first time (Annex 14) (M36). The participant will either be helped to provide text by dictation or (s)he will write it down during the clinical assessment appointment.
28. Study's completion verification (Annex 15). Normally at the end (M36), but could be in anytime in case of premature withdrawal

Group Cii- Long-term Evaluation Group, N=5 in each centre

Steps 1-5 the same as above Group Ci

1. Complete clinical evaluation session (Annexes 2, 6,7, 8, 9, 10, 11) (M31)
2. First FrailSafe system home visit (M31):
    - Blood sampling for telomeres
    - Fill in the evaluation form regarding the participant's housing (Annex 12)
    - Collect any questionnaires filled in by the participant since the last visit: written texts, social media and big five questionnaires
    - Complete any missing information of the clinical evaluation (i.e. scanning of a forgotten prescription, scanning of an older written text provided by the participant, write down dictated text)
    - Installation of the currently available FrailSafe system and explication of the use, the purposes and the technical issues of the FrailSafe material (Session 3.8). Verification of its correct function
    - Provide contact details and instructions in case of any help needed
    - Set the next appointment to retrieve the FrailSafe material (5th day)
3. Maintenance of the FrailSafe system at home during 20 days
4. Short satisfaction interview in the day of FrailSafe system retrieval
5. One follow-up telephone call (M34)(Annex 13)
6. [Only for Patras]: Second blood sampling (M35)
7. Last clinical evaluation (M36) (Annexes 2-11)
8. Data collection of written text after the first time Annex 14) (M36). The participant will either be helped to provide text by dictation or (s)he will write it down during the clinical assessment appointment.
9. Study's completion verification (Annex15). Normally at the end (M36), but could be in anytime in case of premature withdrawal.

Group D- Control Group

Procedure

Steps 1-5 as other Groups above,

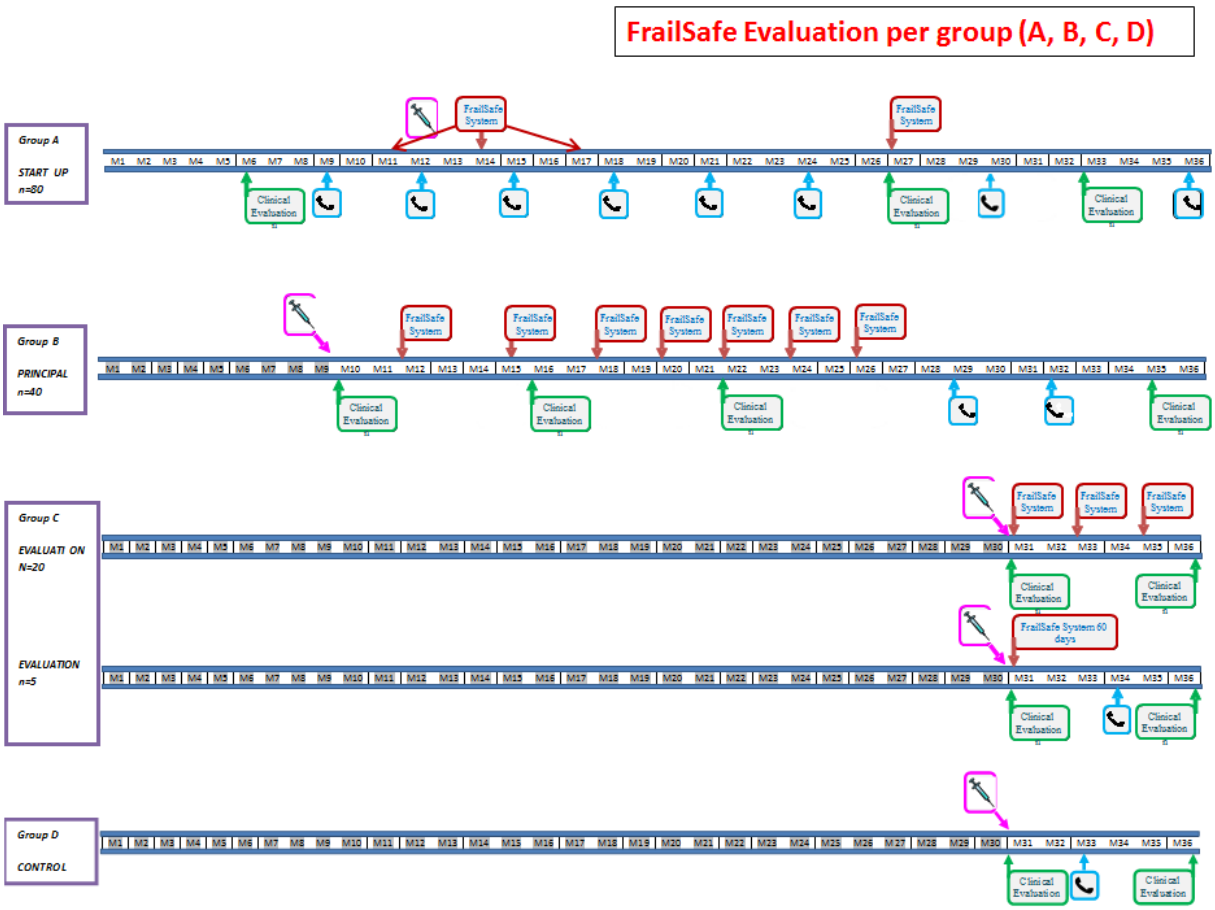
1. Complete clinical evaluation session (M31)

2. Blood sampling for telomeres (M31)
3. One follow-up telephone call (M33)(Annex 13)
4. Last clinical evaluation (M36) (Annexes 2-11)
5. Data collection of written text after the first time (Annex 14) (M36). The participant will either be helped to provide text by dictation or (s)he will write it down during the clinical assessment appointment.
6. Study's completion verification (Annex 15). Normally at the end (M36), but could be in anytime in case of premature withdrawal.

5.2.6 Testing actions timeline

Below is the master plan for the clinical trials of FrailSafe. Groups C and D appear last, showing the interventions for each group and the parallel evaluations they will receive.

Figure 2: FrailSafe evaluation timeline



As shown in the above timeline, the assessment protocol for the older users comprises of the following actions:

Table 7: Clinical Evaluation studies actions

MONTH	EVALUATION ACTIONS
31	Groups Ci, Cii and D receive clinical evaluation and blood sampling
	Group Ci receives a 5-day FrailSafe system session (#1) and a user satisfaction questionnaire kit
	Group Cii receives a 20-day FrailSafe system session
33	Group Ci receives a 5-day FrailSafe system session (#2) and a user satisfaction questionnaire kit Group Cii ends FrailSafe system session and receives user satisfaction questionnaire kit and a one-to-one interview Group D receives follow-up call
34	Group Cii receives follow-up call
35	Group Ci receive a 5-day FrailSafe system session (#3) and a user-satisfaction questionnaire kit and a one-to-one interview
36	Clinical Evaluation of Groups Ci, Cii and D

6 VALIDATION OF THE FRAILSAFE SYSTEM

Validation of the FrailSafe system is a critical process in order to ensure that

- FrailSafe is causing the desired outcome (internal validity) and
- The FrailSafe system application as tested is replicable, producing similar results in different settings (external validity)

6.1 Main Indicative Use Cases for the Assessment Phase

The goal of the system evaluation studies is to collect feedback about the functionality of the system as a whole, through complete usage scenarios (main indicative use cases from the list of identified use cases in D1.2).

Use cases are representative usage scenarios from the perspective of the different identified end-user groups. An indicative set of the main use cases identified in D1.2 will be the basis for the definition of the pilot studies to be executed during the evaluation phase of the project. Safety and Ethics requirements will be a priority in defining this process.

As in D1.2, The following types of use cases will be considered:

- Patient-oriented use cases
- Family-oriented use cases
- Healthcare professional-oriented,

- Researcher-oriented

6.1.1 Use cases to be used for the system assessment/validation

Based on the user requirements collection procedure described in D1.2, the specific use cases of FrailSafe were designed. The use cases are scenarios of usage of the various FrailSafe components, illustrating how they should perform and communicate with each other and as part of the integrated system. The project's use cases were split into four groups, one for each of the main target user types. A total of 27 use cases were designed. A detailed report was provided for each use case (D1.2), including a step-by-step flow of actions.

The above mentioned use cases are the basis for the design of the pilot trials during the evaluation period of the project. For this reason, following the use case definition, the current deliverable also contained an account on the evaluation protocols that will be followed, ensuring safety and ethics requirements throughout all user studies.

The evaluation studies utilizing use case scenarios involve the use of the integrated FrailSafe framework by all the main end-user groups. In a way, it is a compilation of many use cases described in D1.2, in 4 main evaluation test use-cases.

Use Case 1. The older user uses the integrated FS system

Use Case 2. The family uses the integrated FS system

Use Case 3. The health care professional (clinician) uses the integrated FS system

Use Case 4. The researcher uses the integrated FS system.

The verb "uses" in the above titles includes a series of actions and feedback according to the end user group. These actions are recorded in the below tables.

After addressing the different use cases of the FrailSafe system components in the previous months, we are now considering the system as a whole, always in accordance to our UCD methodology. The goal is to collect feedback about the functionality of the system as a whole, on the communication among the individual parts of the system and on the performance of complete usage scenarios. The feedback collected here will be used for the evaluation of the system as a whole by the four main user groups.

Table 8: Use case 1

INTEGRATED SYSTEM USE CASE 1

Use Case Name	OLDER USER INTERACTS WITH INTEGRATED SYSTEM
Version	v0.2
Last Update	January 2017
Brief Description	The older person is given a device kit to run the FrailSafe integrated system at home for 5 days. The system includes • WWBS (including IMUs) • Tablet with Dynamometer for the Game suite

	• Beacons • AR glasses (still under investigation at the time of this report due to safety issues) • FORA BP Monitor • Smartphone The "recommendation" C subgroup will receive a first recommendation following and according to the clinical evaluation. This recommendation will be adapted a week later (Day 7) following the data obtained and analyzed by the FrailSafe System. The respect of the recommendation will be checked by phone every 3-5 days and/or by a nurse visit at home if necessary until Day 20. The older person completes the session and returns the system kit to the clinician who retrieves it.
Assumptions & Pre-Conditions	• All relevant applications are installed on the devices • The indoor monitoring devices (e.g. beacons) have been installed in the house of the older user
Goal (Successful End Condition)	• The older user to use all the components of the system successfully
Post-Conditions	• The FrailSafe database is updated with new data • The older user receives feedback through visibility of their data and individualised recommendations.
Involved Actors	• Older person • Clinician (secondary)
Main Flow	1. The user receives a FrailSafe System from the clinician. 2. The user receives training and instructions from the clinicians on how to use the FrailSafe devices. 3. **SMARTPHONE**: The user/clinician presses the "start logging" button. The user carries the phone with him/her. The user or the clinician upon retrieval presses the "stop logging button". During the usage period, the older user carries the smart phone with them on outdoor activities. The older person uses the front-end visualization to • receive warnings, suggestions and predictions relating to frailty according to their entered data, • view their data and monitor their health condition, • use the virtual community platform to communicate with other older users, clinicians and the public. 4. **GAME SUITE**: The user opens the FrailSafe game suite from the tablet and logs in with his/her FrailSafe account. The user selects and starts a game according to the game recommended settings. The user plays the game, using the needed interaction device if needed (dynamometer, IMUs, AR glasses). The user performance (successful tasks, time to fulfil the tasks, etc.) are recorded locally.

	The user finishes the game and the collected data are transmitted to the FrailSafe online server, when Wi-Fi is available. 5. **WWBS:** The user receives and wears the WWBS and turns on the RUSA monitoring functionality. The user performs daily activities, under the instructions of the clinician. The user turns off and back on the monitor and charges the RUSA device according to the duration of usage. The user returns the WWBS to the clinician. 6. **FORA BP Monitor**: The user measures his/her blood pressure and pulse (3 times per day for the purposes of the clinical trials) according to the clinicians' instructions and training. Measurements are stored in the BP monitor and uploaded by the clinician upon retrieval, or uploaded by the older user according to their capability to do so. 7. **BEACONS**: The user carries the smart phone in their pocket while indoors. The user only has passive interaction, as they perform their daily routine in their space, in which the beacons were placed by the clinician. 8. **SOCIAL MEDIA USAGE**: Older User is active as usual in social media.
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.

UML Sequence Diagram

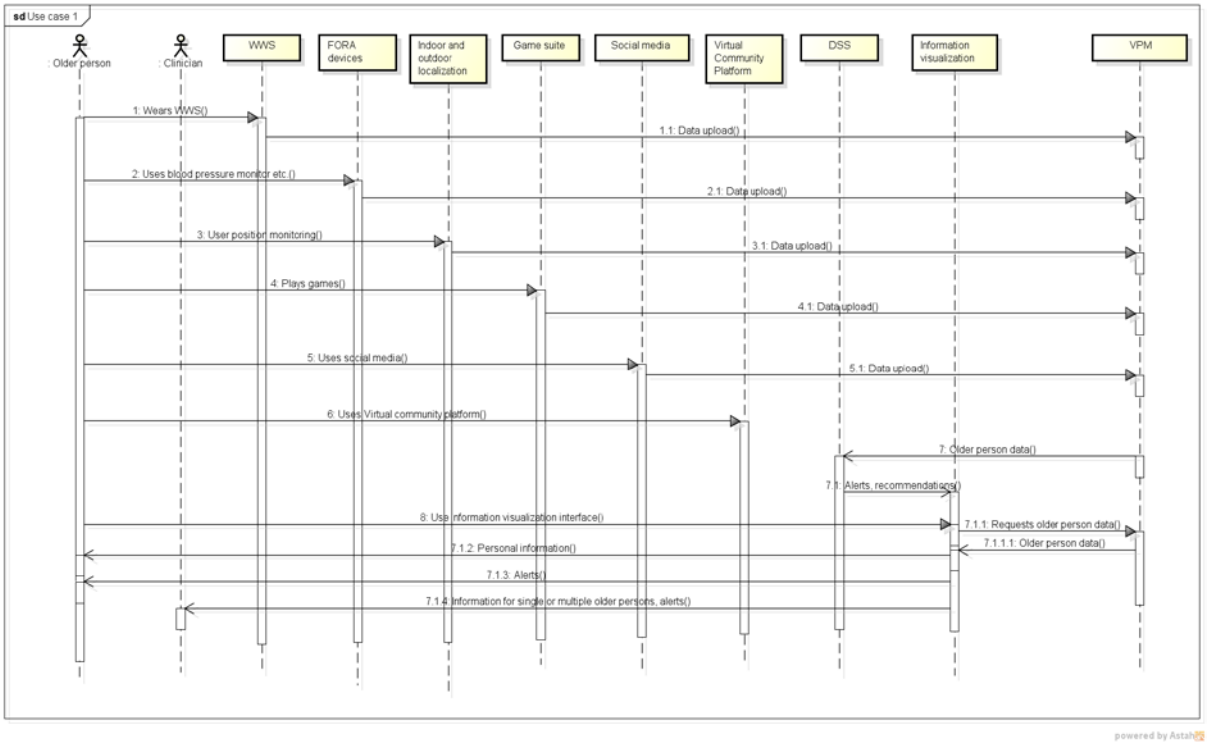


Table 9: Use case 2

INTEGRATED SYSTEM USE CASE 2

Use Case Name	FAMILY MEMBER INTERACTS WITH INTEGRATED SYSTEM
Version	v0.2
Last Update	January 2017
Brief Description	The family member uses components of the FS system to monitor their relative's health
Assumptions & Pre-Conditions	• None
Goal (Successful End Condition)	• The family member to interact successfully with the FS system and to report high user satisfaction and perceived benefit.
Post-Conditions	• The family member receives feedback through visibility of the older user's data and alerts (in case they choose to) in case of unusual or high risk situation.
Involved Actors	• Family member
Main Flow	1. The family member is informed by the older user or the clinician that their relative is using the FS system for a particular time period. 2. The family member uses mobile-ready web front-end to monitor their relative's health condition 3. The family member verifies the presence of alerts in case of unusual or high risk situations, if such a setting is chosen. (call centre handling such alerts and diverting them to preferred relative/health care provider is the idea for the final product) 4. The family member uses the Virtual Community Platform to interact with other people and professionals on matters relating to the older user's health, and to remain updated on issues relating to frailty.
Privacy & Regulation restrictions	The recorded data should not be transmitted outside the framework of the FrailSafe system.
UML Sequence Diagram	

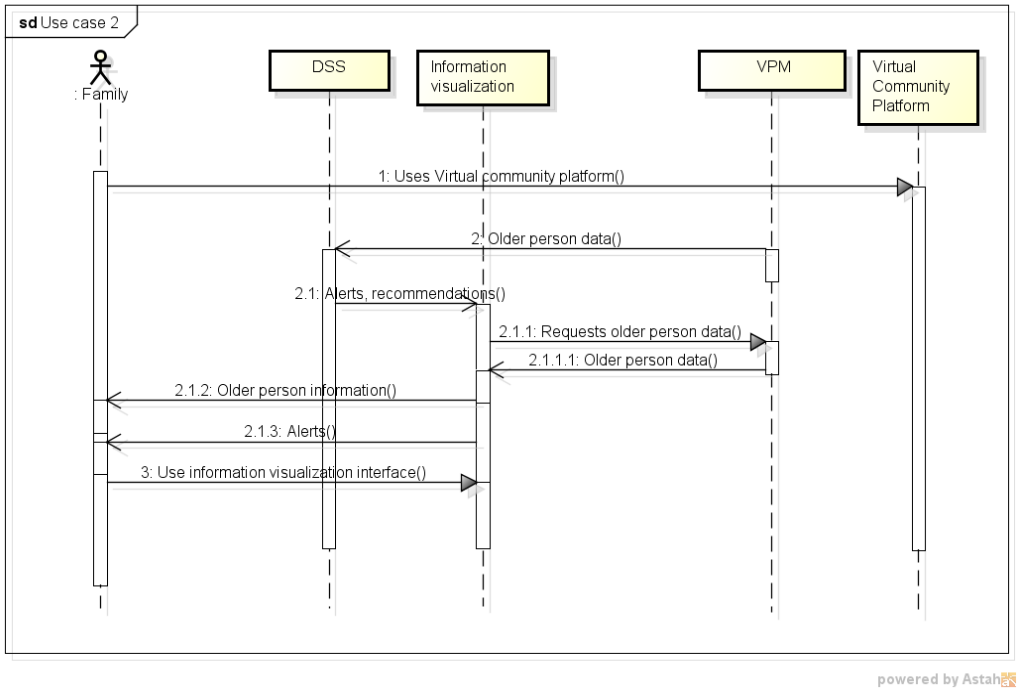


Table 10: Use case 3

INTEGRATED SYSTEM USE CASE 3

Use Case Name	CLINICIAN INTERACTS WITH INTEGRATED SYSTEM
Version	v0.2
Last Update	January 2017
Brief Description	The clinician prepares and allocates a FrailSafe system kit to the older user, making sure the user receives clear instructions / short training on how to use it. The clinician monitors the usage throughout the usage period and retrieves the system at the end of the session. The clinician can have access to and is allowed to manipulate the data of the older user.
Assumptions & Pre-Conditions	• The clinician has access to the FrailSafe data platform • The clinician is aware of and adheres to all ethics and safety issues relating to the FrailSafe system application
Goal (Successful End Condition)	The clinician has a better and more updated picture of the older user's health condition (cognitive, physiological and psychological)
Post-Conditions	• None
Involved Actors	Clinician Older person
Main Flow	1. The clinician prepares and allocates a FrailSafe System kit to the older user, ensuring that the user receives adequate instructions

	and training on how to use the devices. The kit contains the devices described above in Use Case 1. 2. Smartphone: The clinician presses the "start logging" button and upon retrieval, presses the "stop logging button" if the user hasn't done so. During the usage period, the clinician uses the front-end visualization to: • send personal feedback (warnings, suggestions and predictions, reminders) relating to Frailty according to the user's entered data, • view the data in order to monitor the user's health condition, • predict short-term and long-term possible conditions, • locate patterns in the user's behaviour and correlate them to frailty indicators. 3. The clinician uses the virtual community platform to *communicate with other older users, clinicians and the family. *answer questions * send out information and updates relevant to frailty * 4. The clinician reviews the updated VPM to decide on further future actions
Privacy & Regulation restrictions	The information exchanged among the older persons, the clinicians and the families should not be transmitted outside the framework of the FrailSafe system.

UML Sequence Diagram

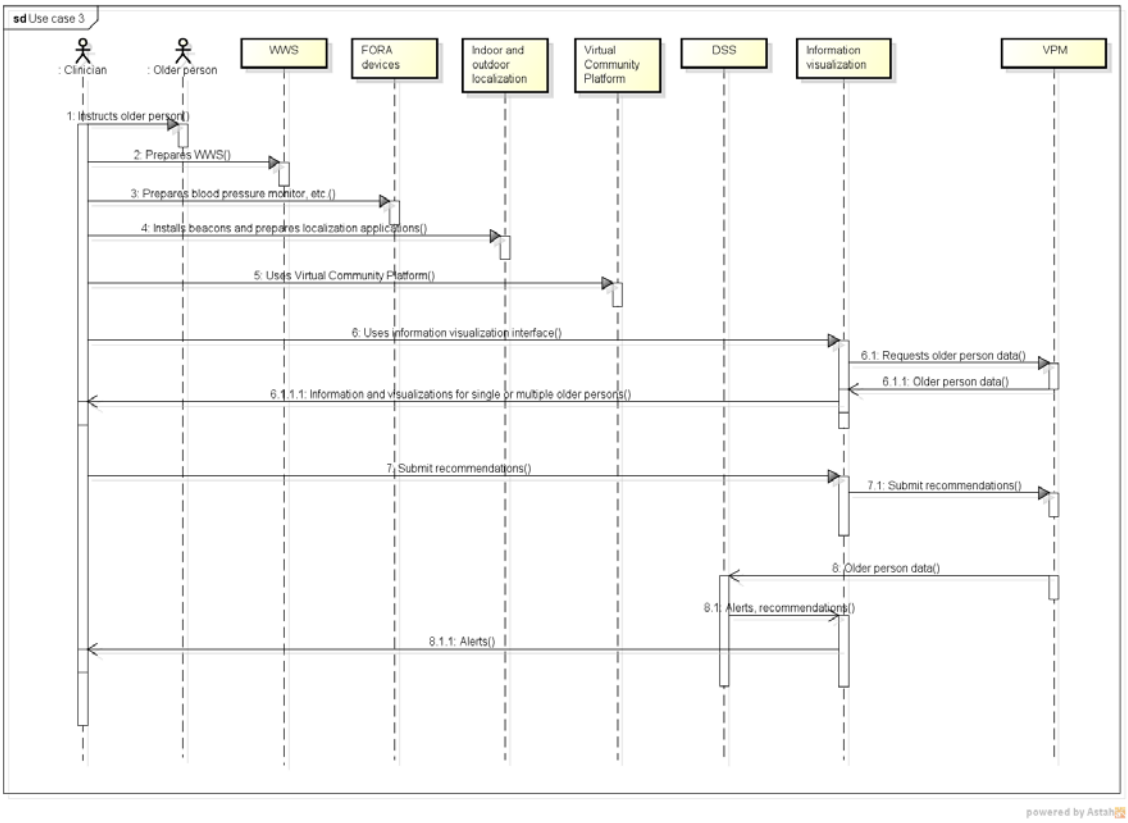


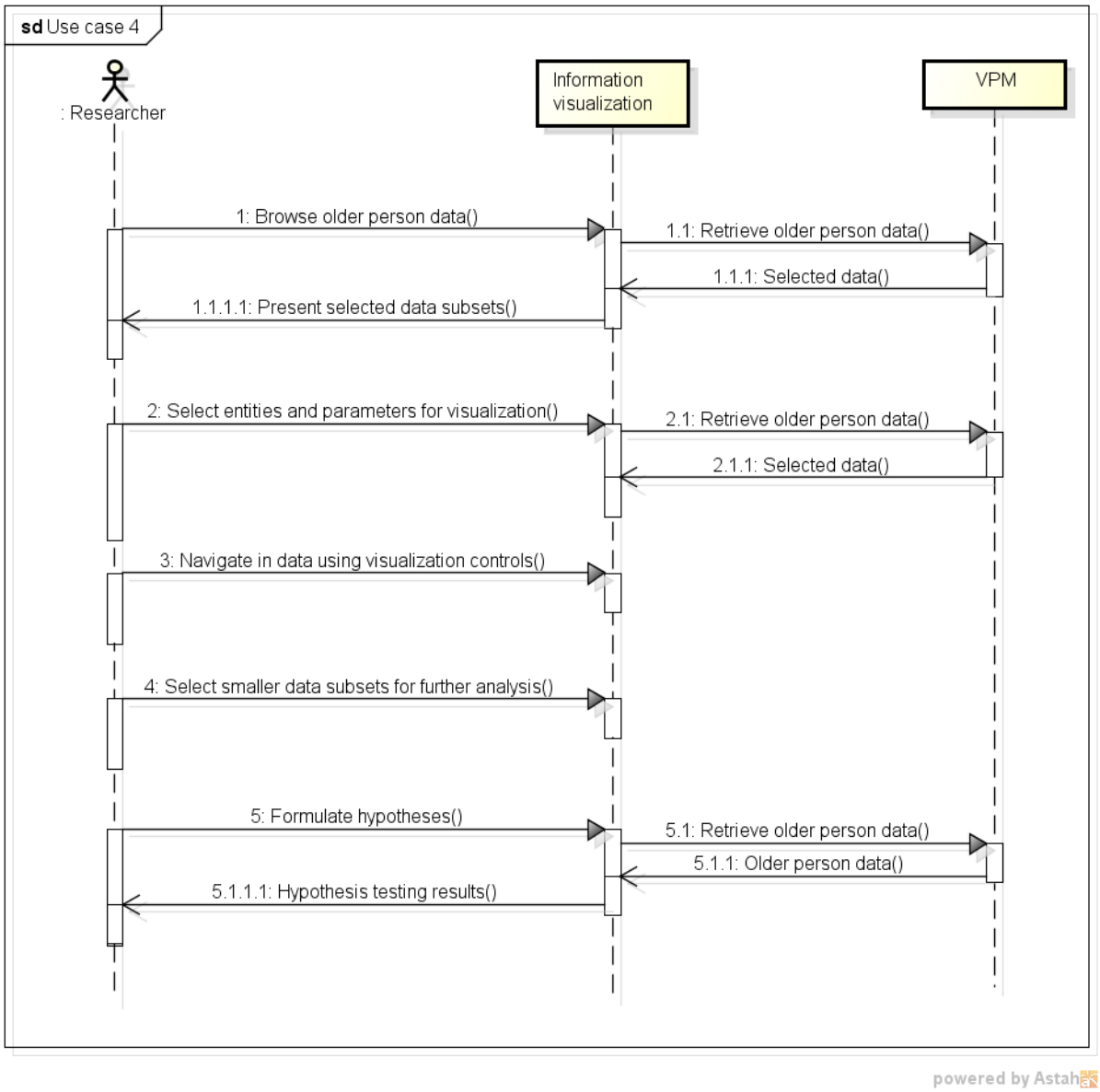
Table 11: Use case 4

INTEGRATED SYSTEM USE CASE 4

Use Case Name	RESEARCHER
Version	v0.2
Last Update	January 2017
Brief Description	The researcher accesses the data on the FrailSafe platform through the front-end application and can view, explore, sort data in categories he/she is interested in, form queries and receive answers, analyse data, form and test hypotheses.
Assumptions & Pre-Conditions	• The researcher must have an account on the FrailSafe system.
Goal (Successful End Condition)	• Researchers to have access to FrailSafe data, always in strict alignment with ethics restrictions, in order for this data to assist in further research on the improvement of the system, frailty, and older age health in general.
Involved Actors	• Researcher
Main Flow	1. The researcher browses the FrailSafe database using FrailSafe front-end. The researcher can view the user data by exploring various available categorizations, e.g. by age, by blood pressure range, etc. The researcher can select a presented data subset for further analysis. 2. The researcher formulates a data retrieval query using the FrailSafe front-end. The researcher can query the data of users having specific characteristics, e.g. within a specific age range, with increased blood pressure, etc., and combinations of them. After submitting the query, the system returns the desired data 3. The researcher engages in data analysis. The researcher uses the visual analytics tools of FrailSafe to analyse a selected subset of data. The user can select features and entities to visualize, combine multiple features and assign different weight to different parameters. The system visualizes the selected data and entities using graph-based visualization methods. The user can use these visualizations to find common patterns and clusters among the data. The user can navigate in the visualization by panning, zooming and selecting smaller subsets for further visualization. 4. The researcher engages in Hypothesis testing. The researcher uses the hypothesis formulation and validation tools of FrailSafe verify specific hypotheses about a selected subset of data. The system uses underlying data analysis techniques or displays extra visualized information in order to assist the researcher in verifying or rejecting the formulated hypothesis.
Privacy &	The displayed data should be anonymised. Information linking the

Regulation restrictions	displayed data with a specific older person should be hidden from the researcher. The FrailSafe data should be available only to registered researcher users, in order to ensure their protection

UML Sequence Diagram



7 EVALUATION TOOLS

The insight gained by the FrailSafe team so far is that participants are happy to give their comments/feedback on the concept and the tools they have used. Many changes have been implemented both in terms of processes, and in terms of design, in our course from testing few fragmented parts of the system in the first months, until the present time (M26), when the system is much more complete. For example, the way the users log in to play the games was changed after their own request.

7.1 Methods for user feedback assessment

The aim of user feedback assessment is the collection of feedback coming directly from users and the examination of its relevance to the objectives and the work plan of the project. Methods for user feedback assessment include the following:

- **Questionnaires:** A questionnaire is a set of questions that are defined and sorted in order to allow the objective and accurate collection of user responses and their translation to useful and statistically significant information.

  Phases of the preparation and the deployment of questionnaires: definition of the questionnaire's objective, definition of the potential user groups and questionnaire participants, formation of the questionnaire, deployment of the questionnaire, analysis of the results.

  Types and indicative examples of questions: General questions, open questions, scalar questions, multiple choice questions, ordered questions

- **Interviews:** The interview is a method to understand the unique point of view of a participant through the face-to-face interaction with an interviewer.

  The preparation and deployment of interview: The selection of questions should be also done in such a way that will allow participants to answer truthfully to the interviewer, the location to carry out the interviews can vary and should ideally be a neutral location that offers privacy, especially when sensitive medical data will be discussed. The questions should be written down in advance and as a form of a discussion plan that can help the interviewer direct the interview in the appropriate area and do not deviate from its main objective. Interviewers may use recording devices in addition to their written notes in order to collect a more detailed record of participant responses.

- **Focus groups:** Participants were positive to talk about their experience, whereas sometimes they are not as willing to answer a written tool. Some of our participants belong to a common senior club/day centre, and it is easy to form small groups there when the clinician is on site. In this method, users are asked to share their opinions, thoughts and ideas about a specific subject and discuss their views towards a conclusion that can express the majority of participants.

  Steps: the moderator should introduce the topic of the discussion and explain to the participants what is expected to derive from this process. The moderator should start addressing some questions to the participants in order to start the discussion process.

- **Expert evaluation:** it is used to collect feedback and specific suggestions from experts based on their experience in the implementation of similar solutions.

- **Usability testing:** it evaluates a system based on the collection of data during the use of the system by actual users and optimally in the intended real world environment.

- **Heuristic evaluation:** it focuses on the understanding of usability issues of a system, based on the input of a small group of expert evaluators with experience in Human Computer Interaction.

  Steps: the definition of the system's interaction flow and the accurate description of the intended scope of the session, the evaluators can focus their analysis on specific

interaction elements and provide their feedback, recommendations and concerns, the group of all the evaluators should discuss the results of their analysis.

- **Think aloud protocol:** participants are asked to describe their thinking process verbally in order to reveal their thoughts, feelings and opinions while interacting with the system under evaluation.
- **Performance measurements:** it focuses on the assessment of quantitative metrics of the performance of various system components.
- **Log file analysis:** Confirm the automatic storing of user-system interactions and their subsequent analysis for the identification of usage patterns as well as potential problems in usability.
- **Feature / Consistency / Standards inspection:** it analyzes specific characteristics of a system and they are usually based on use case scenarios.

Table 12: Evaluation methods [to be] used by each partner and target group

Method of evaluation	Type of user groups	UoP	INSERM	MAT	SIGLA	BRAIN
Questionnaires	Older users	✓	✓	✓		
	Family members			✓		
	Health care professionals		✓	✓		
	IT professionals	✓		✓	✓	✓
Interviews	Older users	✓	✓	✓		
Focus Groups	Family members			✓		
	Health care professionals			✓		
Expert evaluation	Ethics consultants (from the clinical, juridical point of view)	✓				
	Ethics consultants (from the technical point of view)				✓	
Usability testing	Older users	✓	✓	✓		
Heuristic evaluation	IT professionals	✓			✓	✓
Think aloud protocol	Older people			✓		
Performance measurements	Older users	✓	✓	✓	✓	✓
Log file analysis:	Older users	✓				
Feature / Consistency / Standards inspection	Older users	✓				

Challenges in System Assessment which have to be addressed in the evaluation studies protocol:

- To define clear goals to be assessed (what it means for the system “to work”)
- To define clear criteria-measurements stemming from the above goals (criteria selection process may identify data needs that can be included in advance in the pilot program)
- To address selection bias and to include a control group
- To include an adequate timeframe for the evaluation studies to ensure outcomes are observed
- To include an adequate number of participants in order to produce meaningful data

7.2 Questionnaires for the FS system evaluation

A set of User satisfaction questionnaires will be given to each participant in Group C according to the schedule described above. A variety of existing usability and user experience scales were considered. Priority was given to scales which can be used by a variety of user groups (for example the same questionnaire will be administered to older users, their families and health care professionals). In addition, we choose tools which do not refer to a limited part of a system (for example SUMI was ruled out because it refers to the interface of a software), or that had features which the users had previously rated as negative (for example, QSUQ -computer system usability questionnaire was too long for older users).

All three questionnaires are constructed with Likert-type rating scales. Users are asked to rate their level of agreement or disagreement with the statements, ranging from (very) strongly disagree to (very) strongly agree. Various forms of the two existing questionnaires (SUS and USE) have been used to evaluate user attitudes towards a variety of technological consumer products. Factor analyses following each study suggested that users were evaluating the products primarily using three dimensions, Usefulness, Satisfaction, and Ease of Use.”

The set of questionnaires to be used in the assessment of FrailSafe includes:

1. **FrailSafe Satisfaction Questionnaire** (Annex 16) created by the FrailSafe team to address user satisfaction of the components of FrailSafe as part of the whole system. This questionnaire was based on the one created to measure user requirements in WP1.
2. **System Usability Scale - SUS** (Annex 17): One of the most popular questionnaires is the SUS which is short and does seem to yield reliable results across sample sizes (Tullis and Stetson, 2004) regarding the overall usability of a system. The System Usability Scale (SUS) is comprised of 10 items assessed using a five-point response scale which ranges from strongly disagree, to strongly agree. The SUS has a scoring system which delivers a single number that reflects the outcomes of the overall usability of a system (Brooke, 1996).

Scoring: The scoring of SUS derives from the sum of score of each individual item. Each item score can range from 0 to 4 (Brooke, 1996). Specifically, for items 1, 3, 5, 7 & 9 the score yields from the scale value checked minus 1 (Brooke, 1996). For all other items the score derives from the subtracting the value checked from 5 (Brooke, 1996). The value of the overall usability can be found after the multiplication of the sum of each of the 10 scores with 2.5 (Brooke, 1996).

3. **USE** (Annex 18), Measuring Usability with the USE Questionnaire, Arnold M. Lund STC Usability SIG Newsletter, originally published in the October 2001 issue (Vol 8, No. 2). The questionnaire was constructed as a seven-point Likert-type scale, e.g. from -3 (disagree very strongly) to +3 (agree very strongly)
4. **Questionnaire for IT professionals** (Annex 19) created by the FrailSafe team, addressed to IT professionals after evaluating the FrailSafe system.

It is noted that as with all stages of the project, participants will be able to withdraw from the evaluation process at anytime without an obligation to explain the reasons.

7.3 Protocol for the validation of the FS system per target group

7.3.1 Families of seniors

During focus groups and home visits, relatives often are present and positive to provide feedback as well (38 relatives had provided feedback in the user requirement collection process described in D1.2). A set of user satisfaction questionnaires (Annexes 16-18) will be given to relatives of participants of Group C to extract the satisfaction rate of the user group “family” in relation to the user needs which were identified for that group, and the perceived benefit for their loved ones if they were to use FrailSafe as part of their treatment management program.

Protocol for Assessment: Family members from the participants recruited in Group C, will be invited to use the FrailSafe alert system, intended for families, in order to provide their feedback on it. The aim is to have feedback from a total of 30 family members from all three clinical centres without restricting the number to be reached by each country. Their participation will take place from M31 to M36, in the same way as described for the evaluation group of seniors in section 5.

7.3.2 Health care professionals

A set of assessment questionnaires (Annexes 16-18) will be administered to each member of the clinical teams who came in contact with the integrated FrailSafe system (team members from the three centres include healthcare professionals from the fields of medicine, nursing, psychology, gerontology, speech-language therapy and social work). In addition, 5 more healthcare professionals will be asked to sign a Non-Disclosure Agreement (sample can be found in Annex 20), check the FrailSafe system and complete the assigned questionnaires.

Protocol for Assessment: Ten consortium healthcare professionals and five externals will evaluate the FrailSafe system and complete the questionnaire by M33.

7.3.3 IT professionals (Heuristic Evaluation)

A questionnaire (Annex 19) will be administered to each member of the IT teams which has come in contact with the FrailSafe integrated system in addition to selected external IT professionals who will agree to sign a designated Non-Disclosure Agreement. The aim is to receive feedback on all the technical aspects which FrailSafe needs to include according to the stated functional and non-functional system requirements. The internal IT teams will be also asked to assess the performance of the various system components based on several quantitative metrics that will be agreed by month 30; right before the launching of the first trial of the Evaluation Group.

Technological characteristics to be assessed by IT professionals are:

1. Evaluation of System Requirements Satisfaction (information derived from D1.3):
    - Network availability
    - Hardware reliability
    - Data Loss prevention
    - System security
    - System privacy of online personal data

2. Evaluation of non-functional system requirements:
    - Ease of learning. Novices and expert users should be able to easily learn how to use the system;
    - Task efficiency. The system needs to be efficient for the frequent user;
    - Ease of remembering. After a no-use period, the user should be able to remember how to use the system without a guide or instructions;
    - Understandability (Comprehension): During the use of any function the user has to be able to perceive what the system does;
    - Subjective satisfaction: The user should feel satisfied with the system

Protocol for Assessment: IT professionals (10 internal and 5 external) will be asked to complete an assessment questionnaire with their personal evaluation of the technological aspects of FrailSafe (Annex 19). Their evaluation should be completed by M34.

7.3.4 Researchers

A set of user satisfaction questionnaires will be provided to members of the research team that were involved in the retrieval and analysis of data during the evaluation phase of the project. Furthermore, external researchers will be asked to sign a Non-Disclosure Agreement and evaluate the FrailSafe system in terms of the quality and accuracy of the data collected from the FrailSafe system.

Protocol for Assessment: Two members of the consortium research and five external researchers will be asked to evaluate the FS System in M34.

7.3.5 Expert review on safety and ethics

FrailSafe Ethics Advisor Dr. Stefania Maggi, and Liz Mestheneos, FrailSafe Advisory Board member have agreed to review the FrailSafe integrated system in terms of its ethics and safety related features.

Protocol for Assessment: The two experts will hold a checklist (see below in section 7.3) to complete during the assessment session to be held in M35, during which the different features of FrailSafe will be discussed and a team member from each partner will be present to discuss their particular components.

7.4 Ethics Checklist

A selection of some indicative use cases from the ones presented above will be used for the definition of the scenarios to be used for pilot testing during the evaluation phase of the project. Ethics and safety protocols will be strictly adhered to during the execution of the scenarios. Evaluation protocols to be used are directly connected to the outputs of Deliverable D9.9 “Ethics, Safety and mHealth Barriers (regulation, legislation, etc.) Manual”. The evaluation procedures used will comply with the plan proposed in this deliverable. If any new privacy, safety or ethical requirements arise during the project’s lifetime, they will be taken into consideration and the process will be modified. The approval of the Ethics Advisory Board will be requested prior to any modification.

The legislation barriers for the adaptation of the FrailSafe components will also be re-examined, including regulatory issues (security, medical devices, mHealth interfaces), legislation frameworks, policy issues (older person empowerment, reimbursement) and GSMA (Policy and Regulation for Innovation in Mobile Health, 2012).

All research conducted for the purposes of FrailSafe have received an ethical approval from the national ethics committees in the three countries (Greece, France and Cyprus). Thus, all procedures and documents used in all the clinical trials with participants have been approved.

System technical specifications related to ethics will need to be assessed in the pilot evaluation studies for the integrated FrailSafe system. Thus, the checklist to be completed by the ethics expert reviewers will be comprised of the following items:

Has FrailSafe managed to:

- ✓ Preserve the anonymity of data where necessary
- ✓ Be transparent
- ✓ Acquire informed consent when needed
- ✓ Establish a default of not sharing data unless consent is given
- ✓ Treat data with purpose specification and limitation criteria
- ✓ Establish data erasure function which will serve all users
- ✓ Avoid cookies
- ✓ Be accountable
- ✓ Provide satisfactory data security
- ✓ Ensure that the wearable does not harm the users in any way

7.5 Security and Privacy

The FrailSafe project relies heavily on sensitive data, specifically on personal medical data. Hence, security and privacy issues are of paramount importance and must be carefully considered and faced. This is especially true in view of the recent hardening of the relevant European Regulations on the subject of data protection and the latter has become very

precise about personal data acquisition and handling (i.e. the Data Protection Directive - 95/46/EC - and the new General Data Protection Regulation V EU GDPR n. 2016/679).

8 CONCLUSIONS

This is the final version of the assessment protocol for the testing and evaluation of the integrated FrailSafe system.

In order to achieve valid and reliable evaluation results, a range of UCD methods will be implemented in order to effectively evaluate the FS system from a variety of end-users (target groups) and through different methods/tools. Specifically, the integrated system will be assessed by end users, health care professionals, family members, IT professionals, Ethics consultants and researchers.

Methods to be used will be mainly different kinds of data collected during the evaluation clinical trials, questionnaires, interviews, focus groups and expert reviews.

Preservation of ethics, security and privacy is of utmost importance and were foreseen to be addressed within the evaluation tasks.

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10 ANNEXES

Annex 1: Identification data

Participant ID number	
Group	START/ MAIN / EVALUATION/ CONTROL
Date of entry in the study	*Corresponds to the date of the consent signature*
Name initials	*First two letters of First and Last name*
Year of birth	
Sex	M/F

Annex 2: Generalities and demographics

Living conditions	*Choose all that apply:* 1.lives alone 2.live with spouse/companion 3.live with another/other relative(s) 4.family/close friends nearby 5.Presence of regular help (professional or family)
Family status	*Choose one answer:* 1.Single 2.Married or in a relationship 3.Divorced 4.Widow
Profession	*Choose one answer:* 1-Housewife 2-Agriculture Workers (farmer, breeder etc) 3-Workers (manual labour workers, factory workers) 4-Craftsmens, Merchants (enterprising, businessmen etc...) 5-Intermediary professions (ex. sailors? seamen? drivers? Free professionals?) 6-Employees, Officers, Clerks…. 7-Executive employees and intellectual professions (teachers, professors, tutors, physicians, engineers, lawyers etc)
Education	Number of educational years *Write down the number. Values of 0 also acceptable*
Leisure activities	How many times do you go out of your house per week? *Write down the number. Values of 0 or decimals also acceptable. "I don't know" option also provided* Are you member to a club or an association? Yes/No

Social life/ communication	How many times per week do you exchange visits with somebody (either you visit them or vice versa)? *Write down the number. Values with decimals also acceptable. "I don't know" option also provided*
	How many times per week do you receive or give telephone calls (or other means of distance communication) with someone close? *Write down the number. Values with decimals also acceptable. "I don't know" option also provided*
	What is the mean time you spend speaking at the phone per week (in minutes)? *Write down the number. Values with decimals also acceptable. "I don't know" option also provided*
	What is the mean time you spend on videoconference per week (in minutes) either on your own of assisted by someone else? *Write down the number. Values with decimals also acceptable. "I don't know" option also provided*
	What is the mean number of text messages you send per week either on your own or assisted by someone else? *Write down the number. Values with decimals also acceptable. "I don't know" option also provided*

Annex 3: Medical history, Co-morbidities, Medication list

Medical and Surgical conditions	*Co-morbidities as self-reported by the participants and/or revealed by their medication list and/or medical records. (Annex 1)* *Check all that apply* ▪ ARTERIAL HYPERTENSION yes/no ▪ DYSLIPIDEMIA yes/no ▪ DIABETES MELLITUS yes/no ▪ ISCHEMIC HEART DISEASE yes/no ▪ CHRONIC ATRIAL FIBRILLATION/PAROXYSMAL AF OR OTHER ARRYTHMIA yes/no ▪ HEART INSUFFICIENCY yes/no ▪ STROKE OR TIA yes/no ▪ CHRONIC RENAL DISEASE yes/no ▪ CANCER yes/no ▪ RESPIRATORY DISEASE yes/no ▪ IMPAIRED COGNITIVE FUNCTION yes/no ▪ PARKINSON'S DISEASE yes/no ▪ EPILEPSY yes/no ▪ DEPRESSIVE MOOD yes/no ▪ ANXIETY AND/OR SLEEP PROBLEM yes/no ▪ URINARY INCONTINENCE yes/no ▪ PROSTATE PATHOLOGY yes/no ▪ ANEMIA yes/no ▪ JOINT PAIN- MUSCULOSCELETAL COMPLAINTS/DISEASES yes/no ▪ OSTEOPOROSIS yes/no ▪ CONSTIPATION AND OTHER INTESTINAL PATHOLOGY yes/no ▪ DYSPEPSY yes/no ▪ THYROID GLAND PATHOLOGY yes/no ▪ EYE DISEASES yes/no ▪ HEARING PROBLEMS yes/no ▪ DIZZINESS AND/OR VERTIGO yes/no ▪ LOWER LIMP TRAUMA OR OPERATION WITH RESIDUAL SIGNES yes/no ▪ Others (ICD-10 coding) yes/no
Estimation of the effect of each co-morbidity in the individual's function	Do you think that each of the present conditions has a significant impact in the individual's functional capacity? yes/no
Lead co-morbidity among those with special interest	Which is the most important lead co-morbidity *(Annex 2):*

for the study	*One answer possible* • Prior stroke • MCI • Osteoporosis if woman /Osteoarthritis if man • None of the above • No co-morbidity at all
Medication	The whole medication list *(Annex 3)* *(drugs over-the-counter and drug frequently- even not daily- used included)* Frequency of drug administration per day How many times a day (s)he takes each distinct drug
Hospitalization	Number of hospitalizations in the last year *"I don't know" option also provided* Number of hospitalizations in the last year and three years? *"I don't know" option also provided*
Falls	Number of falls in the last year *"I don't know" option also provided*
Fractures	Number of fractures during the last 3 years *"I don't know" option also provided* Number of fractures in lifetime *"I don't know" option also provided* Fractures' anatomic localization. *Click all that apply:* o upper limps o hip-pelvis o vertebral

	o other o multiple fractures *"I don't know" option also provided* How many months before the study did your last fracture occur? *"I don't know" option also provided*
Physical Activity	Do you have regular physical activities (walking gardening, others). *One choice* 1. -No 2. -<2h per week 3. -2-5 h per week 4. - >5 h per week
Smoking status	1. Never smoked 2. Past smoker (stopped at least 6 months) 3. Current smoker
Alcohol use	Number of alcohol units' equivalences consumption per week *(Annex4).* *Values of zero or decimals also accepted*

Annex 4: Fried's Criteria of Frailty

1) Unintentional weight loss >4.5 kg in the past year	*Question to the participant:* "Have you unintentionally lost more than 4.5 kg in the past year?" 1. No 2. Yes 3. I don't know
2) <20th population centile for grip strength	Dynamometer measured grip strength (average of 3 trials, dominant hand) <u>Normal values:</u> [Men] >29kg for BMI≤24, >30kg for BMI 24.1-28 and >32kg for BMI >28 [Women] >17kg for BMI≤23 >17.3kg for BMI 23.1-26 >18kg for BMI 26.1-29 >21kg for BMI >29 Result outside the norms? Yes/No
3) Self-reported exhaustion	*Questions to the participant:* a) I felt that everything I did was an effort in the last week: ▪ Rarely or none of the time (<1 day) ▪ Some or little of the time (1 to 2 days) ▪ Moderate amount of the time (3 to 4 days) ▪ Most of the time b) I could not get going in the last week ▪ Rarely or none of the time (<1 day) ▪ Some or little of the time (1 to 2 days) ▪ Moderate amount of the time (3 to 4 days) ▪ Most of the time Meets criteria for frailty if answer "moderate amount of the time" or "most of the time" for either question: yes/no
4) Low physical activity such that persons would only rarely undertake a short walk	Question to the participant: "Gait requiring physical activity during less than 10min per day (or 75min per week) in average"?
5) Slowed walking speed, defined as lowest population quartile on 4 minute	*Extrapolated from previous walking test.* *Abnormal values for walking 4.57 meters:*

walking test.	*For men; ≥7seconds for height ≤173cm and ≥6seconds for height>173cm.* *For women; ≥7seconds for height ≤159cm and ≥6seconds for height>159cm.* Is the gait speed slower? 1. No 2. Yes 3. Test not adequate (non realizable or acute debilitating condition that affects walking) *In case of acute condition affecting standard gait speed the evaluation should be repeated in another visit after the resolution of the condition.*
Categorization by Fried	1. Non frail (0 criteria) 2. Pre-frail (1-2 criteria) 3. Frail (3 or more criteria)
The case of inadequate data	Adequate data for the Fried's criteria 1. YES (if all the criteria above where answered by Yes or No) 2. NO (if we have missing data, ex gait speed non evaluable, weight loss not able to be reported etc…) Fried's categorization according to clinician's estimation: 1. Non frail 2. Pre-frail 3. Frail Optional free text space will be provided in order to specify special cases of inadequate data

Annex 5: Cognitive, mood and sleep evaluation

Cognitive function	Scale MMSE (Mini Mental State Examination) *(Annex 8 of D2.1)* Scale MoCA (Montreal Cognitive Assessment) *(Annex 9 of D2.1)*
Memory complain	*Question to the participant:* "Do you have the impression that your memory works less well in

	comparison to the people of your age?" 1. No 2. Yes
Depression	Geriatric Depression Scale- 15 items (Annex 10 of D2.1)
Sleep	*Choose the one that applies* *The need of medication to sleep correspond also in a sleep problem* 1. No sleep problem 2. Occasional sleep problem 3. Permanent sleep problem

Annex 6: Clinical examination and instrumental measurements

Arrhythmia detection	Pulse palpation. Is the pulse regular or not? 1. Yes=absence of arrhythmia 2. No= presence of arrhythmia
Height measurement	*In meters*
Weight measurement	*In kilograms*
BMI	Automatically calculated by the formula: BMI=weight(in kgs)/height(in meters)^2
Impedance -Body fat	*Measurement by FORA device*
Waist circumference	*In centimetres*
Chest circumference	*In centimetres*
Blood pressure measurements	3 measurements (one minute apart) in sitting position *(Mean calculation of 2nd and 3rd measurement)* *Measured by electronic tension meter*
Orthostatic hypotension detection	2 measures in standing position (first and then third minute) Comparison to the mean sitting measurement with each of the standing measurements *Measured by electronic tension meter* Impossibility to realize the test of orthostatic hypotension? 1. No 2. Yes Orthostatic hypotension test positive? 1. No 2. Yes 3. Test non realizable *Orthostatic hypotension present if:* *SBP differ≥20mmHg OR* *DBP differ≥10mmHg*
Arterial stiffness evaluation	Pulse wave velocity *Measured by the mobilograph (where available)* Central Systolic Blood Pressure *Measured by the mobilograph (where available)*

Annex 7: Balance and gait evaluation

Lower limb strength	Raise from the chair 5 times without helping from the arms *Number of seconds necessary to accomplish the task* "Test non realizable" option will be provided
Balance	Single foot station 1. <5sec 2. >5sec) 3. Test non realizable
Gait speed	Timed Get Up And Go Test *Time in seconds needed to complete the task* Speed for 4 meters' straight walk *Time in seconds needed to complete the task* *Optional open text field will be provided in order to enter qualitative evaluation of the gait, the balance, the turn and the posture*
Special conditions	Existence of a temporary condition that could affect the performance in these tests? 1. No 2. Yes *If yes, the evaluation should be repeated in another visit after the resolution of the condition.*

Annex 8: Sensory system evaluation

Vision	*Question to the participant AND clinical evaluation/impression* *Choose the one that applies* 1. Sees well 2. Sees moderately 3. Sees poorly
Hearing	*Question to the participant AND clinical evaluation/impression* *Choose the one that applies* 1. Hears well 2. Hears moderately 3. Hears poorly

Annex 9: Nutritional assessment

Nutritional state	MNA short form scale for nutritional problem detection *If score ≤11 in short form, then application of the full questionnaire.* *(Annex 5 of D2.1)* MNA extended version *To be applied only if detection score ≤11* *(Annex 5 of D2.1)*

Annex 10: Activities of daily living

Activities of daily living	Katz Index of Independence of ADL *(Annex 6 of D2.1)*
Instrumental activities of daily living	Lawton IADL scale *(Annex 7 of D2.1)*

Annex 11: Self-evaluation scales

Quality of life self-rating	*Visual analogue scale (Annex 11 of D2.1)* "In generally, and not only referring to your health, how would you grade the quality of your life?"
Health self-rating	"In generally and according to your age, how would you rate your health from 1 to 5, where 1 means very bad and 5 means excellent?" *Check the one that applies* 1. Very bad 2. Bad 3. Medium 4. Good 5. Excellent "Comparing to a year ago, how would you rate your health now?" *Check the one that applies* 1. A lot worse 2. A little worse 3. About the same 4. A little better 5. A lot better
Pain self-evaluation	*Visual analogue scale (Annex 12 of D2.1)* "Please mark on the line the point that you feel better represents your perception of your current state about pain."
Anxiety self-evaluation	*Visual analogue scale (Annex 13 of D2.1)* "Please mark on the line the point that you feel better represents your perception of your current state about anxiety."

Annex 12: Housing conditions' evaluation

Habitation zone	1. Rural 2. Semi-urban 3. Urban
Housing/ surroundings	Does the person think that their housing environment is suitable and adapted to their needs/particularities? 1. Yes, 2.No *If NO, please note all that applies :* 1. unsuitable/ inconvenient in-house facilities/ surrounding , 2. unsuitable/ inconvenient/ too distant environing facilities Does the visiting health care professional estimate that the housing environment is suitable and adapted to the participant's needs/particularities? 1. Yes, 2. No *If NO, please note all that applies :* 1. unsuitable/ inconvenient in-house facilities/ surrounding , 2. unsuitable/ inconvenient/ too distant environing and outdoor facilities 3. hygiene conditions How many stairs has someone to climb in order to access the house? *(floor levels accessed by elevator not included).* *Enter the number*

Annex 13: Follow up questionnaire

Falls	Did any fall occur?	Yes/no
	Number of falls	
	Date of the event	
Fractures	Did any fracture occur?	Yes/no
	Date of the event	dd/mm/yyyy
	Anatomic location	*Click all that apply:* o upper limps o hip-pelvis o vertebral o other o multiple factures *"I don't know" option also provided*
Hospitalizations	Did any hospitalization occur?	Yes/ No
	Date	dd/mm/yyyy
	Length of hospital stay (in days)	+option of "still hospitalized" provided
	Outcome	o totally cured o amelioration o stability o worsening of general health state o death o institutionalization o still hospitalised
Conditions of	o programmed hospitalization	

hospital recourse	o visit to the emergency care room by release without hospitalisation o urgent hospitalization	
Death	Did death occur?	Yes/no
	Cause	Open field for the cause of death +option of "I don't know also provided"
	Date	dd/mm/yyyy

Annex 14: Data collection of written text (in every clinical assessment after the first)

Ask to think of a major life event and ask to write it down.

If possible typed (by preference), otherwise handwritten. If not possible dictated.

Ask to think of a recent, everyday life routine, e.g. write what he/she did in the previous day.

Ask to think a major enjoyable life event, although unpleasant events should not be dismissed.

For instance:

- Wedding
- Child's birth.
- Children's achievements
- Enjoyable travel experience.
- Professional achievements.
- Last time you felt excitement about a forthcoming event.

Annex 15: Study's completion verification

Did the patient complete the study as predicted?	1. Yes 2. No
If no, provide the reason for the premature ending of his/her participation	1. Death 2. Consent withdrawal 3. Emerging condition inhibiting the participation in the study or fulfilling exclusion criteria 4. Participant unreachable/ Lost in follow up

Annex 16: FrailSafe Satisfaction Questionnaire

PART A: GENERAL QUESTIONS

1. Please indicate your relation to the project:

☐ Participant

☐ Healthcare professional (doctor, pharmacist, nurse, psychologist, social worker, sociologist, etc.)

☐ Participant's family member/caregiver

☐ Future business customer (IT company, Care Service Provider, Health Care Facility etc.)

2. Which components of the FrailSafe system have you used?

☐ Blood Pressure Monitor
☐ Strap
☐ Vest
☐ Dynamometer
☐ AR Glasses
☐ Smartphone
☐ Tablet
☐ Games
☐ Beacons

3. Do you think this system contributes to a better quality of life?

☐ Yes ☐ No

4. Please briefly provide 1-2 reasons explaining your chosen answer in Q.3

5. Are you willing to use this system again in your home setting?

☐ Yes ☐ No

PART B: QUESTIONS ABOUT THE SYSTEM

6. Which of the following tools of the system do you think are useful?

☐ Blood Pressure Monitor
☐ Strap
☐ Vest
☐ Dynamometer
☐ AR Glasses
☐ Smartphone
☐ Tablet
☐ Games
☐ Beacons

7. Which of the following tools of the system do you think are <u>NOT</u> useful?

☐ Blood Pressure Monitor ☐ Smartphone

- ☐ Strap
- ☐ Vest
- ☐ Dynamometer
- ☐ AR Glasses
- ☐ Tablet
- ☐ Games
- ☐ Beacons

8. Why do you think they are not useful?

9. Which of the following tools of the system did you like most?

- ☐ Blood Pressure Monitor
- ☐ Strap
- ☐ Vest
- ☐ Dynamometer
- ☐ AR Glasses
- ☐ Smartphone
- ☐ Tablet
- ☐ Games
- ☐ Beacons

10. Which of the following tools of the system you did <u>NOT</u> like at all?

- ☐ Blood Pressure Monitor
- ☐ Strap
- ☐ Vest
- ☐ Dynamometer
- ☐ AR Glasses
- ☐ Smartphone
- ☐ Tablet
- ☐ Games
- ☐ Beacons

11. Please briefly provide 1-2 reasons you didn't like the systems you mentioned in Q9.

12. Which of the following did you find easy to use?

- ☐ Blood Pressure Monitor
- ☐ Strap
- ☐ Vest
- ☐ Dynamometer
- ☐ AR Glasses
- ☐ Smartphone
- ☐ Tablet
- ☐ Games
- ☐ Beacons

13. Which of the following did you find difficult to use?

- ☐ Blood Pressure Monitor
- ☐ Strap
- ☐ Vest
- ☐ Dynamometer
- ☐ AR Glasses
- ☐ Smartphone
- ☐ Tablet
- ☐ Games
- ☐ Beacons

14. Did you need any assistance in using the system?

☐ Yes ☐ No

15. If yes, in which tool or game did you need assistance?

☐ Blood Pressure Monitor ☐ Smartphone

☐ Strap ☐ Tablet

☐ Vest ☐ Games

☐ Dynamometer ☐ Beacons

☐ AR Glasses

16. Did you experience any unpleasant situation while using the system?

☐ Yes ☐ No

17. If yes, what kind of unpleasant situation did you experience?

☐ Loss of balance / fall ☐ Stress

☐ Pain ☐ Discomfort

☐ Other, please specify……

18. Do you feel that the FrailSafe System is safe and secure?

☐ Yes ☐ No

Annex 17: System Usability Scale (SUS)[1]

For each of the following statements, please rate your level of agreement or disagreement regarding your experience while using the FrailSafe system. Circle the number that best represents your opinion on a scale of 1 to 5.

I think that I would like to use this system frequently				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I found the system unnecessarily complex				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I thought the system was easy to use				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I think that I would need the support of a technical person to be able to use this system				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I found the various functions in this system were well integrated				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I thought there was too much inconsistency in this system				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I would imagine that most people would learn to use this system very quickly				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I found the system very cumbersome to use				
1	2	3	4	5

[1]Adopted by System Usability Scale (SUS) developed by John Brooke.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I felt very confident in using the system				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

I needed to learn a lot of things before I could get going with this system				
1	2	3	4	5
Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

Annex 18: USE Questionnaire[2]

The purpose of this questionnaire is to assess your level of satisfaction with the experience you had in using the FrailSafe system. For each of the following statements, please rate your level of agreement or by circling a number that best represents your opinion.

Part A: FRAILSAFE Usefulness

It helps me be more effective						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It helps me be more productive						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It is useful						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It gives me more control in health monitoring						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It makes the things I want to accomplish easier to get done						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

[2]It is based on "Measuring Usability with the USE Questionnaire", author: Arnold M. Lund, Measuring Usability with the USE Questionnaire, STC Usability SIG Newsletter, originally published in the October 2001 issue (Vol 8, No. 2)

Part B: FRAILSAFE Ease of use

It is easy to use						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It is simple to use						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It is user friendly						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It requires the fewest steps possible to accomplish what I want to do with it						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

Part C: FRAILSAFE Ease of Learning

I learned to use it quickly						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

I easily remember how to use it						
1	2	3	4	5	6	7

Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It is easy to learn to use it						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

Part D: Satisfaction

I am satisfied with it						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

I would recommend it to a friend						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It is fun to use						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It works the way I want it to work						
1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

It is wonderful

1	2	3	4	5	6	7
Strongly Agree	Agree	Slightly Agree	Undecided	Slightly Disagree	Disagree	Strongly Disagree

List the most negative aspect(s) of the FrailSafe system

1.
2.
3.

List the most positive aspect(s) of the FrailSafe system

1.
2.
3.

Annex 19: Questionnaire for IT professionals

Please circle the **one number** that best describes your level of satisfaction with each of the following items and complete the questions that follow.

FrailSafe system

How satisfied are you with:

The general performance of the system?				
1	**2**	**3**	**4**	**5**
Very Satisfied	Satisfied	Undecided	Unsatisfied	Not at all Satisfied
Please explain why you gave it that rating:				
Please explain in what conditions was the system evaluated:				

The hardware reliability?				
1	**2**	**3**	**4**	**5**
Very Satisfied	Satisfied	Undecided	Unsatisfied	Not at all Satisfied
Please explain why you gave it that rating:				
Please explain in what conditions was the system evaluated:				

The data loss prevention? *(to be completed by consortium IT professionals only)*				
1	**2**	**3**	**4**	**5**
Very Satisfied	Satisfied	Undecided	Unsatisfied	Not at all Satisfied
Please explain why you gave it that rating:				
Please explain in what conditions was the system evaluated:				

The system security?				
1	**2**	**3**	**4**	**5**
Very Satisfied	Satisfied	Undecided	Unsatisfied	Not at all Satisfied
Please explain why you gave it that rating:				
Please explain in what conditions was the system evaluated:				

The system privacy of online personal data? *(to be completed by consortium IT professionals only)*				
1	**2**	**3**	**4**	**5**
Very Satisfied	Satisfied	Undecided	Unsatisfied	Not at all Satisfied
Please explain why you gave it that rating:				

Please explain in what conditions was the system evaluated:

Ease of learning the platform?				
1	**2**	**3**	**4**	**5**
Very Satisfied	Satisfied	Undecided	Unsatisfied	Not at all Satisfied
Please explain why you gave it that rating:				
Please explain in what conditions was the system evaluated:				

Understandability of the platform?				
1	**2**	**3**	**4**	**5**
Very Satisfied	Satisfied	Undecided	Unsatisfied	Not at all Satisfied
Please explain why you gave it that rating:				
Please explain in what conditions was the system evaluated:				

Which aspects of the platform did you find most positive as an IT professional? List most positive 3 below:

Which aspects of the platform did you find most negative as an IT professional? List most negative 3 below:

Annex 20: Sample of Non-Disclosure Agreement

STATEMENT ON NON-DISCLOSURE

WHEREAS

(A) The FrailSafe Consortium is the partnership of parties who participate in the development and implementation of the FrailSafe project, funded by the European Commission with Grant Agreement number 690140;

(B) As part of the ongoing evaluation and assessment of the FrailSafe project, I will receive confidential information from the FrailSafe Consortium;

(C) The FrailSafe Consortium wishes to have the disclosure of such confidential information governed by a particular set of rules in order to protect its legitimate interests;

I, the undersigned …… **[name], …… [role in the company]** of …… **[company name]** with registered office at …… **[address, city, country]** with company number ……..

HEREBY DECLARE, THAT

1. I shall,

(a) keep and treat the Confidential Information strictly confidential at all times;

(b) not disclose it or allow it to be disclosed in whole or in part to any third party without the prior written consent of the FrailSafe Consortium; and

(c) not use it or circulate it within my own or other organization in whole or in part except solely to the extent necessary for the Permitted Purpose or any other purpose the FrailSafe Consortium may hereafter expressly authorize in writing.

(d) take proper measures to ensure the confidentiality of the Confidential Information. Such measures shall offer a level of protection that is at least as protective as the level of protection generally followed in the industry in which the company I represent is active.

(e) not copy or reproduce Confidential Information without the FrailSafe Consortium's prior written consent. Any such permitted copies will be considered Confidential Information.

(f) without limiting the FrailSafe Consortium's rights, I shall promptly notify the FrailSafe Consortium of any unauthorized possession, use or knowledge, or attempt thereof, of the FrailSafe Consortium's Confidential Information by any third party of which I become aware.

(g) I shall not make, or permit others to make, any reference to the subject matter of this Statement or the FrailSafe Consortium's Confidential Information in any public announcements, promotional, marketing or sales materials or efforts without the FrailSafe Consortium's prior written consent.

(h) permit access to the Confidential Information only:

(i) to those of the directors and employees who reasonably need access to such Confidential Information for the Permitted Purpose and on the conditions that such directors and employees shall have:

(i) entered into legally binding confidentiality obligations on terms equivalent to those set out in this Statement (and such obligations extend to the Confidential Information);

(ii) been informed of the FrailSafe Consortium's interest in the Confidential Information and the terms of this Statement; and

(iii) been instructed to treat the Confidential Information as secret and confidential in accordance with the provisions of this Statement;

2. I acknowledge and agree, that

(i) all Confidential Information shall at all times remain the property of the FrailSafe Consortium.

(j) the property and intellectual property rights in the Confidential Information, including any documents, files and other items containing any Confidential Information, belong to the FrailSafe Consortium, unless otherwise agreed.

(k) at the written request of the FrailSafe Consortium, I shall promptly deliver to the FrailSafe Consortium all materials supplied by the FrailSafe Consortium incorporating any Confidential Information of the FrailSafe Consortium and all copies thereof and destroy or erase any Confidential Information contained in any materials and documentation prepared by or on behalf of the company I represent or recorded in any memory device. Within fourteen (14) days of such request the company I represent shall certify in writing to the FrailSafe Consortium that it has fully complied with its obligations.

(l) I shall comply with these obligations for a period of five (5) years, calculated as from the moment the Confidential Information was disclosed to it.

Definitions

Confidential Information: all information, device, electronic system or online web platform supplied and disclosed by or on behalf of the FrailSafe Consortium. Without prejudice to the generality of the foregoing, the following shall explicitly be considered as Confidential Information: all data that is stored in or processed by the information systems of the FrailSafe Consortium;

Permitted Purpose: means the use of the Confidential Information for the purpose of evaluating the devices, systems and online platform of the FrailSafe project.

Name: **……**

Date: **……**