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# Deliverable No: D9.7

## Periodic Report

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## EXECUTIVE SUMMARY

The FrailSafe project aims to study all domains of frailty and to create new measures of assessments leading to a model which will be able to better understand, sense, detect, predict, delay or even revert frailty. To achieve these aims, plans are made to devise a comprehensive clinical assessment, to develop a viable real-life sensing and intervention platform, and to provide a digital patient model of frailty, sensitive to dynamic parameters. Recommendations will be provided to delay frailty, and all this through a safe, unobtrusive, acceptable and cost effective system.

Progress was made in all work packages. For this 18 month report, an extensive list of the completed deliverables is provided together with the milestone achievements. Following on the review of the state-of-the-art in frailty models and metrics the project has made significant advancements. Progress has been achieved both in the medical and technical domain of the project. Namely, the clinical protocol and guidelines that are based on face-to-face clinical assessment, self-administrated questionnaires, text sampling and phone follow ups have been formalized and they have moved to a new phase where the Frailsafe system is currently administered and Frailsafe data are being recorded. Moreover, the preliminary version of the wearable and sensorised garment (WWBS) has recently been made available too. Inevitably, the data management and analytics aspect of the project has co-evolved to be capable of recording, handling, storing and most importantly analyzing the streaming information from real participants. All data are stored and analysed from all sources and not just the physiological and geospatial recordings of the early Frailsafe system. Another major source of information is the text analysis, via the recently released LingTester and social media sensing tools. The design of the FrailSafe games framework has started and an augmented reality cognitive-based demo game has been developed and is under testing and evaluation. Another augmented reality game is currently under development. The first version of the data processing and analysis platform, as well as the first version of the integrated Frailsafe system have been released. Provided that the central database system has evolved to efficiently handle big data, it is also nearing the point where the user profiling models and modeling and representation framework will be literally dynamic and will provide a platform of unparallel value to all involved parties (medical doctors, reseachers and the participants themselves).

The ultimate goal is to prevent and delay frailty by early detection of frailty signs and biomarkers. As a result, efforts have been focused on discovering relevant and informative indicators for frailty by signal processing algorithms, data fusion and association mining that will eventually lead to the extraction of frailty related indicators.

Ethical issues are continuously being considered and debated in alignment with all current European and National laws. Risk analysis and mitigation procedures have been updated as per case required. Herein, we are also reporting on dissemination strategies, concertation activities, intellectual property rights and exploitation initiatives. All-in-all, an up-to-date progress from all work packages is presented, elaborated and fully explained in the following pages of this 18 month report.

## DOCUMENT INFORMATION

| | | | |
|---|---|---|---|
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| **Abstract (for dissemination)** | This is a confidential report that provides a detailed summary of the progress made during the first half of the project, including management as well as scientific aspects. | | | |
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# Part A

# 1 Summary for publication

## *1.1 Context and overall objectives of the project*

Ageing population is increasing worldwide to reach an estimated two billion people aged over 65 years by 2050. While the increasing life expectancy is a positive outcome due to long-lasting health and social improvements, there is still much to do to improve the Healthy life years' indicator, i.e., the number of years without age-related disability.

Frailty is a syndrome characterized by diminished strength, endurance, and reduced physiological function that increases an individual's vulnerability for developing increased dependency, and/or death. Frailty is also related to multiple pathologies: weight loss, and/or fatigue, weakness, low activity, slow motor performance, as well as balance and gait abnormalities. It makes older persons more vulnerable to stressors and has major health care implications, which in turn have an impact on the planning and delivery of health and social services. Frailty together with functional decline and disability are common conditions among older people, and are increasing with ageing. However, frailty is a dynamic and not an irreversible process; it seems preventable, may be delayed, or even reversed.

The FrailSafe project aims to study all domains of frailty simultaneously and to create new measures of qualitative and quantitative assessments leading to a model which will be able to better detect and predict frailty. Frailty could be delayed by developing a set of measures and tools, together with health recommendations. FrailSafe project objectives can be summarized as follows:

- better understand frailty and its relation to other health conditions;
- identify quantitative and qualitative measures of frailty through advanced data mining approaches and use them to predict risk of frailty, as well as short and long-term outcome;
- develop real-life sensing and an intervention platform;
- provide a digital patient model of frailty sensitive to several dynamic parameters, including physiological, behavioral and contextual;
- create "prevent-frailty" evidence-based recommendations for older persons;
- strengthen the motor, cognitive, and other "anti-frailty" activities through the delivery of personalized treatment programs, monitoring alerts, guidance and education;
- achieve the above through a safe, unobtrusive and acceptable system for the ageing population, while reducing the cost of health care systems.

To achieve these objectives, FrailSafe will combine state of the art information technologies and data mining techniques with high-level expertise in the field of health and ageing.

## *1.2 Work and main achievements within the reporting period*

Regarding WP1 “Requirements, Use Cases, Architecture and Specifications”, a review has been conducted of the current practices in the fields of frailty quantification, sensing systems, virtual patient modeling, data mining, information visualization, virtual and augmented reality games and personalized guidance systems. Being the scope of T1.1, this review has resulted in the completion of D1.1. This review was used as the basis for the end user requirements elicitation procedure (T1.2). The types of users of the FrailSafe system have been identified, along with the basic system components and use case types through the conduction of surveys and focus groups leading to the completion of D1.2. Moreover, this deliverable reports the UCD methodologies (T1.3) that are followed to ensure that the end-user needs remain at the center throughout the design and implementation phases of the project. Finally, the system architecture has been largely defined, leaving only small interconnection details to be finalized until the delivery of D1.4. The system components as well as the parameters being monitored have been defined. The FrailSafe system is composed of three layers: the interfaces layer, containing information visualization and recommendation components; the sensors layer, containing the physiological, physical, cognitive and social sensors and applications used in the project; the data layer, containing the virtual patient model and components related to data storage, security and analysis. Information flows from the sensors to the data layer through an interconnection gateway. End users can view the data collected and interact with the analysis components through the visualization and recommendation interfaces. The works of revision of the first version of the architecture, as described in D1.3, are on going and the overall fully revised version of the system’s architecture has been finalized.

In the context of WP2, a detailed description of methodology and operational procedures has been reported in deliverable D2.1- "Clinical Study Methodology" and in its revised version (M12), in accordance to reviewers’ comments. The series of events have been standardized and the methods and instruments for the clinical assessment and measurements have been selected and adapted. As described in D2.1, the comprehensive clinical assessment was agreed and formalized. The comprehensive clinical assessment is formed by a face-to-face clinical assessment, self-administrated questionnaires, text sampling, and phone follow up assessment. This comprehensive clinical assessment captures all aspects of frailty, i.e., clinical general condition including impairments and disabilities, mood, cognitive status, sleep, nutrition activities of daily leaving, social interactions, personality traits, quality of life, health rating and at the same time basic physiological parameters are recorded. Physiological parameters, such as blood pressure, heart rate, artery rigidity, body mass index, lean and fat body mass, measured at each clinical assessment provide additional information to continuous physiological parameters recorded via the FrailSafe platform.

After acquisition of the approval of the Committee of the Protection of the Person also in Nancy, the clinical study is in full evolution in all 3 clinical centers. Up until M18, 389

participants have been enrolled in the study, 492 (clinical evaluations have been performed). There have been 44 withdrawals from the study, the majority of whom have been replaced by new participants. All three clinical centers have completed the first clinical evaluations in groups A and B. By the end of M18, 103 out of 120 second clinical evaluations of group B have been performed. Data from clinical assessments are entered into tailored made eCRF.

The application of the FrailSafe system devices has started in all clinical centers. Two hundred ninety one (291) FrailSafe sessions have been performed and most of the data obtained have entered either the eCRF platform, either uploaded to the corresponding cloud applications.

The natural language analysis has been introduced to detect subtle cognitive and language changes that might precede transition to frailty states. Three hundred and sixteen written text samples have been collected from participants. The adverse events of frailty are also recorded by phone follow up, including, falls, fractures, hospitalization, and death. Up until M17 466 follow up phone calls have been performed. Milestone 4: Initial measurements from recruited patients, due in M12, has been successfully completed. Deliverables 2.4 Completion of quantification campaign (preliminary version) and 2.6 Behavioural Monitoring have been delivered on M18.

Chronic inflammation has been proposed as an underliing biological mechanism responsible for physiological reserve decline in the elderly. Blood samples have been collected from 80 participants (UoP) to assess the inflammation and endocrine system profile. Collection of the aforementioned blood samples will help us determine and analyze if there is a link between frailty and basic clinical assessments (related to age and inflammation), such as white blood cell count, C-reaction protein, TNF-a, proinflammatory cytokines (IL-1 and IL-6) and inflammatory chemokines (IL-10), adiponectine, klotho protein, sex hormones, IGF-1 and vitamine D. The autonomic nervous system evaluation of cardiovascular function has been performed, so far in 35 participants in UoP. The neurophysiological study is ongoing and is expected to assess a total of 60 participants. Blood sampling from 106 participants, mostly coming from Nancy and Patras, has been collected in order to determine the telomeres' length.

Public meetings have been organized to communicate the scope of the project to the audience, to promote recruitment, as well as to promote awareness. Available FrailSafe material has been demonstrated to older people and comments have been collected; feedback to the technical team generated discussions via teleconferences and decisions were made to adjust materials at the special needs of the target population and to improve the acceptability for use.

Moreover, WP2, in cooperation with other WPs, has contributed to: a) the final version of an operational procedures' check list defining the FrailSafe system installation home visit and clinical evaluation visit, b) the generation of the eCRF for clinical data entry and c) a working document treating practical issues such as study's material and procedures, d) virtual and augmented reality games and WWBS design, e) tables for following up the evolution of the clinical study to be filled in periodically

by all centers and centralized to INSERM. Similarly, documents related to undesirable events, declaration procedures have been distributed in clinical centers.

Finally, adaptations in the informed consent forms have been applied and approved by local ethical committees (in Nancy, Patras and Nicosia), in order to address the issues discussed in the Review Meeting of Brusels in October 2016.

In the context of WP3 and as described in D3.1 and in D3.2, a search for sensors has been performed based on parameters defined and described within the GA and the devices and related monitored parameters have been selected. Bio-impedance scales, blood pressure monitors dynamometers and Mobil-O-Graphs have been purchased and are in use. The Beacons which will monitor participants' position at home, have also been purchased and their distribution will start in M19, together with the dedicated software that is at present under developement; however, final development of these sensors is due for M24. Some sets of commercial inertial platforms have been purchased as useful tools to start collecting data from users during the initial phase of the project, to let the consortium develop dedicated algorithms and improve overall knowledge on short-term monitoring. A first version of WWBS has been developed, produced and EC ceritified (for electrical and electromagnetic safety), so that it can be used according to Ethical Committee requirements. 8 systems have been produced and distributed, in accordance with Amendment #1 to the Contract. A second, final version of WWBS, implementing feedback from partners and all stakeholders will be produced and distributed in 15 units at M24. Regarding T3.3, several algorithms for activity classification and behavioral monitoring have been tested to make them ready for further integration. One of them, GPS Tracker Application for distance measurement and step counting, has successfully been implemented and used in the first trials.

In the context of WP4, the development of new methods for the offline and online management and analysis of multimodal and advanced technology data from various types of activities of older adults as well as the generation of FrailSafe virtual patient models are to be conducted. Towards the design of the database which is part of Task 4.1 - "Offline Data Management and Analysis", a detailed analysis of the state-of-the-art solutions was made. HBase was chosen as the best candidate, since it is part of the Hadoop ecosystem, which provides high scalability in data analysis and knowledge discovery algorithms as well. Data is being collected and stored at the Amazon Web Services (AWS) cloud. Additionally, preliminary work towards the detection of patterns and associations between clinical indicators and frailty states was performed by analyzing the multidimensional time series acquired by the frailsafe system. The objective of the analysis is to reveil associations among signals and symptoms that are connected to the frailty syndrome.

Task 4.2 - "Online Data Management and Analysis" concerns the online data analysis where a special effort has been made on the identification of the device that will be used as a gateway to collect the sensor data and run the real-time analysis. The goal of this type of analysis is to identify instability, tendency to fall, and loss of orientation for older people. It is stressed that the FrailSafe team will not be aware of any emergency in real time. However, the system will include a real-time analysis and

response, developed in the lab using off-line participants' data; the real-time analysis is a feature which will be included, after the end of the project, in the market product. In Task 4.3 - "Dynamic User Profiling Models", openEHR, which is a reference model for building VPM (Virtual Patient Models) via archetypes has been adapted to address critical issues of FrailSafe' human-computer interaction as well as to provide user groups with interface and tools fitting to their specific needs. The identification and classification of the entities/concepts of interest relevant to FrailSafe is initially offered including monitored parameters, clinical data, diagnosis results, risk factor, action plans, interventions, (patient record, etc., to meet the defined requirements (D1.2). A detailed conceptual definition of FrailSafe' patient model representation format has been defined and analytically discussed in D4.6. The final version of the VPM has been implemented and is being tested by the technical and clinical teams.

In Task 4.4 - "Sensing social media", elderly data from social media, e.g. social media analytics, which are used to monitor and capture user's behavior as well as the social interaction of the older people, are collected. Concretely, we have proposed a set of questions plus big five questionnaires to correlate (with use of machine learning approaches) the word usage and the social media behavior of subjects to frailty symptoms. In particular, we have conducted detailed experiments for the Big Five Personality Traits Extraction for Greek, Cypriots and French participants. Moreover, utilising eCRF API, we were able to retrieve all available raw data, stored by each medical team, containing detailed answers to the questionnaire, along with uploaded files of present and past text.

Moreover, we initiated the development of the online mode of the LingTester tools, which covers all steps needed to support all necessary user actions while also removing any sensitive information, and thus, protecting participants' data. The LingTester online mode is constructed based on two main sub modules, frontend and backend. Each submodule is also based on different layers of processes which interact altogether through predefined APIs, existing or custom ones. At this point, the prototype is in early alpha stage, but still it is able to perform classification according to levels of frailty. The LingTester module includes four computational linguistic components: a Word Speller, a Morphological Processor, a Readability Parser, and a Mispelling Processor. After further studying, state of the art methodology, a language model was implemented with linguistic information based on all predefined languages as part of Task 4.5 - "Processing social media". The language model is composed of a formal component representing the lexicon, grammar and syntactic rules of the language, and a statistical component containing results of word and bigram frequencies.

Task 4.6 - "Signal Processing for extraction of frailty-related indicators" aims at extracting frailty-related indicators from signal processing. Preliminary work was performed on signal processing and data mining techniques towards discovering associations between frailty, and physiological or behavioral patterns. We started to assess the correlation of frailty indexes to multi-channel recordings from the FrailSafe system. For the latter purpose, all sensor data (ECG recordings, Breathing Amplitude, Breathing Rate, Heart Rate, R-R intervals, Heart rate variability) were time synchronized to allow multichannel analysis.

Finally, in Task 4.7 - "FrailSafe clinical state prediction engine and risk assessment", an investigation of the role of inflammation in the pathogenesis of frailty has been made. Thus, recent studies support this association between inflammation, frailty, and age-related disease. As an objective, we have developed a novel platform that will aid the clinician to collect, analyze and report the relationships between biochemical and blood related markers to chronic inflammation and thereof the link between chronic inflammation and frailty of the elderly. The role of cytokines, interleukins, cardiovascular abnormalities in combination with chronic high blood pressure, hyperlipidemia and diabetes has been extensively researched in a systematic review article that has been prepared to be submitted to an international, peer-reviewed journal in the biomedical domain. Additionally, the VPM, which will serve as a risk assessment panel for the clinicians, is being tested. On a different note, task 4.7 is also focused on the development of the clinical state prediction engine and its potential to efficiently simulate the behaviour of the existing patient model. This is achieved by taking into account all measurements from physiological factors. The aim is to calibrate the system so that eventually it will be capable of integrating diverse results from different sources and sensors in an effort to provide the end user with focused and highly informative feedback. Finally, a repertoire of soft computing and statistical techniques will be used to analyse the sensors' signals in an effort to efficiently identify the meaningful data, discard/remove noise and false-positives so that it will provide error-free analysis and decision support.

WP5 has focused on the analysis of smart devices, operative systems, end game engines to be used in FrailSafe. Different important decisions have been taken regarding the tablet and the smartphone to be used in FrailSafe as well as the operating system of these devices and the the games engine to be used for developement. This way, most of the developments will be possible to be compiled for other devices and operating systems. Regarding developments, the design of the FrailSafe Games Framework has started and the first tests based on Unity have been performed, accessing device sensors, accelerometers, IMUs, 3D rendering, and tactile screen. A third-party software (CERTH's virtual supermarket game) has been included after necessary modifications to improve project's data collection towards the fulfilment of project's objectives. An augmented reality cognitive-based demo game for Tablet devices has been finalized and is currently under usability and safety issues testing as well as ergonomics evaluation. Finally, an augmented reality beta game for Epson Glasses is currently under development.

Activities of WP6 "Integration and FrailSafe Application and Services" can be summarized as follows, concerning the period till M12: (a) worked on M4 trials technical solution proposal, in collaboration with WP1; (b) discussed and deployed questionnaires web platform, in collaboration with WP2 and WP4; (c) designed front-end architecture, based on Data Flow, in collaboration with WP1; (d) investigated Data Security and Privacy EU Directives and Regulation; (e) deployed pre-α version of Clinical Web Portal for ECRF (Electronic Case Report Form) features first test run to be performed by WP2 (this activity, belonging to T6.3 has been anticipated at M6 respect, as stated in DoW, the scheduled start time that is M16). This kind of activity has been moved up to provide WP2 the possibility to collect digitalized data (instead of the

paper one) since the beginning of the project to facilitate data collection. The results achieved during the first project's period can be summarized as follows: (a) State of the Art of Data security privacy and regulation; (b) Analysis of Privacy by Design and by Default; (c) Designed front-end architecture, based on Data Flow, in collaboration with WP1; (d) Deployment of pre-α version of Clinical Web Portal for ECRF (Electronic Case Report Form) features first test run to be performed by WP2 (e) Analysis of the Virtual Community Platform specifications regarding the data that will be imported and stored in the Database Management System as well as the data that will be available for older people families and caregivers.

After M13, several activities on all the tasks of the WP6 have been performed - starting, progressing or concluding - and, in particular, the T6.3 (that is *System Integration*) officially started (M16). For the task T6.1 a revision of the analysis of the Virtual Community Platform objectives and processes has been performed. A relevant progress has been reached on the activities of the task T6.2: the user management and security system has been implemented, tested, deployed and made available to the whole consortium for the integration activities. As said here before, the works of the task T6.3 officially started with a sensible number of actions executed. In particular, the most tangible result of this task is that the first version of the FrailSafe mHealth Integrated system has been implemented and released (deliverable D6.3, M18).

Regarding WP7 "Testing and Evaluation", formal work has just started in M18 with T7.1, Pilot planning and assessment protocol (ongoing), leading to the first delivarable (D7.1, Assessment protocol (vers.a), due in M20. The rest of the tasks and deliverables begin in M24 onwards, as WP7 has the main objective of testing and evaluating the integrated Frailsafe system in validation senarios, to achieve quantification and evaluation of the metrics which affect frailty. Initial work has focused on literature reviews (also in relation to WP2), and drafting the main areas of D7.1. There are no significant results and achievements to report up to the point of this report.

Regarding WP8 "Dissemination and Exploitation" and in order to raise awareness of the project developments (T8.1) among key user groups, the scientific community and the general public, the website was launched in April 2016, where information could be found, such as partners' participation to major events or project deliverables. Other communication materials (leaflet and newsletter) were also produced to reach the mentioned objectives, in accordance with the two versions of the FrailSafe Dissemination Plan (D8.1, D8.2) delivered in M3 and M12 respectively.

The preliminary version of the Data Management Plan (DMP) (deliverable D8.12) was also submitted in M6. It summarizes the datasets expected to be generated or collected in FrailSafe and also the strategy adopted to achieve open access to FrailSafe results. The FrailSafe DMP is a living document and is expected to be updated as the project evolves. Therefore, an updated version of the DMP will be available in M24, while the final version will be delivered in M36.

During this period, a first approach to the FrailSafe business model issue has been faced in T8.2. Firstly, we started to investigate different approaches to business modelling to promote the adoption of ICT-based solution for study, supporting and

contrast frailty and co-morbidities. This is done by combining the specific basic components of the traditional business models (user/customer, application/services offering) to maximize the impact on the healthcare ecosystem, according to the following main topics: (a) User's/customer's central role in the definition of FrailSafe Business Model; (b) Opportunities to FrailSafe business modelling; (c) Threats to FrailSafe wrong business modelling; (d) Earnings logic; (e) Key resources; (f) Orchestration of FrailSafe business model.

Then, the activities performed concentrated on how to develop a business framework with illustrative business models and their interfaces between actors to understand how the services can be created and delivered in the FrailSafe marketplace. Furthermore, the model Canvas and the Customer Development Model (by Steve Blank) are currently under evaluation in order to verify their usefulness to start to design the business model and, consequently, the FrailSafe business plan. In this direction, the first draft version of the FrailSafe Exploitation Plan (D8.6) is submitted in M18.

Additionally, the Intellectual Property Rights (IPR) Working Group was defined inside the project to work towards the compilation of the IPR agreement (T8.3). Discussions on the technical architecture of the FrailSafe platform are currently underway and are expected to be finalized pretty soon. In this architecture, the various exploitable components expected to be developed during the project lifecycle are also included (WWBS, games, data analysis and visualization tools, Virtual Patient Model, clinical and community platform, etc.). The IPR agreement focused exactly on these components to compose the first version of the IPR management plan (D8.8) delivered in M12.

Concerning standardization and concertation actions (T8.4), the first steps task dealt with the EU directives and regulations on data protection, privacy and security as well as the US HIPAA. Results coming from this activity have been shared with WP1, WP3 and WP6 so as with the FrailSafe Ethics Committee for the composition of the FrailSafe Ethics Manual (D9.9), another living document and is being updated as the project evolves. The first version of the standardization and concertation activities report (D8.10) will be made available in M24.

## *1.3 Progress beyond the state of the art*

The progress beyond the state of the art for the first 18 months of the project can be summarized as follows.

Some novel work on the analysis of physiological function and motor performance of the older people has been performed towards multimodal behavioral and environmental monitoring. Specifically, after extracting many time and frequency domain features from the sensor signals (obtained from datasets of similar studies) a human motion identification module was developed [1] that classifies basic activities of daily living (ADLs) to obtain preliminary evaluation results for the proposed

architecture. The proposed classification model achieved a 97% accuracy which is a slight improvement compared to previous approaches evaluated on the same dataset. However, such an improvement can be considered significant given the fact that it is achieved with lighter processing using a smaller number of features. Additional work on designing a framework for retrieving, analyzing, and storing medical information as a multilayer graph has been made [2]. The framework is strongly based on the explicit assumption that the medical data as well as their interconnection patterns can be expressed as graphs. The benefit of using multilayer graphs is the data fusion and further processing capabilities they offer. Moreover, sensor data correction and preprocessing was also investigated. As sensor data often contain many outliers or missing/corrupted values, regularization methods need to be imposed.

In our preliminary work the theory and practice of a regularization class based on finite differences and implemented through the conjugate gradient method were examined. Some encouraging preliminary results were obtained from applying the proposed regularization techniques to heart rate time series from the MIT-BIH dataset [3]. This dataset was used as well to evaluate our scheduling policy in [4]. In this work a flexible scheduling policy based on higher order moments of the estimated process size distribution is proposed, which aims to achieve both better performance and perceived QoS in distributed systems such as Hadoop.

Further novel work performed on fall detection is described in [5], where we investigate the location where such wearable sensors should be placed in order to optimize the discrimination of falls from other Activities of Daily Living (ADLs). As a result, we perform feature extraction and classification based on data acquired from a single sensor unit placed on a specific body part each time. The investigated sensor locations include head, chest, waist, wrist, thigh and ankle. The evaluation of several classification algorithms revealed the waist and thigh as the optimal locations.

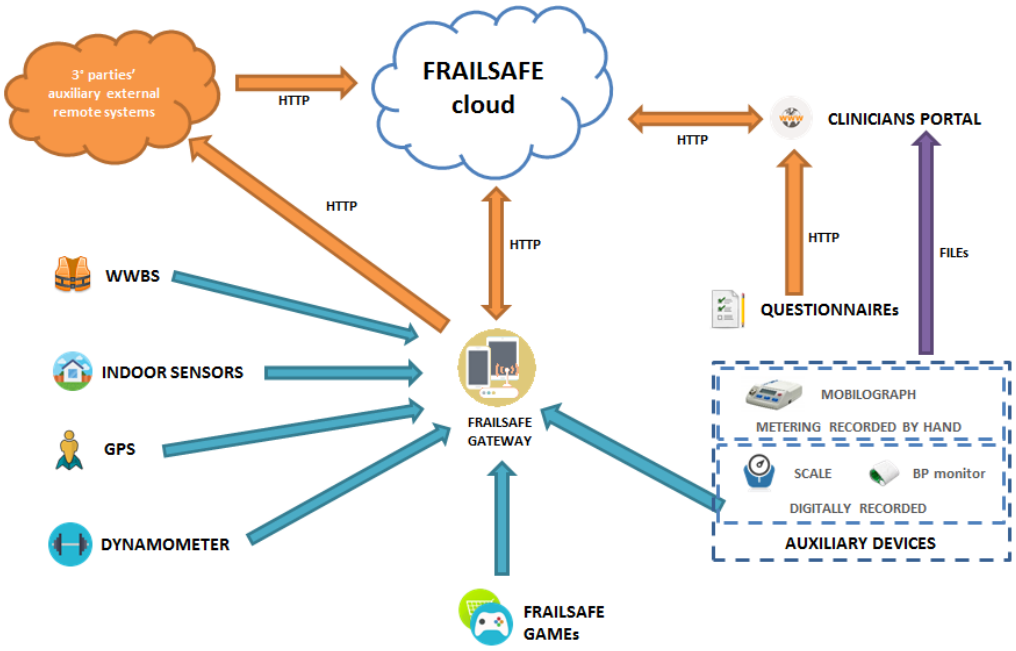


**Figure 1: Data flows based architecture**

A preliminary draft of a novel architecture has been developed and later on presented in the deliverable D1.3. After its presentation, it has been revised and mostly finalized. Particularly, the design of front-end architecture, based on data flow, has been faced in collaboration with WP1 and all the other WPs. Furthermore, the design of back-end architecture has been concluded, always in collaboration with WP1 and all the other WPs. Regarding the FrailSafe architecture, we dealt with:

- How each module of the system interacts with other ones;
- Mapping the security/privacy features to be implemented;
- Identifying eventual missing modules / features to be implemented;
- Working to achieve a services oriented architecture.

During the public meetings with candidate participants the available FrailSafe material has been demonstrated to older people and comments have been collected, feedback to the technical team and discussed in teleconferences to adjust our material in the special needs of our target population and improve the acceptability for use.

The autonomic nervous system (ANS) plays a major role in the regulation of the physiological processes of the human organism both during normal and pathological conditions. Among the techniques used in its evaluation, the heart rate variability (HRV) has arising as a simple and non-invasive measure of the autonomic impulses, representing one of the most promising quantitative markers of the autonomic balance. The relationship between aging and HRV has been well documented. A novel technique is being adapted to measures HRV by using color channels in video recording to extract the blood volume pulse from the facial region. The participants' tablets will be used for this purpose recording signals whilst playing with game applications.

Successfully predicting visual attention can significantly improve the real-time image generation for supporting complex photorealistic global illumination effects, such as order-independent transparency, in VR/AR games. In our preliminary work [6], we have introduced a novel buffer that dynamically distributes the desired storage space (instead of assuming the same memory for all pixels) according to an importance-based distribution function, thus, allowing higher quality complexity in regions that are deemed more important. The importance map is dynamically determined based on three general, but highly sensitive to older people, factors: (i) the depth complexity, (ii) the distance of pixel from the fovea region and (iii), the Fresnel term.

Moreover we have further investigated on techniques that perform text mining on text produced by the elderly. Default learning methods do not exploit uncategorized files which are in abundance on several fields. In order to boost learning performance of supervised algorithms using only a small number of annotated examples, we applied active learning which incorporates both labeled and unlabeled data and integrates human’s expertise knowledge with the obtained predictions by supervised learners [7].

**Publications produced:**

[1] E. Pippa, I. Mporas, and V. Megalooikonomou. "Feature Selection Evaluation for Light Human Motion Identification in Frailty Monitoring System", *In Proceedings of the International Conference on Information and Communication Technologies for Ageing Well and e-Health, (ICT4AWE), Rome, Italy, 2016.*

[2] G. Drakopoulos and V. Megalooikonomou. "A Graph Framework for Multimodal Medical Information Processing", *In Proceedings of the International Symposium on Mobile and Assistive Technology for Healthcare (MATH) at the Eighth International Conference on eHealth, Telemedicine, and Social Medicine (eTELEMED), Venice, Italy, 2016.*

[3] G. Drakopoulos and V. Megalooikonomou, "Regularizing Large Biosignals with Finite Differences", *In Proceedings of the 7th International Conference on Information, Intelligence, Systems, and Applications (IEEE IISA 2016) Chalkidiki, Greece, 2016.*

[4] G. Drakopoulos and V. Megalooikonomou, "A Higher Order Scheduling Policy with An Application To Biosignal Processing", *IEEE Symposium Series on Computational Intelligence 2016*, Athens, Greece.

[5] P. Ntanasis, E. Pippa, A. Turanozdemur, B. Barshan and V. Megalooikonomou, “Investigation of sensor placement for accurate fall detection”, *6th EAI International Conference on Wireless Mobile Communication and Healthcare (MOBIHEALTH 2016)*, Milan, Italy, Nov. 14-16, 2016.

[6] A-A. Vasilakis, K. Vardis, G. Papaioannou, K. Moustakas, "Variable k-buffer using Importance Maps", In *Proceedings of the 38th Annual Conference of Eurographics (EG ’17)*, Short Papers, pages 21-24, Lyon, France, April 24-28, 2017. DOI: 10.2312/egsh.20171005.

[7] S. Karlos, N. Fazakis, S. Kotsiantis, K. Sgarbas, “An Empirical Study of Active Learning for Text Classification”, *International Conference on Knowledge Based and Intelligent Information and Engineering Systems (KES2017)*, 6-8 September 2017, Marseille, France.

# 2 Deliverables

**Table 1: Table of FrailSafe deliverables**

| Del. no. | Deliverable name | WP no. | Lead beneficiary | Type | Dissemination level | Delivery date from Annex I | Actual delivery date | If deliverable not submitted on time forecast the delivery data if appropriate | Status | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| D8.1 | Dissemination plan and FrailSafe dissemination material | 8 | AGE | R | PU | M3 | M3 | | Approved | Detailed report of the communication policy of FrailSafe<br>Preparation of the dissemination and communication tools (logo, website, press release, standard PPT presentation, leaflets, social media profiles) |
| D8.5 | Project Web presence | 8 | HYPERTECH | OTHER | PU | M3 | M3 | | Approved | Creation and launch of the FrailSafe official website (http://frailsafe-project.eu/)<br>Social media channels |

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| | | | | | | | | | | Wiki<br>Repository (including meeting minutes) |
| D9.1 | Project reference manual and quality plan | 9 | UoP | R | CO | M3 | M3 | | Approved | Presents the management structure, the quality procedures, and the various operational tools of the Project<br>Summarizes the project facts, namely the project's work breakdown, its inter-dependencies, and the project timetable regarding deliverables and milestones |
| D9.2 | Project Quality Plan | 9 | UoP | R | CO | M3 | M3 | | Approved | Quality control<br>General (success criteria, corrective and preventative actions, contingency planning and risk management)<br>Deliverables and documentation (document types, documents naming, and document templates)<br>Whole project (peer-reviewing evaluation of project's deliverables) |
| D9.9 | Ethics, Safety and mHealth Barriers (regulation, legislation, etc.) Manual | 9 | UoP | R | PU | M5, M36 | M5 | | Approved | Overview of Health, Safety and Wellbeing<br>Legal Framework for Privacy Protection<br>Legal and Ethical framework for Involvement of Human Subjects<br>Cloud Computing on Privacy Issues |

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| | | | | | | | | | | FrailSafe Ethics Guidelines<br>Data protection checklist |
| D1.1 | Analysis of current practices | 1 | CERTH | R | PU | M6 | M6 | | Approved | The main goal of this document is to report on the current advances in knowledge management systems and sensors for monitoring physical and cognitive capabilities as well as AR serious games and rehabilitation programs |
| D2.1 | Clinical study methodology | 2 | INSERM | R | PU | M6 | M12 | | Resubmitted on M12 after making revisions as requested by the reviewers | This report is a living document and provides an overview of the sensor devices and measurement procedures that will potentially be included in the first quantification campaign. The current selection of methodologies will be based on careful selection of potentially interesting parameters with respect to the management of frailty and technologies that are available within and outside the FrailSafe consortium. |
| D3.1 | Definition of sensor components and communication strategy | 3 | SMARTEX | R | PU | M6 | M6 | | Approved | This deliverable reports on the choices done in the selection of sensors for data collection and management. It uses results coming from the analyses of current practices (Task 1.1) and also preliminary results of the analyses of user requirements, user centred design (UCD) and use cases (Task 1.2). |
| D4.5 | Dynamic User | 4 | CERTH | R | PU | M6 | M6 | | Approved | It reports on the user-profiling models |

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| | Profiling models and Patient modeling and representation framework (vers. a) | | | | | | | | | developed based on data collected from participants belonging to different frailty stages plus healthy participants. |
| D5.1 | Analysis of hardware devices and software tools. Game hardware and software design. | 5 | BRA | R | PU | M6 | M6 | | Approved | This document will contain the studies made on the different devices, architectures, and software platforms available for the project's game system. It will identify the devices taking part in the FrailSafe game architecture and the graphics engines to be used for games development. |
| D8.12 | Data Management Plan | 8 | HYPERTECH | R | CO | M6 | M6 | | Approved | This deliverable will generate a Data Management Plan (DMP) that will be maintained also beyond the project's lifetime addressing in full the lifecycle of the data to be generated in WP4 and WP6. Thus, an open data repository will be available, conforming to potential ethical issues in which the DMP will describe in details the derived models (WP4), anonymized data/metadata, action plans and educational content related to frailty that will be included in this repository. |
| D9.3 | Periodic | 9 | UoP | R | CO | M6 | M6 | | Approved | First 6 month progress report |

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| | Management Reports | | | | | | | | | |
| D1.2 | User requirements, use cases, UCD methodology and final protocols of evaluation studies | 1 | CERTH | R | PU | M12 | M12 | | Submitted | The goal of this document is to analyze and specify the user requirements, to define and deliver several representative use cases and user scenarios, and to define the User Centered Design (UCD) methodology that will be used throughout the project. |
| D1.3 | FrailSafe technical specifications and end-to-end architecture | 1 | SIGLA | R | CO (with PU parts) | M12, M24 | M12 | | Submitted | The main objective of D1.3 is to describe in good details the high-level overall system architecture as a whole, and all the components, both hardware and software, composing it. |
| D4.6 | Dynamic User Profiling models and Patient modeling and representation framework (vers. b) | 4 | CERTH | R | PU | M12 | M12 | | Submitted | Final version of D4.5. It reports on the user-profiling models developed based on data collected from participants belonging to different frailty stages plus healthy participants. |
| D4.10 | Ling Tester (Preliminary version) | 4 | UoP | Prototype | PU | M12 | M12 | | Submitted | LingTester is the FrailSafe language analysis tool that aims to process the user's typed text and detect abnormal behaviour. At this point, the prototype is in early alpha stage, but still it is able to perform classification according to levels |

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| | | | | | | | | | | of frailty. The present deliverable describes the development of the prototype, the algorithms used, the training process and some preliminary test results. |
| D4.14 | Signal processing algorithms for extraction of frailty related indicators (Preliminary version) | 4 | UoP | R | CO | M12 | M12 | | Submitted | In this deliverable, our primary efforts were focused on discovering a set of relevant and informative indicators for frailty. During this process, the state of the art was analyzed and the clinical experts of our consortium gave their valuable input. Flowingly some preliminary work was performed on signal processing and data mining techniques towards discovering associations between frailty, and physiological or behavioral patterns. Finally fueled by our previous work on data fusion, we developed three schemes which will be tested on the collected FrailSafe data. |
| D8.2 | Dissemination plan and FrailSafe dissemination material | 8 | AGE | R | PU | M12 | M12 | | Submitted | An updated version (ver. b) of deliverable D8.1 |
| D8.8 | IPR Protection Plan | 8 | HYPERTECH | R | PU | M12 | M12 | | Submitted | This deliverable were to raise public awareness of the project developments among key user groups, the scientific community and the general public through different communication |

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| | | | | | | | | | | channels. Moreover, another important action was to facilitate sharing of knowledge inside the consortium. |
| D9.4 | Periodic Management Reports | 9 | UoP | R | CO | M12 | M12 | | Submitted | First 12 month progress report |
| D3.2 | Preliminary WWBS prototype | 3 | SMARTEX | R | CO | M15 | M17 | | Submitted | This deliverable describes the Wearable WBAN System (WWBS), a wearable system composed by sensorised garment, an electronic device and a software tool. It will allow to monitor older adults at home during standard day-time activities, collecting data from their heart, their respiration, their posture and their activity. Those data will be saved and them uploaded to cloud to let FrailSafe consortium to analyse them and develop algorithms and classifications in order to better understand frailty. The system will monitor one ECG lead, respiration and movement from 3 inertial platforms. |
| D5.2 | Beta version of the Synthesized AR game system. | 5 | BRA | R | PU | M16 | M16 | | Submitted | This deliverable is a demonstrator of the system, including all the modules and systems but the database connection. It will also contain a beta version of two of the proposed games that will make use of the described hardware and software |

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| | | | | | | | | | | modules |
| D2.2 | Clinical Guidelines Formalized (vers a) | 2 | MATERIA | R | PU (report+data) | M18 | M18 | | Submitted | This is a public report analysing the data streams related to typical off-line clinical measurements ranging from physiological parameters to complete patient health records targeted to the quantification of frailty and the implementation of the prediction framework. |
| D2.4 | Completion of quantification campaign (preliminary version ) | 2 | INSERM | R | PU (report+data) | M18 | M18 | | Submitted | This is a public document reporting the specific tests targeted to the quantification and optimization of the FrailSafe framework. |
| D2.6 | Behavioural Monitoring | 2 | INSERM | R | PU (report+data) | M18 | M18 | | Submitted | This is a public document reporting on the analysis of measured patient behaviours on specific tasks, such as gait, grasping, etc. |
| D4.1 | Offline analysis of data (vers a) | 4 | UoP | R | PU | M18 | M18 | | Submitted | The main focus of this deliverable is to report on the usage of existing and new developed echniques towards offline data management, preprocessing and analysis. |
| D4.3 | Online analysis of data (vers a) | 4 | UoP | R | PU | M18 | M18 | | Submitted | The main focus of this deliverable is to report on the usage of existing and new techniques for real-time online data pre-processing and data reduction. |
| D4.7 | Linguistic Corpus (vers a) | 4 | UoP | R | PU | M18 | M18 | | Submitted | This document is reporting on the social data collection phase. Specifically, in this |

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| | | | | | | | | | | phase, e-mails, Facebook posts and Twitter messages from several older people will be gathered and tagged according to each patient's mental frailty condition. The linguistic corpus is focused on the Greek and French languages. |
| D4.8 | LingTester Test Results – Active (on-line) mode (vers a) | 4 | UoP | R | PU | M18 | M18 | | Submitted | This deliverable reports on the choices made in the design of the online LingTester system, sub-systems, echnical specifications and architecture. Firstly an overall introduction to the system concepts, modules and processes is given; secondly a more detailed resentation of different layers composing the system architecture - devices, frontend interfaces, server backend infrastructure is presented in all its parts |
| D4.12 | LingTester Test Results – Passive (off-line) mode (vers a) | 4 | UoP | R | PU | M18 | M18 | | Submitted | This deliverable reports on the choices made in the design of the prediction model of the LingTester tool and its regarding Test esults. The main topics discussed are feature extraction/selection techniques, classification methods and Evaluation metrics. A detailed test & evaluation of the results is presented and a suicidal model tendency is discussed and analysed. |

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| D6.3 | FrailSafe mHealth Integrated version (vers a) | 6 | SIGLA | R | CO | M18 | M18 | | Submitted | The aim of this report is to document the state of the art and the workplan of the FrailSafemHealth Integrated system. |
| D8.6 | Exploitation Report and FrailSafe Business models (vers a) | 8 | HYPERTECH | R | CO | M18 | M18 | | Submitted | This document represents the first version of the exploitation report and business plans of the FrailSafe project and is based on the collaborative work of the FrailSafe project partners, who have reviewed and delivered their comments and exploitation intentions. |
| D9.7 | Periodic Report | 9 | UoP | R | CO | M18 | M20 | | Submitted | Project's periodic report (currect deliverable). |

# 3 Milestones

**Table 2: List of FrailSafe milestones**

| Milestone No | Milestone Title | Related WP(s) no | Lead Beneficiary | Delivery date from Annex I | Means of verification | Achieved Yes / No | If not achieved Forecast achievement date | Comments |
|---|---|---|---|---|---|---|---|---|
| Ms1 | Web site available | WP8 | HYPERTECH | M3 | Web site available on the internet | YES | | |
| Ms2 | Definition of requirements, use cases and UCD methodology available. | WP1 | CERTH | M9 | Analysis of use cases with at least 30 experts and/or user/ stakeholder representatives | YES | | |
| Ms3 | Definition of system architecture and specifications | WP1 | CERTH | M12 | Technical specifications and preliminary version of system architecture available | YES | | |
| Ms4 | Initial data measurements from recruited patients | WP2 | INSERM | M12 | Data from clinical evaluations and FrailSafe system applications from the recruited participants | YES | | |
| Ms5 | First version of the FrailSafe | WP3 | SMARTEX | M12 | Internal report + s/w + h/w | YES | | |

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| | sensing infrastructure | | | | | | | |
| Ms6 | First version of the data processing and analysis platform | WP4 | UoP | M18 | First prototype of the platform is integrated in the cloud | YES | | |
| Ms7 | First version of AR game system | WP5 | BRAINSTORM | M18 | First Prototypes of tablet and AR games | YES | | |
| Ms8 | First Integrated System Prototype | WP3, 4, 5, 6 | SIGLA | M18 | First prototype of the integrated platform. The infrastructure of the system is implemented and, on top of it, the security system modules, the Clinical Web Portal and the Offline Data Analysis modules are deployed, integrated and working. | YES | | |

# 4 Ethical Issues

**Table 3: List of Ethical issues of FrailSafe project**

| Ethic Requirements | Due date for the compliance of the ethic requirement | Report of the independent ethics advisor/advisory board if applicable | Comments |
|---|---|---|---|
| Obtain ethical approval | Done in all centres | N/A | Final ethical approval has been obtained in all centres |
| Obtain Informed consent | Ongoing | N/A | In course in centers with ethical approval. Participants are aware of all policies, clinical assessments, follow up procedures, use of data, withdraw of consent and erasure of data. |
| Updated versions of participants' informed consents and local ethical committees have been obtained | Obtained for Nancy, Patras and Cyprus | N/A | Updated versions after adjustment for comments made during the first Review Meeting in Brusels in October 2016, mainly dealing with liability issues. |
| Independent ethics supervisor | | N/A | Prof. Stefania Maggi, National Research Council of Italy Aging Section, President, European Union Geriatric Medicine Society has been appointed. Prof Maggi has provided us with a signed letter as requested by the reviewers (see Appendix, page 181) |
| Data management plan | | N/A | In place, including plans for anonymization, encryption, storage, and specific uses of data. |
| Handling of sensitive data | | N/A | Policies in place following local clinical centre policies. |
| Cloud data: handling & safety | | YES | Policies are in place for encryption, sharing and transferring data<br>Legal opinion on the adequacy of the chosen cloud provider |

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| | | | services was requested and consequently produced on the 22th of May 2017 by an independent law firm – i.e. *Studio legale Bassoli* of the lawyer Professor Elena Bassoli, based in Genova (Italy)<br><br>Letter from Ethics Supervisor Prof. Stefania Maggi expressing her opinion on the data protection issue in the cloud (M18 Periodic Report) is included in Appendix B. |
| Handling of geolocation data | | N/A | Policies are in place |
| Handling of biological samples | | N/A | Management policies for obtaining, storing, and transferring biological sample are in place |
| Safety of participants | | N/A | Policies are in place |

Deliverable No: D9.6 vers. a (D9.9) in Ethics, Safety and mHealth Barriers Manual (vers. a) submitted on the 6th of June 2016 describes in detail the legal framework for privacy protection, as well as the legal framework for data quality and data security. The legal framework for involvement of Human Subjects has also been considered. Technical and cloud computing on privacy issues related to the FrailSafe project have been analyzed. The approach for ethical approval, handling of biological samples for research, protection of personal data, as well as protection of geolocation data collected via GPS, Bluetooth and beacons, is carefully described. Social media mining and monitoring tools to be deployed in the project will be abiding to all relevant rules and recommendations of the national legislation and the respective EU recommendations and directives. Not least, the right to be forgotten with the procedure to erase all personal data has been considered. Professor Stefania Maggi, Professor of Geriatric Medicine in Padova and President of the European Union Geriatric Medicine Society (EUGMS) is serving as the Ethics Supervisor of FrailSafe.

The FrailSafe project strictly complies with the following directives and recommendations: Directive 95/46/EC on protection of personal data (Data Protection Directive), Directive 2002/58/EC on privacy and electronic communications (e-Privacy Directive), Directive 2009/136/EC (Cookie Directive), European Human Rights Convention, UK Data Protection Act 1988 deals with similar issues, EU recommendations for the previous FP7 research projects (ICT FP7 Ethical Guidelines), and Directive (EU) 2016/680 on the protection of natural persons with regard to the processing of personal data. Furthermore, the National legal framework of the countries involved with collection, handling and analysis of data has also been considered.

Written informed consent from particpants is obtained in all cases. Agreement to participate is voluntary and participants are to withdraw their consent at any point in the project. Data collected during the clinical assessment by members of the research team are anonymized and encrypted. Data contain no identifying information. These anonymized and encrypted data are then passed to other members of the FrailSafe consortium to be used freely, without requiring further consent or any additional regulatory approval. The consortium guarantees that all personal data collected during the project are and will be kept secure and unreachable by unauthorized persons. The data are and will be handled with appropriate confidentiality and technical security, as required by law in the individual countries and EU laws/ recommendations. Personal dignity, physical and mental health and emotional wellbeing, protection from abuse and neglect, control by the individual over their day-to-day life are and will be ensured in all cases. Personal privacy of participants is and will also be respected. Research personnel is and will be flexible and clinical assessment sessions are and will be adapted to participants' everyday activities and needs, so that the monitoring period have and will have the least possible impact on personal life and day-schedule. Personal data is and will be collected just for the specified purposes of the participation process and not further processed in a way incompatible with those purposes. In case that participants wish to withdraw their consent, the recording of any further information will be prevented, and all gathered data will be erased if they indicate in writing that they wish so.

A common and clear regulation on cloud computing exists since the recent enforcement of the article 3 of EU Regulation 2016/679; this Regulation applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not. Specific recommendations, however, on cloud computing in relation to FrailSafe project have been given and described in the D9.6 deliverable.

Geolocation data are considered personal data. The regulations identify three functional entities involved in geolocation data usage: i) the controller of the geolocation infrastructure, ii) the provider of the specific geolocation application or service, and iii) the developer of the operating system of a smart mobile device. Each of these entities processes personal data when they are directly or indirectly use geolocation data of the users, thus they are under the obligations of the data protection directive.

Participants' clinical reports and questionnaires, and other sources of data are collected and preprocessed to create a dataset. The collected data are anonymized and then transferred using encryption technology in various forms of communication services. None third party is able to alter information as access to collected information is restricted only to the related tasks. The social media mining and monitoring tools deployed in the project collect and/or process publicly available personal data, abiding to all relevant rules and recommendations of the National legislation and the respective EU recommendations and directives.

Blood specimens are and will be collected according the local medical institution procedures, only after consent has been obtained. A protocol will address issues

including the intended use of the collected samples, the length of time that the samples will be stored, sample coding procedures, management and limits of access of the data collected, maintenance of subject privacy and confidentiality, sample storage locations and storage conditions, sample destruction, publication and dissemination of results.

Blood sampling is being performed in order to perform telomere length measurements (analyzing the extreme parts of the chromosomes of the cells). Therefore, although, telomere length is not genetics, since it is influenced by age, genetic and environmental factors, it can be assimilated to a genetic analysis since the measurements concern the patient's DNA. Thus, participants either sign a specific informed consent, or this information is included in their initial informed consent document, indicating that this genetic analysis is performed exclusively for scientific purposes of this study in an anonymous way. National and EU legislation are respected. The specimen collection and analysis of TL are conducted in strict adherence to the Convention for the Protection of Human Rights and Fundamental Freedoms, and EU regulations on ethical issues including Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Directives 2001/20/EC, 2005/28/EC, and 2016/680EC relating to implementation of good clinical practice in the conduct of clinical trials. The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes was also considered, 2008/EC [1x]. The partners follow the Regulation 536/2014 of the European Parliament and of the Council on clinical trials on medical products for human use as soon as it enters force. The project works closely with National and Local Ethics Committees and other regulatory authorities for the submission and the conduct of the planned clinical trials. FrailSafe members use the highest standards in Good Laboratory, Clinical and Epidemiological Practices and Ethics that are applied at the International and European level.

Leucocyte DNA extraction and leukocyte TL measurements will be carried out exclusively at INSERM. The French National Law No 94-653 of 29 July 1994 on respect for the human body [2x] which modified the Civil Code, states that "genetic studies of an individual's characteristics can only be carried out for medical purposes or scientific research", and only after consent has been obtained from the individual concerned. The National Consultative Ethics Committee for the Life and Health Sciences (CCNE) has released opinions and guidelines related to genetics since the early 1980s with regular updates, and these were adopted in the so called "Bioethical Laws" [3x]; these national laws have been observed.

During the clinical assessments and monitoring sessions, possible physical risks are and will be eliminated by the constant presence of a study's member near the participant while performing test and activities that are considered to be hazardous. Rules of hygiene are and will be respected in all cases that wearable material or devices which get direct body contact, will be used. If the researcher during the clinical evaluation finds out medical issues, which according to his or her professional judgment, need to be reported, the guidelines of the protocol on incidental clinical findings will be followed. This protocol has be devised locally in each clinical centre, will be put to the attention of the local Ethics Committee, and briefly described in the

participant's information sheet. In Patras this protocol has been put to the attention and approved by the Committee on Research and Ethics of Univ. Hospital of Patras (protocol number 178/04.04.2017) by the Scientific Council of Univ. Hospital of Patras (protocol number 9475/19.04.2017) and by the Administrative Council of Univ. Hospital of Patras (protocol number 17/26.4.2017).The protocol states that in such events the participant will be informed, and his permission will be sought for his medical practitioner and/or his family and/or carer to be notified. A section on incidental clinical findings has been added on the Ethics, Safety and mHealth Barriers Manual which we keep up to date for the duration of the project.

Emergencies, such as a fall or serious arrhythmias, may occur during the use of the FrailSafe system. The FrailSafe team will not be aware of any emergency in real time, as the analysis of data will be off-line. However, the system will include a real-time analysis and response, developed in the lab using off-line participants' data; the real-time analysis is a feature which will be included, after the end of the project, in the market product.

Incidental findings during FrailSafe evaluation, are expected to be infrequent, as continuous data will be analysed in batches, and not individually. However, single cases may need to be considered individually, and so, such events may still occur. Continuous data will be analysed off-line at a later stage, thus, incidental events will be historical. As such events still need to be reported a similar procedure as in incidental findings during clinical evaluation will be followed. A protocol on incidental findings during FrailSafe evaluation is set up locally in each clinical centre, has been put to the attention of the local Ethics Committee or corresponding Authorities, and briefly described in the participant's information sheet. The protocol will state that in such an event, in case this is feasible, the participant will be informed, and his permission will be sought for his medical practitioner and/or his family and/or carer to be notified. In Patras this protocol has been put to the attention and approved by the Committee on Research and Ethics of Univ. Hospital of Patras (protocol number 178/04.04.2017) and by the Scientific Council of Univ. Hospital of Patras (protocol number 9475/19.04.2017) and by the Administrative Council of Univ. Hospital of Patras (protocol number 17/26.4.2017).

All participants have the right to obtain the erasure of their personal data and the abstention from further dissemination of such data according to the General Data Protection Regulation. Participants are informed about this right; the consortium will take all reasonable steps, including technical measures, to comply with the right to be forgotten.

In Patras has been put to the attention of the Scientific Council of Univ. Hospital of Patras (application filing number 13632 / 08.06.2017), the amended consent form for the on site visit of a small number of participants during the Review Meeting of September 2017.

**Bibliography**

[1x] Council of Europe. Additional protocol to the convention on human rights and biomedicine concerning genetic testing for health purposes. Strasbourg: Council of Europe, 2008. Accessed 2013 Oct 3. Available from:

http://conventions. coe.int/Treaty/en/Treaties/Html/203.htm.

[2x] Law No 94-653 of 29 July on respect for the human body. IDHL (45)1994: 498-500

[3x] Comité consultative national d'éthique pour les sciences de la vie et de la santé (CCNE). Avis n° 25 Avis sur l'application des test génétiques aux études individuelles, études familiales et études de population, Paris, juin 1991

# 5 Critical Implementation risks and mitigation actions

## *5.1 Risks identified in the project's Annex*

| Risk Nr | Description of Risk | Work Packages Concerned | Proposed risk-mitigation measures |
|---|---|---|---|
| 1 | Conflicts within the consortium | 9 | Decision-making mechanisms are described in section 3.2.2. Early definition of common project vision and exploitation requirements. |
| 2 | Delays and/or administrative oversights | 9 | Compliance with Milestones and regular communication in meetings and phone conferences will avoid missing deadlines. Coordinator experienced in EU projects, aware of possible management issues. |
| 3 | Partner(s) decide to leave project | 9 | Competencies are covered by more than one partner, allowing backing up work in case of any partner leaving the consortium or failing to deliver work according to its declared responsibilities. |
| 4 | Low communication among partners | 9 | Utilize more often interactive communication means, like direct phone communication; also regular teleconferences and face-to-face meetings. |
| 5 | Delayed submissions of deliverables | 9 | Coordinator follows a strict policy quality management and will minimize the risk of delays from the early beginning. |
| 6 | Lack of interest by Policy makers | 8, 9 | Full involvement in project workshops and seminars. |
| 7 | IPR conflicts | 8, 9 | Intellectual property issues will be analysed and managed and communicated among all consortium partners |
| 8 | Technical outcomes not commercially viable | 8 | Early definition of Exploitation plan and establishment of Advisory board for steering project in commercial directions and assessing the project |
| 9 | Insufficient dissemination of project results | 8 | Continuous monitoring by Dissemination Manager and communication among work packages |

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| | | | to identify common publishable results during the whole period of the project. |
| 10 | Users specifications do not describe adequately the needs of the users (elderly people with different motor and cognitive disorders) | 1 | The high involvement since the early phases of the project of users will allow to get full specifications in line with true needs of all the concerned actors |
| 11 | Fast advance in sensors technology could make obsolete the developed platform | 3 | The platform will be open and flexible as much as possible and will be able to interface various sensors; it will ensure inter-operability of the developed solution also with new and more advanced sensors. Moreover standardization efforts (WP8) will mitigate the risk of lack of compatibility. |
| 12 | Data collected by the sensors are not enough to provide adequate warnings and inputs for treatment changes | 3, 4 | Big efforts in lab experiments and collection of available knowledge to develop robust algorithms for the extraction of clinically relevant information from the collected data. User profiling and personalisation of the solution will give additional inputs for the interpretation of the data. |
| 13 | Low accuracy of the selected sensors could cause the lack of clinical relevance of the collected data | 3, 4 | Requirements of measurement accuracy will be deeply analysed with the medical specialists;<br>Benchmarking of commercially available sensors will allow selecting the most suitable ones; special algorithms (i.e. data completion and de-noising) will be used to reduce measurement artefacts. |
| 14 | Game interface too complex and not accepted by the patients | 5, 6 | AR Game interfaces will be designed keeping in mind simplicity; moreover it will be adapted and personalised according to the older people preferences and special needs. Usability will be checked in advance by involving user groups and by following UCD methodology, described in T1.3. |
| 15 | The project is ambitious with many novel approaches as well innovation to be created and verified | 3, 4, 5, 6 | The main milestones are firmly achievable, as they are purely based on the consortium members previous work and their research areas of excellence in Europe. Thus, even if |

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| | in large non-lab community | | 100% success in each of the constituent parts is not achieved within the expected timeline, the overall functionality of the framework will remain within the predefined requirements and the effect of unexpected problems on some components will be minimised. |
| 16 | Dealing with smart sensing devices, smart phones and AR applications, could be unaccepted and obtrusive | 3, 4, 5, 6 | Comfort of the users while experiencing the FrailSafe novel solutions will be a top priority; training sessions will be planned before starting the clinical campaigns. |
| 17 | Selected technologies are not adequate | 2, 3, 6 | The architecture design will be built on user functional requirements matching interoperability and integration specifications. The selected technologies have to require the identified functional requirements. Most of technologies are off the shelf or functioning prototypes have already been developed (e.g. wearable sensors). |
| 18 | Prototypes not ready in time for pilot evaluation | 3, 5, 7 | Prototypes will be deployed at user's sites as soon as integrated system is available allowing early hands-on experiences and advance knowledge of the system prior to actual evaluations. |
| 19 | Feature extraction not sufficient for significant physical and cognitive state estimations | 4, 5, 6, 7 | Involving additional sensors and adaption of sensor and fusion algorithms |
| 20 | Models of the different aspects underperforming | 4, 7 | The data obtained to learn models of affect and learning will be further analysed with additional data mining and machine learning techniques to better exploit available data. More emphasis will be given to dimensionality reduction including variant feature extraction and selection that will be tested and compared. In addition, sample size estimation in the initial design steps will allow defining the exact needs of the amount of data to be collected. |

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| 21 | Affect data from WP4 come too late and delay work in WP7 | 7 | BRA has a strong experience in creating adaptive games and development has been foreseen in cycles and with participatory design. Therefore inputs can initially be simulated to avoid delays and integration can be performed at a later stage |

## *5.2 Risks*

| Risk Nr | Description of Risk | Work Packages Concerned | Proposed risk-mitigation measures |
|---|---|---|---|
| 1 | Delay obtaining approval from Ethical Committees in Nancy, France (INSERM) | 2, 9 | Approval obtained on 6th October 2016 (amendments to the application for the local Ethics committee will be needed for the approval of any new device) |
| 2 | Technical challenges regarding some FrailSafe system devices | 1-6 | Continuous interactions among all WPs, prevention of possible practical obstacles and effort to adapt devices in the target population's specificities in terms of both performance and tolerance/usability<br><br>FrailSafe system devices already tested, fine-tuned and available for use (initial version for some of them). First versions ready for use. Process to be continued for next versions |
| 3 | Recruitment rate delay<br><br>Deviation from the desired analogy of non-frail/pre-frail/frail **->** | 1-6 | Recruitment campaigns intensification and study's beginning shifting. Parallel recruitment of groups A and B in Nancy<br><br>A document outlining the background, current issue, different alternatives and a proposal for a line to take (i.e., parallel recruitment of groups A and B) has been communicated to the Project Officer on M13.<br><br>Forthcoming recruitment oriented towards structures crowded by "fitter" individuals<br><br>By M18, Nancy managed to totally keep up with the recruitment rate of other |

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| | | | centers, despite the late initiation of the inclusions. |
| 4 | Use of augmented reality glasses may be difficult for some of the subjects | 5 | Perform a technical hands-on evaluation of existing glasses in our labs before choosing the product to purchase<br><br>Develop AR games that can be played without the use of AR glasses (e.g., gravity bal). |
| 5 | Delayed availability of some of the FrailSafe system's devices and sessions with FrailSafe's system devices delay | all | Sessions with FrailSafe's system devices started in M9 and elaboration of a modified timetable in order to apply the FrailSafe system devices in all participants (see risk #3 along with the proposed mitigation measure) |
| 6 | Possible issue with soundness of conclusions of the study due to sample size selected given the number of parameters measured and missing data | 2, 4 | Possible solutions regarding data analysis have been presented in revised D2.1 and D2.4 |
| 7 | Possible liability risks in case of an "emergency" event for recruited persons | all | Clarifications in relevant deliverables and a second amendment request (approved) to clarify these issues in the DoA<br><br>Changes in Informed Consent forms reflecting these issues approved by Local Ethics Committees of all three clinical sites |
| 8 | Role of clinicians in the final release of FrailSafe not clear | all | Clarifications in relevant deliverables and a second amendment request (approved) to clarify these issues in the DoA<br><br>Changes in Informed Consent forms reflecting these issues approved by Local Ethics Committees of all three clinical sites |

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| 9 | Expected outcomes of the study not clearly identified | 2 | Better identify the expected outcomes in revised deliverable D2.1 |
| 10 | Phone calls during project execution and motivation of subjects for recruitment may have an influence on the results of the study | 2 | Address these points in revised deliverable D2.1 |
| 11 | Selected gateway device not capable of meeting the requirements | 1,3,6 | Consider other alternatives for the gateway device and the architecture |
| 12 | Cost of equipment may be a barrier for future exploitation | 3,5,8 | Consider other alternatives for the AR games<br>Search for minimizing production costs still maintaining quality of signals and materials, search for alternative commercial approaches to offer cheaper solutions<br>Develop AR games that can be played without the use of AR glasses (e.g., gravity bal). |
| 13 | Limited experience of IT device usage by older adults may lead to insufficient use of system | 2,5,7 | Offer training support to participants, emphasis on user-friendly devices, take risk into consideration for explotation purposes. |
| 14 | Safety issues of see-through AR glasses | 3,5 | Early decision for inclusion or not of these devices in the tests<br>Develop AR games that can be played without the use of AR glasses (e.g., gravity bal). |
| 15 | AR games not acceptable by the older people | 3,5 | Design the games together with the participants and rely heavily on the user requirements analysis |
| 16 | Planned use of cloud services and referred lack of compliance with GDPR | 6 | Explore alternatives to the use of cloud services and potential impact<br>Letter from Ethics Supervisor Prof. Stefania Maggi expressing her opinion on the data protection issue in the cloud (M18 Periodic Report) included in Appendix B. |

## *5.3 State of Risk Mitigation*

**Foreseen Risks (identified in the project's Annex-I)**

| Risk Nr | Period | Did you apply risk mitigation measures? | Did your risk materialize? | Comments |
|---|---|---|---|---|
| 1 | 1 | Yes | No | No conflicts within the consortium. Great communication between the ICT and medical teams and early definition and common understanding of project objectives of great importance to guarantee no conflicts. |
| 2 | 1 | Yes | Yes | Some minor delays (to obtain approvals from Ethics committees, recruitment rate delays and delayed availability of some Frailsafe devices) were overcome applying risk mitigation actions as shown in unforeseen risks 1, 2, 3, and 5 below. |
| 3 | 1 | No | No | No such issues for the reporting period |
| 4 | 1 | Yes | No | We are being proactive having regular communication through physical and virtual (skype, teleconference) meetings among partners. The consortium holds physical plenary meetings twice a year and WP leaders meetings every month. In addition we have multiple bilateral meetings to resolve all issues that appear. ICT and medical people work together toward achieving the project objectives and there is a common understanding of all issues. |
| 5 | 1 | Yes | Yes | Other than very minor delays for a few deliverables for which permission from the PO was obtained in most cases we had a delay of 1 month and a half for deliverable D3.2 (Preliminary WWBS prototype). The reasons for the delay were explained in the deliverable and the delay did not create major implications in the project's timeline. |
| 6 | 1 | Yes | No | Ongoing dissemination actions reach policy makers |
| 7 | 1 | Yes | No | Being proactive we have analyzed and managed IPR issues early on. These have been communicated among all partners. Additional issues are being discussed as they appear. |

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| 8 | 1 | Yes | No | A preliminary exploitation plan has been defined. The advisory board has been established and there were several meetings with the whole board as well as meetings with individual members of the board exchanging ideas regarding Frailsafe innovations, exploitation strategies, promotion of Frailsafe results, possible business models, possible markets, etc. Other risks related to the cost of certain equipment that may be a barrier for exploitation are discussed below (see unforeseen risk 12). |
| 9 | 1 | Yes | No | Continuous dissemination efforts of project results |
| 10 | 1 | Yes | Yes | Early involvement of older people in the design process of several Frailsafe devices such as WWBS, games, user interfaces, etc enabled taking into account their limitations and needs. |
| 11 | 1 | Yes | No | Using an open and flexible platform that can interface with multiple sensors (existing and future) as well as applying standardization efforts and considering interoperability reduces this risk. |
| 12 | 1 | Yes | No | This risk is also related to the unforeseen risk 6 below. Solutions that we have followed have been presented in D2.1 (revised) and D2.4. This is in addition to following the proposed mitigation actions. |
| 13 | 1 | Yes | Yes | Requirements of measurement accuracy have been analysed together with the medical specialists. The sensors have been selected considering all these aspects and algorithms have been used (both existing and new) to reduce measurement artefacts. |
| 14 | 1 | Yes | Yes | Game interfaces were designed keeping in mind simplicity; moreover they were adapted and personalised according to the older people preferences and special needs. Usability was considered in advance by involving user groups and by following a UCD methodology. |
| 15 | 1 | Yes | No | Although the project remains ambitious the objectives are being achieved. The studies with over 500 participants are ongoing. Expected outcomes of the whole study have been clearly defined (see also unforeseen risk |

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| | | | | 9 below). The effect of unexpected problems on some components of the FrailSafe system are being minimised. |
| 16 | 1 | Yes | No | In addition to offering training support to participants our main emphasis is on developing older user-friendly devices and interfaces. See also unforeseen risk 13. |
| 17 | 1 | Yes | Yes | The selected technologies cover the identified functional requirements. Most of technologies are off the shelf or functioning prototypes have already been developed (e.g. wearable sensors). |
| 18 | 1 | Yes | Yes | Prototypes ready for pilot evaluation. Some minor delays for WWBS (first version) have occured due to the fact that these devices are to be used with real users in their home environment, so a not-planned EC-certification was needed, testing their safety (both electric and electromagnetic), for their acceptance by Ethical Committees. |
| 19 | 1 | Yes | No | Adaptation of feature extraction and fusion algorithms is ongoing considering all the multiparametric data being collected. |
| 20 | 1 | Yes | Yes | Advanced data mining and machine learning techniques are being used in addition to standard statistical techniques for analyzing the data collected exploiting them as much as possible. Related unforeseen risks 6 and 9 and mitigation actions are discussed below. |
| 21 | 1 | Yes | No | Data from the games as well as from all other devices are already available and are being analyzed. Some results of the analysis are already available. |

## Unforeseen Risks

| Risk Nr | Period | Did you apply risk mitigation measures? | Did your risk materialize? | Comments |
|---|---|---|---|---|
| 1 | M1-M6 | Yes | Yes | Approval obtained on 6th October 2016 (amendments on ethics will be needed for the approval of any new device) |
| 2 | M1-M6 | Yes | Yes | Continuous interactions and effort to adapt the material proposed and to develop ameliorated devices in terms of both performance and tolerance/usability.<br>First versions ready for use |
| 3 | M4-M6 | Yes | Yes | The delay of the study's beginning for 2-3 months, has been compensated by more intense recruitment rates since, following our communication during this period, a large number of subjects expressed their willingness to participate to the project.<br>All clinical centers have completed the recruitment for groups A and B and have a sufficient number of eligible participants stand by to replace drop-offs. |
| 4 | M6-M18 | Yes | Not yet | Existing glasses evaluated in the lab while at the same time developed AR games that do not require use of AR glasses. |
| 5 | Since M9 | Yes | Yes | Sessions with FrailSafe's system devices started in M9 and elaboration of a modified timetable in order to apply the FrailSafe system devices in the participants of groups A and B already clinically evaluated |
| 6 | Since M10 | Yes | Not yet | The proposed plan for data analysis (including statistical analysis) will be applied and results will be included in future reports especially reports of WP2, WP4 and WP7. |
| 7 | Since M10 | Yes | No | We provided clarifications in relevant deliverables (D2.1 (revised), D1.2 and D4.6). In addition, we amended the DoA on M13 and changed the Informed Consent Forms (which were approved by the Local Ethics Committees) to clarify these issues |

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| 8 | Since M10 | Yes | No | We provided clarifications in relevant deliverables (D2.1 (revised), D1.2 and D4.6). In addition, we amended the DoA on M13 and changed the Informed Consent Forms (which were approved by the Local Ethics Committees) to clarify these issues |
| 9 | Since M10 | Yes | Yes | Expected outcomes of the study presented in more detail in revised D2.1 |
| 10 | Since M10 | Partially | Not yet | Possible ways to address these issues are outlined in D2.1 |
| 11 | Since M7 | Yes | Not yet | A more flexible architecture with respect to the gateway device presented in D1.3 (ver.a). A docking station for the indoors scenario is under consideration. |
| 12 | Since M8 | Yes | Not yet | We are considering this important issue especially in the device choices, in the games design and in the commercial approach. In particular in games design w develop AR games that can be played without the use of AR glasses |
| 13 | Since M7 | Yes | Not yet | We are experimenting with different alternatives that will reduce the possible risks. We focus on older user friendly devices and interfaces and consider their feedback to make improvements |
| 14 | Since M7 | Yes | Not yet | We are considering all existing AR glasses while also developing AR games that can be played without the use of AR glasses |
| 15 | Since M7 | Yes | Not yet | We consider the issues of acceptability of these games by the older people population taking into account their feedback in the design process (see D1.2) |
| 16 | Since M7 | Yes | No | We evaluated alternatives which were communicated to the Project Officer as requested. We obtained legal advice on this issue and a letter from our Ethics Supervisor Prof. Maggi about compliance of the could service we selected to GDPR. |

# 6 Dissemination and exploitation of results

## *6.1 Scientific publications*

Publications accessible via OpenAIRE will be displayed automatically. Beneficiaries will only need to check if the publications are linked to the project.

In case of publications not registered via OpenAIRE, the beneficiary encodes the Digital Object Identifier (DOI) and all the rest of information is complete automatically.

Both the joint publications coming from public and private project participants as well as from private/public project participants with public/private organizations outside the consortium (as long as they are related to the funded project) should be reported.

| No. | Type of Scientific Publication | Title | DOI | ISSN or eSSN | Authors | Title of the Journal or Equivalent | Publisher | Place of Publication | Year of publication | Relevant pages | Public & Private participation | Peer Review | Is/Will open access provided for this publication[1] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **PUBLICATIONS FOR THE REPORTING PERIOD** | | | | | | | | | | | | | |
| 1. | Conference proceedings paper | *A Graph Framework for Multimodal Medical Information Processing* | N/A | N/A | Georgios Drakopoulos, Vasileios Megalooikonomou | *The Eighth International Conference on eHealth, Telemedicine, and Social Medicine* | *Curran Associates, Inc.* | *Red Hook, NY* | *2016* | *278-282* | both | YES | YES |

[1]Open Access is defined as free of charge access for anyone via Internet. Please answer "yes" if the open access to the publication is already established and also if the embargo period for open access is not yet over but you intend to establish open access afterwards.

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| | | | | | | *(eTELEMED), Venice, Italy, 2016* | | | | | | | |
| 2. | Conference proceedings paper | *Feature Selection Evaluation for Light Human Motion Identification in Frailty Monitoring System* | 10.5220/0005912200880095 | 978-989-758-180-9 | Evangelia Pippa; Iosif Mporas; Vasileios Megalooikonomou | Proceedings of the International Conference on Information and Communication Technologies for Ageing Well and e-Health, Rome, Italy, 2016 | SCITEPRESS – Science and Technology Publications, Lda. A | *Portugal* | *2016* | *85-95* | Both | YES | YES |
| 3. | Conference proceedings paper | *Regularizing Large Biosignals with Finite Differences* | 10.1109/IISA.2016.7785346 | 978-1-5090-3429-1 | Vasileios Megalooikonomou; Georgios Drakopoulos | *7th International Conference on Information, Intelligence, Systems, and Applications (short name: IEEE IISA 2016), Chalkidiki, Greece, 2016* | *IEEE* | *New York, NY* | *2016* | *1-6* | *both* | *yes* | *no* |
| 4. | Conference proceedings paper | *Investigation of sensor placement for accurate fall detection* | *10.1007/978-3-319-58877-3_30* | *978-3-319-58876-6* | Periklis Ntanasis, Evangelia Pippa, Ahmet Turan Ozdemir, Billur Barshan and Vasileios Megalooikonomou | *6th International Conference, MobiHealth 2016, Milan, Italy, November 14-16, 2016* | *Springer* | *Cham, Switzerland* | *2017* | *225-232* | *Both* | *Yes* | *Yes* |
| 5. | Conference proceedings paper | *An Adaptive Higher Order Scheduling Policy With An Application To* | *10.1109/SSCI.2016.7849897* | *978-1-5090-4240-1* | *Georgios Drakopoulos and Vasileios Megalooikonomou* | *IEEE Symposium Series on Computational Intelligence (IEEE SSCI 2016)* | *IEEE* | *New York, NY* | *Nov 2016* | *1-8* | *Both* | *Yes* | *Yes* |

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| | | *Biosignal Processing* | | | | | | | | | | | |
| 6. | *Conference* | *Variable k-buffer using Importance Maps* | *10.2312/egsh.20171005* | *1017-4656* | *CERTH* | *Procceding of Eurographics 2017 Short Papers* | *Eurographics Digital Library* | *Graz, Austria* | *2017* | *21-24* | *both* | *Yes* | *Yes* |
| 7. | *Conference paper* | *Lag Correlation Discovery and Classification for Time Series* | *10.5220/0006215901810188* | *978-989-758-245-5* | *UoP - G. Dimitropoulos, E. Papagianni and V. Megalooikonomou* | *Proceedings of the 2nd International Conference on Internet of Things, Big Data and Security (IoTBDS) 2017, Porto, Portugal* | *SCITEPRESS - Science and Technology Publications, Lda* | *Portugal* | *2017* | *181-188* | | *Yes* | *Yes* |
| **FORESEEN ACCEPTED PUBLICATIONS** | | | | | | | | | | | | | |
| 1. | *Conference paper* | *An Empirical Study of Active Learning for Text Classification* | *N/A* | *N/A* | *UoP - S. Karlos, N. Fazakis, S. Kotsiantis, K. Sgarbas* | *International Conference on Knowledge Based and Intelligent Informationand Engineering Systems* | *Elsevier* | *Netherlands* | *Sept 2017* | | *both* | *Yes* | *Yes* |
| 2. | Journal | *Smart in-home monitoring system for older people via beacons technology* | | | *CERTH* | *Transactions on Information Technology in Biomedicine* | | | *2017* | | | *Yes* | |
| 3. | Journal | *Usability study on physical & cognitive training of older people via* | | | *CERTH* | *Serious Games and Applications for Health* | | | *2017* | | | *Yes* | |

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| | | *augmented reality glasses* | | | | | | | | | | | |

## *6.2 Dissemination and Communication Activities*

### 6.2.1 Type of Dissemination Activities

| Type of dissemination and communication activities* | Number of activities |
|---|---|
| Organization of a Conference | 1 |
| Organization of a workshop | 9 |
| Press release | 3 |
| Non-scientific and non-peer reviewed publications (popularized publications) | 15 |
| Exhibition | 3 |
| Flyer | 6 |
| Training | 0 |
| Social media | 2 (Twitter, Facebook) |
| Web-site | http://frailsafe-project.eu/ |
| Communication campaign (e.g. radio, TV) | 6 |
| Participation to a conference | 9 |

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| Participation to a workshop | 3 |
| Participation to an event other than a conference or workshop | 14 |
| Video/film | 0 |
| Brokerage event | 0 |
| Pitch event | 0 |
| Trade fair | 0 |
| Participation in activities organized jointly with other H2020 project(s) | 1 |
| Other | 1 |
| **Total funding amount** | 44,322.25 € |

### 6.2.2 Type of Audiences Reached

| **Type of audience reached in the context of all dissemination & communication activities*** **(multiple choices is possible)** | **Estimated number of persons reached** |
|---|---|
| Scientific Community | 500 |
| Industry | 100 |
| Civil Society | 50 |
| General Public | 1000+ |
| Policy makers | 10 |
| Medias | 1 |

| | |
|---|---|
| Investors | 0 |
| Customers | 0 |
| Other | 0 |

### 6.2.3 List of Dissemination Activities

**TABLE A2.1 : LIST OF DISSEMINATION ACTIVITIES WITHIN THE REPORTING PERIOD (INCLUDING PRESS COVERAGE, DEMONSTRATION AND TECHNOLOGY TRANSFER)**

| NO. | Type of activities[2] | Partners involved | Title | Date | Place | Type of audience[3] | Size of audience | Countries addressed |
|---|---|---|---|---|---|---|---|---|
| **ATTENDED** | | | | | | | | |
| 1. | *Article* | *Materia* | *Frailty, active ageing and Frailsafe project* | *14/02/2016* | *Nicosia* | *General public* | | *Cyprus* |
| 2. | *Newsletter* | *Materia* | *Information on frailsafe project and call for participants* | *Dec 2016 – Feb 2016* | *Nicosia* | *General public* | | *Cyprus* |
| 3. | *Article* | *AGE* | *AGE takes part in new EU project to prevent frailty in old age* | *4 Feb 2016* | *Brussels, Belgium* | *Older people, European Stakeholders* | *N/A* | *Europe* |
| 4. | *Press Release* | *AGE* | *Launch of FrailSafe: A new EU project to delay frailty among older persons* | *10 Feb 2016* | | *Civil Society, Clinicians, ICT, policy-makers* | *N/A* | *Europe* |

[2]A drop down list allows choosing the dissemination activity: publications, conferences, workshops, web, press releases, flyers, articles published in the popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters, Other.

[3] A drop down list allows choosing the type of public: Scientific Community (higher education, Research), Industry, Civil Society, Policy makers, Medias ('multiple choices' is possible.

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| | | | *by bridging health data and new technologies* | | | | | |
| 5. | *Organization of a workshop* | *Materia Group* | *Frailsafe Presentation* | *24 March 2016* | *Polidinamo Lakatameias (day care center)* | *General public* | *25* | *Cyprus* |
| 6. | *Organization of a workshop* | *Materia Group* | *Frailsafe workshop* | *30 March 2016* | *Polidinamo Lakatameias (day care center)* | *General public* | *15* | *Cyprus* |
| 7. | *Participation to an event other than a conference or workshop* | *Materia Group* | *Free Memory Test & Frailsafe Presentation* | *9 April 2016* | *ITHAKI foundation* | *General public* | *100* | *Cyprus* |
| 8. | *Participation to an event other than a conference or workshop* | *Materia Group* | *Active aging and Frailsafe presentation* | *20 April 2016* | *SALMEK (retired teachers)* | *General Public* | *100* | *Cyprus* |
| 9. | *Participation to a Conference* | *Gruppo SIGLA* | *Life Tech Forum* | *6-7 April 2016* | *Genoa, Italy* | *Scientific community and stakeholders* | *80 key note speaker.*<br>*500 participants.*<br>*30 sponsor company.* | *Italy* |
| 10. | *Article* | *AGE* | *Frailty, what is it?* | *11 April 2016* | *Brussels* | *Civil Society, Clinicians, ICT, policy-makers* | | *Europe* |
| 11. | *Participation to an event other than a conference or workshop* | *INSERM* | *Informative meeting with ONPA* | *22 April 2016* | *Nancy, France* | *Older people* | *50* | France |
| 12. | *Participation to a Conference* | *AGE* | *Societal Impact of Pain (SIP 2016)* | *24 April 2016* | *Brussels, Belgium* | *health care professionals, pain advocacy groups,* | | Europe |

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|---|---|---|---|---|---|---|---|---|
| | | | | | | *politicians, insurances, representatives of health authorities, regulators and budget holders* | | |
| 13. | *Participation to a Conference* | *Gruppo SIGLA, UOP* | *IARIA conference, Digital Healthy Living – Math Symposium (The International Symposium on Mobile and Assistive Technology for Healthcare).* | *25-28 April 2016* | *Venice, Italy* | *ICT, Technical and scientific community* | | *World* |
| 14. | *Newsletter* | *Materia* | *Information on frailsafe project and call for participants* | *March – May 2016* | *Nicosia* | *General public* | | *Cyprus* |
| 15. | *Article* | *UoP* | *EU Project to delay frailty among older persons by bridging data and new technologies* | *12 May 2016* | *Brussels* | *Policy makers, European stakeholders* | *N/A* | *Europe* |
| 16. | *Participation to an event other than a conference or workshop* | *INSERM* | *Join the FrailSafe Study* | *25 May 2016* | *Nancy, France* | *Older people* | *25* | France |
| 17. | *Communication Campaign* | *UoP* | *Σύνδρομο ευθραυστότητας των ηλικιωμένων (Syndrome Frailty of the older people)* | *26 May 2016* | *Greece* | *General Public* | *1000+* | Greece |
| 18. | *Participation to an event other than a conference or workshop* | *INSERM* | *Join the FrailSafe Study* | *6 June 2016* | *Nancy, France* | *Older people* | *25* | France |
| 19. | *Participation to an event other than a conference or workshop* | *INSERM* | *Join the FrailSafe Study* | *7 June 2016* | *Nancy, France* | *Older people* | *25* | France |

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| 20. | *Participation to an event other than a conference or workshop* | *INSERM* | *Join the FrailSafe Study* | *16 June 2016* | *Nancy, France* | *Older people* | *25* | France |
| 21. | *Participation to an event other than a conference or workshop* | *INSERM* | *Join the FrailSafe Study* | *29 June 2016* | *Nancy, France* | *Older people* | *25* | France |
| 22. | *Participation to an event other than a conference or workshop* | *INSERM* | *ONPA Open House Event* | *30 June – 1 July 2016* | *Nancy, France* | *Older people* | *50* | France |
| 23. | *Newsletter* | *AGE* | *Newsletter #1* | *30 June 2016* | *Brussels, Belgium* | *Civil society, Medical, technical, policy makers* | | Europe |
| 24. | *Article* | *AGE* | *FrailSafe publishes first newsletter* | *5 July 2016* | *Brussels, Belgium* | *Older people, European Stakeholders* | *N/A* | Europe |
| 25. | *Article* | *UoP* | *Frailty indicators could help prevent problems with ageing* | *13 July 2016* | *Brussels, Belgium* | *Researchers, policy makers,* | *N/A* | Europe |
| 26. | *Organization of a workshop* | *Materia Group* | *Frailsafe Workshop* | *5 sept 2016* | *Xalkanoras (day care center)* | *General Public* | *15* | Cyprus |
| 27. | *Participation to an event other than a conference or workshop* | *CERTH* | *1st ACROSSING Training Event* | *14-16 Sept 2016* | *Thessaloniki, Greece* | *Scientific community (ACROSSING partners, ICT PhD students)* | *30* | Europe |
| 28. | *Participation to an event other than a conference or workshop* | *INSERM* | *Lorraine Université d'Excellence* | *29 Sept 2016* | *Nancy, France* | *Technical and scientific community* | *50* | France |

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| 29. | *Communication campaign (radio)* | *INSERM* | *France Bleu Lorraine Nord* | *30 Sept 2016* | *Lorraine, France* | *General Public* | *N/A* | France |
| 30. | *Participation to an event other than a conference or workshop* | *INSERM* | *Réunion des trois universités* | *30 Sept 2016* | *Nancy, France* | *Health and care professionals* | *30* | France |
| 31. | *Participation to a Workshop* | *UoP; Gruppo Sigla; AGE Platform* | *Towards early detection of age-related health risks: understanding users' needs, unobtrusive sensing and data analysis* | *4 October 2016* | *Brussels, Belgium* | *ICT* | *20* | Europe |
| 32. | *Press release* | *INSERM* | *Le CHRU de Nancy lance un appel à volontaires pour tester des nouveaux outils contre la perte d'autonomie* | *9 Oct 2016* | *Journal : L'Est Républicain, Lorraine, France* | *General public* | *N/A* | France |
| 33. | *Communication campaign (tv)* | *UoP* | *ΥγείαςΘέματα - Εκπομπή 53 - ΣύνδρομοΕυθαστότηταςΗλικιωμένων - Β' μέρος* | *15 Oct 2016* | *Ionian tv* | *General public* | *N/A* | Greece |
| 34. | *Participation to an event other than a conference or workshop* | *INSERM* | *Join the Frailsafe Study* | *18 Oct 2016* | *Ludres, France* | *Older people* | *40* | France |
| 35. | *Participation to a Workshop* | *UoP* | *Active, Healthy Ageing in the EU: Growing the Silver Economy through Innovation and Partnership symposium* | *26 October 2016* | *Brussels, Belgium* | *Older people, European Stakeholders, Policy makers, General Public, Scientific and Technical community* | | |
| 36. | *Participation to an event other than a* | *UoP* | *A public event was held regarding FrailSafe project. which was* | *7 November 2016* | *Patras, Greece* | *Older people, practitioners,* | *70* | Greece |

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| | *conference or workshop* | | *organized by "Panathinaiki Women's Association"* | | | *informal carers, general public* | | |
| 37. | *Participation to a conference* | *European Commission* | *European Summit on Innovation for active and healthy ageing "Transform the future of health and care in Europe"* | *5-8 December 2016* | *Brussels, Belgium* | *ICT* | *500* | Europe |
| 38. | *Newsletter* | *AGE* | *Newsletter #2* | *December 2016* | *Brussels, Belgium* | *Civil society, Medical, technical, policy makers* | | Europe |
| 39. | *Collaboration with other projects working in the field of Digital Innovation for Active and Healthy Ageing.* | *Age Platform* | *ICT 4 Life* | *01/01/2017* | *Europe* | *Civil society, practitioners,* | *20* | *Europe* |
| 40. | *Organization of a workshop* | *Materia Group* | *Frailsafe information* | *09/01/2017* | *Nicosia, Polidinamo Strovolou* | *General public* | *20* | *Cyprus* |
| 41. | *Newsletter* | *AGE – Digital Single Market* | *Projects news and results – Frailsafe: early detection of frailty through virtual patient model and supermarket game* | *11/01/2017* | *Europe* | *EU stakeholders* | | *Europe* |
| 42. | *Organization of a workshop* | *Materia Group* | *Frailsafe information* | *23/01/2017* | *Nicosia, Polidinamo Strovolou* | *General public* | *20* | *Cyprus* |
| 43. | *Organization of a workshop* | *Materia Group* | *Frailsafe information* | *06/02/2017* | *Nicosia, Polidinamo Strovolou* | *General public* | *20* | *Cyprus* |
| 44. | *Organization of a workshop* | *Materia Group* | *FrailSafe Presentation* | *6 Feb 2017* | *nicosia, polidinamo lakatameias* | *General public* | *20* | Cyprus |
| 45. | *Article* | *Materia Group* | *Article in newspaper for FrailSafe* | *8Feb 2017* | *Filelefttheros newspaper* | *General public* | | Cyprus |

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| 46. | *Participation to a conference* | *University of Patras* | *Days of Neurology and Primary Treatment* | *10-11/03/2017* | *Patras, Greece* | *General Public* | *100* | *Greece* |
| 47. | *Press release* | *AGE* | *OFFICIAL RELEASE OF THE FRAILSAFE HIGH -LEVEL SYSTEM ARCHITECTURE* | *13/02/2017* | *Brussels* | *General Public* | | *Europe* |
| 48. | *Communication campaign (e.g radio, TV)* | *INSERM* | *Interview about the FrailSafe study and the usage of connected devices in the service of older people* | *21/03/2017* | *France 3 Lorraine (local tv station)* | *General public* | *Undeterminable* | *France* |
| 49. | *Organization of a workshop* | *Gruppo Sigla* | *MATH 2017 - The International Symposium on Mobile and Assistive Technology for Healthcare* | *22/03/2017* | *Nice (France)* | *Scientific community* | | *World* |
| 50. | *Exhibition* | *INSERM* | *Presentation of the FrailSafe study by Nancy's University Hospital in the exhibition Cité* | *25/03/2017* | *Centre Prouvé de Nancy, France* | *Scientific community* | *About 50* | *France* |
| 51. | *Organization of a Conference* | *INSERM* | *How to get old at your own home? How can new technologies help to age well at home.* | *25/03/2017* | *Centre Prouvé de Nancy, France* | *Civil Society* | *About 50* | *France* |
| 52. | *Participation to a conference* | *CERTH* | *Eurographics 2017* | *24-28 April 2017* | *Lyon, France* | *Scientif community* | *500+* | |
| 53. | *Participation to a conference* | *University of Patras* | *4th Hellenic Geriatric Congress* | *28/04 – 01/05/2017* | *Kyllini, Beach Hotel* | *Scientific community* | *200* | *Greece* |
| 54. | *Organization of a workshop* | *Materia Group* | *Frailsafe information* | *07/04/2017* | *Adonis, day care center* | *Customers* | *15* | *Cyprus* |
| 55. | *Exhibition* | *University of Patras* | *PATRAS IQ* | *7-9/04/2017* | *Patras, Greece* | *General public* | *7000* | *Greece* |
| 56. | *Communication campaign (e.g radio, TV)* | *INSERM* | *Short presentation of the study by Prof Benetos and call for volunteers* | *14/04/2017* | *Radio France Bleue* | *General public* | *Undeterminable* | *France* |
| 57. | *Communication campaign (e.g radio, TV)* | *INSERM* | *Short messages of recall about the study recruiting daily on radio* | *15/04/2017 and on* | *Radio France Bleue* | *General public* | *Undeterminable* | *France* |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 58. | *Non-scientific and non-peer reviewed publications (popularized publications)* | *INSERM* | *Short announcement-call for volunteers* | *16/04/2017* | *L'Est républicain* | *General public* | *Undeterminable* | *France* |
| 59. | *Participation to a conference* | *CERTH* | *Eurographics 2017* | *24-28 April 2017* | *Lyon* | *Scientific Community* | *500+* | *France* |
| 60. | *Presentation/ Exhibition* | *CERTH* | *Demonstration of indoor localization using Bluetooth beacons* | *16/05/2017* | *Thessaloniki* | *General public, industry* | *200+* | *Greece* |
| 61. | *other* | *AGE* | *Distribution and information on Frailsafe to AGE Members* | *7-8-9/06/2017* | *Brussels* | *Older people* | *200* | *Belgium* |
| 62. | *Participation to a conference* | *Brainstorm Multimedia* | *EC meeting organized by CHAFEA (EC), focusing on the "Coordination for Health Programme projects and the joint action focusing on frailty of older persons"* | *28/06/2017* | *Valencia* | *Scientific Community* | *40* | *Spain* |
| 63. | *Participation to a workshop* | *UoP, INSERM* | *EUGMS executive board meeting ; workshop "The Development of Geriatric Medicine: A perspective for a new approach towards the older patient."* | *June 2017* | *Athens* | *Scientific community* | | *Greece* |
| 64. | *Participation to a workshop* | *Brainstorm Multimedia* | *VLC Health Ecosystem Meeting* | *13/07/2017* | *Valencia* | *Scientific Community* | *60* | *Spain* |
| 65. | *Newsletter* | *AGE* | *Newsletter #3* | *14/07/2017* | *Brussels* | *Civil society, Medical, technical, policy makers* | | *Europe* |
| 66. | *Newsletter* | *AGE – EIP AHA A3* | *EU Health Policy Platform : latest updates* | *23/07/2017* | *Europe* | *Medical partners, EU stakeholders, policy makers* | | *Europe* |
| **FORESEEN ACTIVITIES** | | | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *1.* | *Non-scientific and non-peer reviewed publications (popularized publications)* | *Materia* | *Article on frailsafe project in Politis Newspaper* | *30/07/2017* | *Nicosia* | *General public* | | *Cyprus* |
| *2.* | *Participation in an event other than a conference or workshop* | *Materia* | *Present FRAILSAFE to annual meeting of Gerontology Research Center, University of Nicosia* | *28/7/2017* | *Nicosia* | *Scientific community* | *50* | *Cyprus* |

## *6.3 Intellectual Property Rights*

As reported in deliverable D9.1 the Intellectual Property Rights (IPR) Working Group was defined to work towards the compilation of the IPR agreement. This group is chaired by Hypertech and comprises a representative from each partner organization. Moreover, the Advisory Stakeholder Board chaired by Brainstorm (again as reported in D9.1) will also assist in this process and in the exploitation of the project results.

There is already an informal agreement as to a mechanism by which the rights to intellectual property of each partner should be commensurate with the amount of effort each partner will contribute to the development of exploitable outcomes. The baseline for IPR negotiation is that Brainstorm has background ownership of the real-time graphics engine to be used in the 3D gaming platform, while clinical data are the sole property of the clinical trial party that generates them.

Additionally, discussions on the technical architecture of the FrailSafe were finalized in M12. In this architecture, the various exploitable components expected to be developed during the project lifecycle are also included WWBS, games, data analysis and visualization tools, Virtual Patient Model, clinical and community platform, Authentication UI and eCRF, etc.).

The IPR management plan focuses exactly on these components, by trying to distinguish contribution of partners to individual modules and to the final integrated FrailSafe system, indicating IPR restrictions, licenses required and target markets-audiences for the exploitation of the FrailSafe solution as a whole or partially.

Planned activities will ensure that all project results are formulated and compiled into a protectable form and lead to the finalization of the IP / Joint Ownership Agreement to enable exploitation actions to execute smoothly.

The first draft IPR Management Plan (D8.8) was completed in M12 while a final version will be available by month 24.

## *6.4 Innovation*

***Does the project include the following activities and if so how many of each?***

| Activities developed within the project | Number |
|---|---|
| Prototypes | 18 |
| Products | 1 |
| Testing activities (feasibility/ demo) | 3 |
| Clinical trials | 3 |

**Prototypes**

3 prototypes of WWBS (both electronics and garments) before of the release of WWBS 1.0.

8 Game prototypes; Games suit capable to be extended in the future with extra games, and also a set of initial games as Red Wings, Force Analyzer, Memory, Reflex, Simon, Gravity Ball and Floating Archery Target AR game prototypes.

Preliminary information visualization and DSS dashboard, to visualize the FrailSafe data.

First prototype of the Virtual Patient Model.

First prototype of the data processing and analysis platform.

First release of the Clinical Web Platform including the Authentication UI and the eCRF.

**Products**

Production and certification of WWBS, composed by a sensorised shirt, two external IMUs and an electronic device and a software tool for data management. 8 units have been distributed to clinical and R&D partners

**Testing activities**

Several feasibility tests and demonstration have been performed in order to check acceptability and feasibility of the different aspects of the Frailsafe system.

On the top of the clinical trials, WWBS 1.0 has been severely tested before being sent to the laboratory for EC certification, and testing will continue in the view of WWBS 2.0 development.

Extensive testing during the development of games, with the use of dynamometers and AR glasses, to ensure feasibility and acceptability.

Extensive testing of the eCRF platform to fully comply with the WP2 requirements.

**Clinical trials**

The FrailSafe system is applied and evaluated in 3 simultaneous clinical studies in Cyprus, Greece and France.

***Will the project lead to launching one of the following into the market (several possible):***

| | |
|---|---|
| New product (good or service) | Integrated FrailSafe system, WWBS system (a commercial ready system enabling a comfortable monitoring of physiological parameters (heart, respiration) and upper body activity to be used for collecting data and generate analysis), Signal Processing & Data Analysis tool, |

| | |
|---|---|
| | Social Media Sensing tool, Risk Assessment tool, Virtual Patient Model (VPM), Dynamically Synthesized Games, Visualization & DSS module, Clinical Web Platform (eCRF), Virtual Community Platform. |
| New process | |
| New method | |

***How many private companies in your project have introduced or are planning to introduce innovations? (within the project lifetime or 3 years thereafter)***

| Description | Number |
|---|---|
| Companies introducing innovation(s) new to the market: | |
| How many of these are SMEs? | |
| Companies introducing innovation(s) new to the company: | |
| How many of these are SMEs? | |

# 7 Impact on SMEs

| SME Name | Turnover of the company at the beginning of the project / most recent accountability period from the beginning of the project | Number of employees at the beginning of the project / most recent accountability period from the beginning of the project | Turnover of the company at the most recent accountability period | Number of employees at the most recent accountability period |
|---|---|---|---|---|
| Brainstorm | 2.154.605 | 34 | 2.098.424,92 | 38 |
| Smartex s.r.l. | 509.205 | 7.6 | 633.674 | 8.2 |
| HYPERTECH | 1.253.410,20 (2015) | 25 (2016.01) | 989.460,37 (2016) | 24 (2017.01) |
| Gruppo SIGLA S.r.l. | 5.002.500,00 Euro (2015) | At 01/12/2015: 68 employees | 5.315.846 € Euro (2016) | At 31/12/2016: 64 employees |

# 8 Open Research Data

As already expressed in the Description of the Action, the FrailSafe consortium guarantees the open access to its publications according to Article 29.2 of the Grant Agreement, by undertaking the measures specified below:

- Comply with the latest "Open Access to Scientific Publications and Research Data in Horizon 2020" guide (v3), published by the EC on 26 July 2016.
- Ensure open access to the deposited publication — via repositories to be selected through OpenAIRE— at the latest on publication, if an electronic version is available for free via the publisher, or within six months of publication in any other case.
- Deposit the research data needed to validate the results presented in these publications ('underlying data').

Working in this direction, the FrailSafe website already includes a dedicated section to publish the project's results (publications, demos etc.): http://frailsafe-project.eu/frailsafe-results.

For further analysis and experimentation by other researchers and in compliance to the Article 29.3 of the Grant Agreement, FrailSafe also takes all the measures to ensure open access to selected datasets collected as part of the project's research. These actions lead to the composition of a comprehensive Data Management Plan (DMP), as described in section 16 of the current document.

# 9 Gender analysis

| Beneficiary | Number F (Female) including third parties (if appropriate) | Number M (Male) including third parties (if appropriate) | Total including third parties (if appropriate) |
|---|---|---|---|
| UoP | 5 | 11 | 16 |
| BRA | 3 | 5 | 8 |
| SMARTEX | 4 | 5 | 9 |
| AGE | 3 | 0 | 3 |
| CERTH | 6 | 18 | 24 |
| MATERIA | 6 | 2 | 8 |
| SIGLA | 3 | 7 | 10 |
| HYPERTECH | 1 | 4 | 5 |
| INSERM | 2 | 0 | 2 |
| Total | 32.6 | 51.6 | 84.2 |

# Periodic Technical Report

Part B

# Explanation of the work carried out

## 10 Progress towards FrailSafe main objectives

Concerning the technical progress of the project it can be summarized in the following points:

- State-of the-art analysis and benchmarking of existing methods has been successfully performed
- Design of signal processing methods to be used has been also performed
- Selection of sensors and hardware components of the FrailSafe solution, their purchase and delivery to clinical partners have been finalised (only beacons for indoor monitoring are missing, but, even if they are due at M24, they will be delivered in July 2017 - M19)
- WWBS first version has been designed, produced, EC certified and delivered to clinical partners
- Design of the database and the virtual patient model has been finalized
- Offline and real-time data analysis algorithm development has progressed significantly and is expected to be finalized by the end of 2017
- Design of game components has started, while existing games developed by the consortium are evaluated so as to identify shortcomings and use evaluation results in the development of the FrailSafe serious games
- Design and development of several feature extraction methods, via low-level signal processing, for behavior monitoring and activity classification has been also performed.
- The lightweight APIs for the secure communication between the Frailsafe devices (vest, dynamometer, etc) and the mobile devices (smartphone, tablet) has been developed.
- Several mobile applications for patient behavior analysis including indoor & outdoor localization monitoring and risk events detection (fall, loss of stability & orientation) have also been developed.
- A dedicated graphics framework has been developed to support the easy development of AR games for mobile devices (tablet & glasses).
- Two augmented reality demo games are currently under development on both tablet and glasses, testing the ergonomics, user-friendliness, compactness and unobtrusiveness.
- The existing virtual supermarket game for cognitive function monitoring has been enhanced with respect to graphics, usability and ease of learning.

- Preliminary dashboards for the visualization of the FrailSafe data have been implemented, using various visualization means, having both patient-oriented and clinician-oriented views.
- Design and implementation of the security infrastructure and software modules
- Implementation of the first integrated prototype of the FrailSafe system

| Obj. | Description | Status | Indicative completion percentage |
|---|---|---|---|
| TO1 | Design and development of hardware components (ambient and wearable sensors, body node coordinator (e.g., smart phone) optimized 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 individualpatient's condition for purposes of detecting/alerting/averting of frailty events, merged to an integrated system, explicitly taking into account security and privacy issues **(*Measurable Result (MR)*: WP3 & WP6 - Ms5, Ms8, Ms9, Ms10)**. | Design of WWBS has been completed and the first version of the device has been produced and EC certified for acceptance of the Ehtical Committees: 8 units have been delivered to partners for device testing, with positive results. A second (final) version of this device is due for end of year 2. Indoor monitoring has been further developed, together with the app for outdoor monitoring. Selection of off-the-shelf components was finalized, as planned.<br><br>The architecture and the interactions among the different sub-systems involved has been refined and finalized, as well as the means of data transferring to a exactly defined server storage. | 80%<br><br>Design of hardware components: 80%<br><br>development of hardware components: 75%<br><br>merged to an integrated system: 70%<br><br>taking into account security and privacy issues: 10 %<br><br>WWBS: 75% in terms of hardware development, 75% in terms of ergonomics, user-friendliness compactness, unobtrusiveness and energy consumption<br><br>Indoor localization: 80% - SENSORO bluetooth beacons have been selected. Mobile application for in-place setup and configuration of the beacons has been developed.<br><br>IMUs: 90% - Commercial X-IMUs have been purchased from X-IO. An API has been developed for their use in FrailSafe applications as well as an Android application in order to discover and connect with multiple IMUs.<br><br>Auxiliary Devices (FORA & Mobilograph): 80% - the interactions and the means |

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|---|---|---|---|
| | | | of data exchange have been designed, tested and documented<br>Degree of completeness: 80% |
| TO2 | Design and development of efficient signal processing algorithms for low level processing including signal enhancement, activity classification, energy expenditure, and behavioral monitoring **(MR: WP3 - Ms6)**. | Several algorithms for behavioral monitoring and activity classification have been developed based on FrailSafe data that has become available | 75%<br>Preliminary work has been done on applying time series analysis and peak detection in existing electrocardiogram (ECG) data from Internet databases.<br>An application for room-level indoor localization and behavioural monitoring using the mobile phone and installed beacons has been developed.<br>A GPS outdoor location tracking (joined with step counting process) mobile application has been implemented. This app can also be used for classification of walking or driving activity.<br>Algorithms for instability & fall detection have been developed and are currently under testing.<br>Algorithms and Android applications for activity classification based on signals collected from the strap have been developed. GPS signals and strap signals have been fused for more reliable activity recognition.<br>Degree of completion: 75% |
| TO3 | Development of a self-adaptive virtual patient model offering optimal services for | The VPM has been designed, the parameters to be included have been defined and the implementation has been completed. The integration | 85%<br>The design and implementation of the Virtual Patient Model to be used in FrailSafe has been |

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|---|---|---|---|
| | managingfrailty ranging from critical situation management, facilitating social integration to day-to-day self-management and health preservation based on a personalized patient profile **(MR: WP4, WP6 & Ms6, Ms8 - Ms10).** | with the FrailSafe system and the real-time update is being developed. | completed. Modifications are expected after system validation and user feedback. Existing archetypes based on the openEHR model have been adapted and modified, and new archetypes were built as needed. Integration with the rest of the FrailSafe system is ongoing.<br>Degree of completion: 85% |
| TO 4 | Development of a generic monitoring and management infrastructure on which modular services and patient-specific applications will be built **(MR: WP3, WP4, WP5, WP6 & Ms3, Ms5, Ms6, Ms8 - M10).** | Requirements of the data management infrastructure are discussed and database has been designed<br>- The first version of the architecture of the FrailSafe system has been designed and released (D1.3) while its revision (D1.4) is actively on progress.<br>- WWBS first version has been released in 8 units (according to Amendment to contract #1). Due to the fact that these devices are to be used with real users in their home environment, a not planned EC certification testing their safety (both electric and electromagnetic) was needed and this brought to a slight delay in device delivery.<br>- First prototype of the data management and analysis platform is developed and integrated in the cloud services of the FrailSafe project.<br>- A first version of the FrailSafe system has been released. The cloud infrastructure to host the sub-systems implemented during the project has been designed and setup, the backbone | 30%<br>Development of a generic monitoring and management infrastructure: 30% |

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| | | software infrastructure to manage users and security of the system has been deployed as well as some of the core sub-systems.<br>- The games framework is under development taking into account the FrailSafe sensors. Some of their correspondent modules and plugins have been finalised.<br>- Regarding data visualization and Decision Support System, a preliminary dashboard has been developed, providing patient- and clinician-specific interfaces, utilizing various presentation types for the available data. | |
| TO5 | 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 | The data management infrastructure has been designed, implemented and deployed to the cloud. Part of the fusion and analysis methods for social and physical activities have been developed. A first analysis of the eCFR data has been performed. A new frailty index has been extracted showing correlation with standard clinical metrics. The analysis of multimodal sensor recordings has started.<br><br>Visualization approaches for presenting frailty-related information to both the older person (infographics appropriate for mobile devices) and the clinician (visual analytics methods from previous European projects) have been included in the developed information visualization dashboard. Graph-based visualization | 60%<br><br>Data management: 90%<br><br>Implementation and deployment is completed; minor modifications are expected for the future.<br><br>Data analysis: 60%<br><br>Preliminary analysis on eCRF and multimodal sensor data has been performed; models will be improved with the accumulation of data.<br><br>Data visualization: 40%<br><br>Visualization dashboard is being developed; integration with the FrailSafe database is ongoing.<br><br>Degree of completeness: 60% |

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|---|---|---|---|
| | **(MR: WP4, WP6 & Ms6, Ms8-Ms10).** | methods incorporate data fusion techniques. | |
| TO6 | 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 utterancesor suicidal manifestationsin electronic written text[4]) 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)**(MR: WP3, WP4, WP6& Ms3, Ms5, Ms6, Ms8-Ms10)**. | Several methods for real-time data management and analysis have been investigated and design decisions have been made. Work on real-time fall detection has been performed. State of the art techniques for streaming data management were applied. Investigation of state-of-the-art for gait analysis and loss of balance is ongoing. Real-time analysis of written text is being developed.<br><br>The architecture and the interactions among the involved sub-systems has been refined and finalized besides its internal details. | 55%<br>Real-time data management: 70%<br>Data mining techniques: 50%<br>Degree of completeness: 55% |
| TO7 | 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 | Investigation of real-time trade-offs and data reduction techniques is being further investigated.<br>Compressed sensing techniques have been implemented for data reduction and energy | 50%<br>Degree of completeness: 50% |

[4] A speech recognition component is not provided. Incoherent utterances and suicidal manifestations refer to written messages communicated via electronic social media.

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| | techniques for reducing raw streaming data to secondary or tertiary parameters.<br>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**(MR: WP3, WP4, WP6 & Ms3, Ms5, Ms6, Ms8-Ms10)**. | efficiency, in order to be integrated in the WBAN.<br>Dimensionality reduction of extracted feature vectors for reduction of computational costs was performed. | |
| TO 8 | Development of a dynamically synthesized, personalized, and highly innovative AR game consisting of different scenarios that will take place in the real world than in a virtual one that measures parameters of behavioural, cognitive and physical domain while implementing various intervention strategies **(MR: WP5, WP6 & Ms7-Ms10)**. | Requirements discussed, hardware prerequisites analyzed, plans available, design has been performed and implementation is ongoing | 70%<br><br>Game prototypes have been implemented to test the communication with input devices (e.g. AR tablet and glasses, dynamometer). An existing game assessing the cognitive status of the users (**Virtual Supermarket**) has been used to collect usefulness and usability feedback from older people and improved in terms of graphics and usability. Several rounds of feedback acquisition from clinical partners have been conducted, regarding conceptual ideas about game designs, regarding their relevance to frailty. A beta version of the **Red Wings** gameis available, which employs a dynamometer. Beta versions of two AR games, namely **Gravity Ball** and **Floating Archery Target**, have been implemented, targeted for tablet and AR glasses devices, |

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| | | | respectively, for assessing physical, cognitive and executive functions.<br>Degree of completeness: 70% |
| TO9 | Extensive testing of the FrailSafe integrated system in several validation scenarios while ensuring compliance with ethics standards **(MR: WP7 & Ms11 - Ms14).** | Preliminary integration has been performed.<br>The integration is continuously ongoing and the situation evolving. Further sub-systems, already available and seamlessly testable independently, will be progressively integrated according to the implementation plans provided by each WP. | 33% |

Concerning the medical progress of the project it can be summarized in the following points:

- State-of the-art analysis and benchmarking of existing frailty assessments have been performed. A comprehensive list of clinically applied frailty assessments has been linked to the relevant publications in the literature.
- Clinical study methodology and planning has been described in full
- A comprehensive clinical assessment has been finalized
- The clinical requirements for the physiological parameters measured by the FrailSafe system have been described and incorporated into the FrailSafe design
- The clinical requirements for the games, dynamometers, and AR glasses have been discussed and incorporated into designs.
- The clinical requirements for Smartphones and Tablets have been set to fit with the needs of older people.
- The methodology for the study of the Autonomous Nervous System and the parameters for the study of inflammatory and endocrine profile of participants have been described.
- Ethical issues have been debated and settled.
- Local clinical meetings with older people have been organized, conferences with general and internal medicine practitioners have been planned, interviews and debates in medical TV transmissions have been carried out and are programmed.
- Recruitment of participants has started using available systems.
- Clinical study’s measurements and follow up, along with the FrailSafe system application is running.

- The recruitment of group A and B and their clinical evaluations are completed for all clinical centers
- Participants who dropped off are about to be replaced.
- The eCRF features of the Clinical Web Portal were delivered by WP6 and already in use.
- Data from clinical evaluations and FrailSafe devices are being fed in the corresponding databases in order to render them available to the whole consortium for analysis.

| Obj. | Description | Status | Indicative completion percentage |
|---|---|---|---|
| MO1 | Better understand frailty and its relation to co-morbidities | Current literature has been analyzed. Detailed list of conditions and diseases of the elderly, possibly related to frailty, has been compiled and recorded during clinical assessment. Current medications are also recorded for similar reasons. Preliminary results of the analysis of the FrailSafe data collected show indications regarding better understanding of frailty. New data collection and analysis, even though still preliminary, has added to our understanding of frailty. In addition, collection of existing guidelines for frailty phenotypes and implementation in Frailsafe model has also contributed to this objective | 30% |
| MO2 | Develop quantitative and qualitative measures to define frailty | A comprehensive clinical assessment has been formalized. It includes a face-to-face clinical assessment, self-administrated questionnaires, text sampling, and phone follow up assessment. Clinical general condition, mood, cognitive status, sleep, nutrition, activities of daily living, social interactions, personality traits, quality of life, health rating and physiological parameters are included. The physiological parameters to be monitored by continuous recordings | 33 % |

| | | | |
|---|---|---|---|
| | | via any kind of agreed sensors have also been defined.<br><br>Up until M18, 389 participants have been enrolled in the study, 492 (clinical evaluations have been performed. There have been 44 withdrawals from the study, the majority of whom have been replaced by new participants. All three clinical centers have completed the first clinical evaluations in groups A and B. By the end of M18, 103 out of 120 second clinical evaluations of group B have been performed.<br><br>The D2.4 has described the procedure of all data integration to be followed in the forthcoming phase of data analysis. | |
| MO3 | Use the above measures to predict short and long-term outcome | Follow up data have almost being collected by the second evaluations of group B.<br><br>Data derived from the three-months' phone follow up have just started to be fed in eCRF, since the corresponding questionnaire has been recently available in the eCRF. | 15% |
| MO4 | Develop real life tools for the assessment of physiological reserve and external challenges | Current literature has been analyzed. Potential markers of physiological reserve and external challenges have been introduced into comprehensive clinical assessments, as well as into the FrailSafe continuous measurements.<br><br>Up until M18, 492 clinical evaluations have been performed. All three clinical centers have completed the first clinical evaluations in groups A and B. By the end of M18, 103 out of 120 second clinical evaluations of group B have been performed.<br><br>In all 3 centers 291 FrailSafe sessions have been performed up until M18. | 30% |

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| MO5 | Provide a model sensitive to change in order that will facilitate the testing of non-pharmaceutical interventions, which will be designed to delay, arrest or even reverse the transition to frailty, can be tested | Follow up evaluation of proxy and hard outcomes has started but not analysed yet. | 10% |
| MO6 | 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, games, monitoring alerts, guidance and education and estimate the influence of these interventions | Has started. Clinical guidelines formalized (D2.2) M18<br><br>Data collected, even though a small % of the final data, confirm many existing guidelines and recommendations and thus lead to a basic list, however, the recommendations to be created by this project will not emerge until later on when we have more conclusive data, paired up with our VPM model. | 10% |
| MO7 | Achieve all with a safe and acceptable to older people system | Much care and effort has been placed in ethical and the older person's protection issues. Preventive measures are applied during all clinical tests and evaluations.<br><br>The feedback we receive from participants has allowed us to increase acceptability features. | 25% |

# 11 Success Indicators as Related to the FrailSafe Main Objectives

| WP No. | Indicator | Success Criteria |
|---|---|---|
| | | M17 |
| General Success Indicators associated with WP8 and 9 | | |
| Number of publications, number of workshops organized by the consortium and audience size, number of conferences attended, number of leaflets and newsletters, website, size of user forum, membership to biometric organizations and forums/ - to disseminate project concept, vision and innovation - to spread out the outcomes and achievements of the project to all interest groups | | 1. 1. Web site of FrailSafe available (Month 3)<br>2. Project dissemination material available (posters, leaflets) as defined in WP8<br>3. At least 7 presentations of project objectives and results (conference proceedings, etc.) |
| Delivery of an effective, pragmatic and viable business & exploitation plan for project results uptake and commercialization potential | | FrailSafe draft dissemination exploitation strategy and decisions |
| Increasing public interest in FrailSafe concept measured by web server logs | | 500-1000 |
| WP1 (Requirements, Use Cases, Architecture and Specifications) | Review and comparative benchmarking of available frameworks. | 100% |
| | User requirements and system specifications clearly address FrailSafe needs | 95% of user requirements and FrailSafe needs identified through questionnaires and first phase of test campaign. The work for finalizing the architecture of the system is on-going. |
| WP2 (Clinical studies, measurements, clinical analysis) | Percentage of clinical studies completed successfully resulting in data both for quantification and benchmarking data successfully used to quantify and fine-tune the WP4 data management/analytics and WP5 Intervention services | 50% |
| | Standardization of the procedures and protocols for the clinical studies and objective measurementsof performance collected through various means and analyzed | 85% |

| | | |
|---|---|---|
| WP3 (Smart Sensing, data acquisition and signal processing) | Integration of sensors and definition of the communication framework | 75% |
| | Sensing environment working properly and unobtrusively | 75% of the supported sensing capabilities ready and functional |
| WP4 (Data Management and Analytics) | Completion of data analysis algorithms based on specific physiological input parameters | 60% |
| | Measurable improvement of the developed approaches with respect to the SoA schemes in a simulated environment | 20% |
| | Percentage of developed elderly models that capture clinical and physiological data | 60% |
| | Number of physiological variables of the elderly models linked to frailty | 60% of the analysis completed |
| WP5 (Dynamic Intervention Services) | Review and comparative benchmarking of available Game hardware devices and software tools | 100% |
| | Development of the game controllers and of the visualization interfacing | 50% |
| | Graphical users interfaces customizable to the user requirements/needs | 20% |
| | Information visualization framework fully parametric and customizable | 30% -> of the functionality available for demonstration purposes |
| WP6 (Integration and FrailSafe Application and Services) | Completion of FrailSafe sensing and intelligent processing modules integration | 33% A first integrated system has been implemented and deployed at M18. |
| WP7 (Evaluation) | Number of novel biomarkers and frailty metrics identified based on information visualization | 0% |

| | | |
|---|---|---|
| | Percentage of number of users with positive feedback on the FrailSafe system | 0% |

# 12 Explanation of Work Carried per Work Package

## *12.1 WP1 – Requirements, Use Cases, Architecture and Specifications*

The main objectives of WP1 are the definition of the needs and requirements of the end users of the FrailSafe system, such as older people, clinical personnel and researchers, followed by the determination of the system specifications, use cases and the design of the FrailSafe architecture. In order to achieve these objectives, an examination of the current practices needs to be conducted, followed by the definition of the user requirements and use cases, leading to the detailed design of the system architecture.

WP1 is split into four tasks, as presented in the following table:

| WP1 Tasks | Effort (M/M) | Leadership |
|---|---|---|
| T1.1 State-of-the-art assessment and acquisition of methodological tools | 11.5 | CERTH |
| T1.2 User requirements, clinical procedures and FrailSafe use cases | 13.5 | MATERIA |
| T1.3 FrailSafe UCD methodology | 11.5 | CERTH |
| T1.4 Architecture and system specifications | 19.5 | SIGLA |

The outcomes of WP1, in terms of deliverables and milestones, are presented in the following table:

| | | |
|---|---|---|
| **Deliverables** | D1.1 Analysis of current practices | M6 |
| | D1.2 User requirements, use cases, UCD methodology and final protocols of evaluation studies | M12 |
| | D1.3 FrailSafe technical specifications and end-to-end architecture | M12: first version<br>M24: second version |
| | | |
| **Milestones** | MS2 Definition of requirements, use cases and UCD methodology available | M9 |
| | MS3 Definition of system architecture and specifications | M12 |

### 12.1.1 WP1 – Objectives of WP1 during the period

The main objectives of WP1 during this first period were the following:

- The assessment of the state-of-the-art in the main research topics related to FrailSafe, such as frailty quantification, sensing systems, virtual patient modeling, data mining, information visualization, virtual and augmented reality games and personalized guidance systems.
- The determination of the process for the collection of the user requirements and for the definition of the use cases of the FrailSafe project, which lead to the formulation of the specific user requirements and use cases.
- The selection of the User Centered Design (UCD) methodology that is used throughout the design and development of the FrailSafe components ensuring that the user requirements are met. This lead to the definition of UCD guideline evaluation protocols and checklists.
- The design of initial drafts of the FrailSafe architecture and specifications, detailing the distinct components and their interconnections. These drafts lead to the first version of the FrailSafe architecture.

### 12.1.2 WP1 – Summary of progress

The progress in the four tasks of WP1 during this period is summarized in the following.

#### T1.1 State-of-the-art assessment and acquisition of methodological tools

- The state of the art assessment has been targeted towards the following main topics: frailty quantification, sensing and monitoring systems, patient modeling, virtual and augmented reality games, and personalized guidance systems.
- Regarding frailty quantification, works about co-morbidities, disabilities, frailty models and frailty metrics have been examined.
- Regarding sensing and monitoring systems, both stationary devices, such as heart rhythm monitors, and portable/wearable devices, such as wearable activity trackers, have been examined. Signal processing algorithms have also been covered.
- Regarding patient modeling, current patient model representations from existing standards and other projects have been examined. Data management and knowledge discovery methods have also been examined, such as social media and time series analysis, which will lead to the extraction of characteristics comprising the virtual patient models.
- Regarding virtual and augmented reality games, existing rehabilitation programs have been examined, in combination with user-friendly interfaces and interactive environments.

- Regarding personalized guidance systems, visual analytics tools facilitating the data exploration for both patient and clinical personnel have been examined. Modern personalized health support tools, mobile and cloud-based interfaces and existing cross-platform infrastructures have also been investigated.
- The above state-of-the-art assessment has been presented in detail in deliverable D1.1, “Analysis of current practices”.

**T1.2 User requirements, clinical procedures and FraiSafe use cases**

- The FrailSafe user groups have been identified, namely older people, families of older people, doctors, nurses, researchers, commercial organizations and technology developers.
- The main FrailSafe components, which will be used by the above user groups, have been identified. These include hardware components, such as the FrailSafe vest (WWBS) with its accompanying sensors, external devices such as dynamometer, indoor sensors and smartphones, IMUS, AR glasses, as well as software components, such as mobile applications, virtual and augmented reality games, data analysis software and visual analytics.
- The basic types of user requirements to be gathered have been identified and organized hierarchically, in terms of importance, in the following qualities: safety, ethics, utility, functionality, usability and desirability.
- Existing methods for the acquisition of feedback, such as questionnaires, interviews, surveys and focus groups, from the end user groups (elderly people, family members, healthcare professionals) regarding the use of the various Frailsafe components have been partially performed. This feedback is currently under usage for the design of the final system requirements.
- Final FrailSafe use cases have been prepared. Three types of use cases have been identified, namely *patient-oriented*; describing actions performed by the patient such as daily actions wearing the vest, *healthcare professional-oriented*; describing actions performed by the healthcare personnel such as interacting intervention strategies to adjust medication and provide lifestyle recommendations, and *family-oriented*; describing actions performed by the family members such as viewing the patient’s data and being notified from a number of potential alerts. The above preparatory steps lead to the determination of the specific user requirements and use cases.
- The above user requirement analysis and system modeling have been presented in detail in deliverable D1.2.

**T1.3 FrailSafe UCD methodology**

- The interactions between the FrailSafe user groups and the hardware and software components have been identified.

- Methods for the assessment of user feedback have been examined, such as questionnaires, interviews, surveys and focus groups.
- Methods for user-assisted design, where the end users participate in the design phase of the components, have been examined, such as participatory design, co-discovery and prototyping.
- Methods for user-assisted implementation, where the end users participate in the implementation phase of the components, have been examined, such as expert reviews, heuristic evaluation, usability testing and performance measurements.
- Three focus groups have been formed for the collection of end-user feedback. The focus groups consisted of older people and feedback was gathered regarding the usability and usefulness of various hardware and software FrailSafe components.
- An online questionnaire has been prepared for the prioritization of the initial version of the FrailSafe use cases by experts and end-user representatives. The feedback from the questionnaire, along with the feedback from the focus groups, will be used to refine the system requirements and use cases.
- The design of the specific UCD guidelines protocols and checklists to be used throughout the design and implementation phases of the project has been included in the deliverable D1.2.

**T1.4 Architecture and system specifications**

- The main patient parameters that will be monitored in FrailSafe have been identified. These include heart rate, respiration rate, blood pressure, weight, arterial stiffness, steps per minute, instability, strength, posture, indoor activities, outdoor activities, nutrition, co-morbidities, social interaction and cognitive state.
- The main means used for the acquisition of the above parameters have been identified, including the FrailSafe vest with its embedded sensors and inertial measurement units (aka WWBS), the dynamometer, the VR and AR games, the indoor sensors, the smartphone sensors, the web portals (Clinical Web Portal, aka e-CRF, and the Virtual Community Platform). The hardware and software components available for the first round of clinical trials, as well as those expected to be available in the second round of trials have been taken into account. Details regarding the data acquisition process, storage and what needs to be purchased have been specified.
- Preliminary versions of the FrailSafe architecture have been designed. At the center of the architecture there is a data aggregation and processing unit, which could be a smartphone, which collects the data from all the stationary and wearable sensors and measurement devices attached to the users and

their environment, as well as from the games. The Bluetooth protocol is mostly used for the communication between the sensors and the aggregation unit. The data collected are transferred to the FrailSafe cloud, for long-term storage, from where they can be consulted for data analysis and generation of the virtual patient models. The communication between the aggregator and the cloud is bi-directional, so that e.g. the virtual patient models can affect gaming parameters.

- This preliminary architecture will be used as the basis for the first version of the FrailSafe architecture and is discussed in detailed in deliverable D1.3.

A deep and significant revision of the architectural concepts is in progress with the aim of preparing the forthcoming D1.4, due for M24. The contents of the D1.3 have been profoundly revised and the description of the interactions among all the sub-system of the platform has been finalized but for a few details internal to the individual WPs and modules.

### 12.1.3 WP1 – Significant results and achievements

The most significant results and achievements with regard to WP1, in this first 9-montηperiod, following the above summary, are the following:

- An assessment of the state-of-the-art of the main research topics related to FrailSafe, which has led to the compilation of deliverable D1.1, “Analysis of current practices”.
- The design of a methodology for the user requirements collection and the use cases definition.
- The collection of end-user feedback and comments from three focus groups, regarding the usability and usefulness of various FrailSafe components.
- We have prepared an online survey that contains short descriptions of FrailSafe use cases in order to get feedback regarding the necessity/priority that should be put on each of them, which, along with the end-user feedback from the focus groups, has led to the completion of milestone MS2, “Design of use cases, user requirements, UCD methodology”.
- The selection of common UCD methodologies, to be used throughout the project design and implementations.
- A first version of the FrailSafe architecture, in collaboration with WP6, focusing on the monitored information and the data flow within the main components of the FrailSafe system.

### 12.1.4 WP1 – Deviations and critical issues

There are no critical deviations from the plan. The deliverables D1.1 (which is the outcome of Task 1.1), D1.2 (which is the outcome of Tasks 1.2 and 1.3), D1.3 (which is

the outcome of Task 1.4) and have been delivered and achieved on time (M6 and M12, respectively). Milestone Ms2 has also been achieved on time (M09).

### 12.1.5 WP1 – Use of resources

CERTH has used an additional effort of 2.25 PMs in task T1.1, "State-of-the-art assessment and acquisition of methodological tools", due to the importance of investigating and covering all current practices and technologies, upon which the solutions developed for FrailSafe will be based.

### 12.1.6 WP1 – Corrective actions

Currently, no corrective actions are needed.

## *12.2 WP2 – Clinical studies, measurements, clinical analysis*

### 12.2.1 WP2 – Objectives of WP2 during the period

All four tasks of WP2 were programmed to start in M1.

In Task 2.1-Clinical study methodology and planning (M1-M6) the main aim is to create a consensus for clinical strategies. The goal of these strategies is to identify and quantify appropriate physiological and behavioral characteristics in order to define potential biomarkers of frailty of significant predictive value.

The Task 2.2-Clinical monitoring of older people was planned to start in M4and carry on up until M31. This task includes the actual application of the clinical part of the study, recruiting, assessing and testing the FrailSafe system on the study's actual participants.

The Task 2.3-Clinical Guidelines for System development (M1-M19) uses information capture, analysis and modeling to make an overall assessment of an individual's dietary, nutritional, physical activity patterns and compare this with current healthcare recommendations to identify where improvements could be made.

The Task 2.4-Behavioral monitoring (M1-M19) is focused on collecting and analyzing "objective" measurements of performance and eventually to measure subjects' behaviors in specific tasks while using both typical clinical tests and novel semi-automated computerized motor tests.

### 12.2.2 WP2 – Summary of progress

In the context of Task 2.1-Clinical study methodology and planning, the clinical evaluation battery, consisting of a series of carefully selected questionnaires and some clinical instrumental measurements, was consolidated during this period of time. More specifically, the clinical assessment subsets and the tools employed are described in the following table:

| Clinical assessment's subsets | Tools to be employed |
|---|---|
| 1. Identification data | Questions |
| 2. Generalities: demographics, leisure, social life/communication assessment | Questions |
| 3. Medical history, comorbidities, medication list | Questions, self-reporting, drug prescriptions, medical records when available |
| 4. Clinical examination and instrumental measurements | Pulse palpation, measure tape, bio-impendence scales, blood pressure monitors, electronic tension meter, mobil-o-graph |
| 5. Balance and gait evaluation | Stopwatch, meter |
| 6. Fried's criteria of frailty assessment: allocation into frailty categories | Questions, dynamometer |
| 7. Sensory system evaluation: vision, hearing | Questions and clinician's estimation |
| 8. Nutritional Assessment | MNA short and extended form |
| 9. Activities of Daily Living | Katz Index of Independence of ADL, Lawton IADL scale |
| 10. Cognitive, mood and sleep evaluation | MMSE, MoCA, questions, GDS-15items |
| 11. Self-evaluation scales | Questions and VAS |

The parameters selected to be monitored correspond to aspects of an older person's general health and well-being status either already related to frailty or susceptible to emerge possibly significant relations, in a holistic model of approach. Moreover, to this direction aims the use of the various sensors of the FrailSafe system described in Task 3.1 of WP3 and the work of WP5-Parameterization of the Intervention Services. After interactions with all partners, the study's protocol has been finalized, its rationally explained and its operational details described in D2.1-Clinical study methodology. The time schedule and the protocol of follow up for each participant (according to the group of allocation) have been determined and described in detail in D2.1.

Deliverable D2.1 was revised according to reviewers' comments and propositions and the medical objectives referring to the clinical study were better defined. Arithmetic indices quantifying collected data were determined and hard and clinically significant

outcomes were clarified. Medical objectives were expressed in the form of hypothesis statement. The architecture of the statistical analysis was outlined.

Furthermore, for reasons of standardization of clinical procedures and prevention of omissions, a series of checklists was constructed and distributed in the 3 clinical centers, describing in detail the before, during and after procedures of the visits both of the clinical evaluation and the FrailSafe session.

In the context of Task 2.2, the clinical monitoring of participants is in full development in all 3 clinical centers and although it started with a certain delay in Nancy (acquisition of the approval of the Committee of the Protection of the Person in 6$^{th}$ October 2016), this clinical center has also managed to catch up with the overall recruitment rate.

Up until M18, 389 participants have been enrolled in the study, 492 clinical evaluations have been performed. There have been 44 withdrawals from the study, the majority of whom have been replaced by new participants. All three clinical centers have completed the first clinical evaluations in groups A and B. By the end of M18, 103 out of 120 second clinical evaluations of group B have been performed. Data from clinical assessments are entered into tailored made eCRF.

The application of the FrailSafe system devices has started in all clinical centers. Two hundred ninety oneFrailSafe sessions have been performed and most of the data obtained have entered either the eCRF platform, either uploaded to the corresponding cloud applications, being accessible to all relevant WPs.

Moreover, data regarding natural language analysis and the attitude towards social media are being collected in parallel. Some deviations of the clinical study protocol are discussed in the relevant session.

This task has produced the deliverables 2.4 (preliminary version) and 2.6, submitted on M18.

In the context of Task 2.3 – Clinical guidelines for system development, a review of the literature was conducted in order to investigate the existing and most well-supported recommendations referring to the prevention/delay/slowing down of frailty related phenotypes. Preliminary data analysis was conducted and some preliminary results emerged. All these together with the measurements of D2.2 will ground the WP4 models with experimental data providing sufficient data for the quantification of the patient models and prediction framework.

More specifically, deliverable 2.2 used information capture, analysis and modelling and conducted an overall preliminary assessment of an individual's dietary, nutritional and physical activity. This was compared with current healthcare and European advices in order to identify where improvements could be made. Therefore, Frailsafe data combined with existing recommendations, led to FrailSafe preliminary recommendations set. It is expected that these recommendations will lead to formal guidelines by M27, when the final version of the deliverable is due, and when Frailsafe will have a lot more data analysed.

Recommendations are directed to older adults, clinicians/researchers/doctors and families/care-givers. Moreover, preliminary recommendations were created both for prevention and for intervention purposes.

This report along with the collected data, is being delivered on M18. The first version of the D2.2 contains preliminary recommendations regarding clinical guidelines, while the second and final version of the deliverable (due M27) will contain formalized clinical guidelines.

In the context of Task 2.4, some objective clinical measurements to be monitored have been determined and thoroughly described in D2.1-Clinical study methodology and its revised version, and already started being collected without significant difficulties; Available devices are also being introduced, and technical and practical issues identified, and resolved. The natural language analysis has been introduced to detect subtle cognitive and language changes that might precede transition to frailty states. Three hundred and sixteen written text samples have been collected from participants.

The adverse events of frailty are also recorded by phone follow up, including, falls, fractures, hospitalization, and death. Up until M17 466 follow up phone callshave been performed.

Task 2.4 has contributed to the deliverable 2.6, submitted on M18.

The clinical requirements for the physiological parameters measured by the FrailSafe system, as well as the practical framework of this monitoring, have been discussed, described and incorporated into the FrailSafe design. Arithmetic indices were defined and constructed in order to better quantify collected data (revised deliverable 2.1). Clinical assessments, physical and cognitive activity monitoring leads to data accumulation from FrailSafe tracking systems and contributes to patient's individual profile construction (WP4), even though still in an early stage.
Available FrailSafe material has been demonstrated to users, comments have been collected and feedback to IT teams. Furthermore, a working document treating practical issues such as study's material, anticipated problems and procedures has been generated.

The clinical requirements have been discussed and incorporated into the study's designs regarding:

a) Construction of the eCRF platform (WP6)
b) Construction of games and use of dynamometers, and AR glasses (T 5.2; 5.3) and their feasibility and acceptability issues
c) Design, development and production of WWBS (T 3.2)
d) Smartphones and tablets to fit with the needs of older people

### 12.2.3 WP2 – Significant results and achievements

Significant achievements have been accomplished up until the time this report is being written:

The clinical assessments' battery has been finalized and consolidated in the form of a Clinical Guide sheet, constituting the paper document of the clinical evaluation session (D2.1).

Questionnaires and also objective clinical measurements taking part of the medical examination session were included (D2.1).

The clinical methodology of data collection for natural language analysis has been determined (D2.1) in cooperation with WP4.

Significant parameters to be monitored by the FrailSafe system, as well as the practical framework of this monitoring has been discussed and approached to the most accurate level possible considering the evolution stage of the system's devices.

The computerized equivalent of the CRF (case report form) is created with the contribution of WP2 and WP6 and data are being fed almost simultaneously or a bit after their acquisition.

Recruitment procedure has started and evolved all three clinical centers carrying out various informational and recruitment activities, aimed at triggering eligible population's interest and willingness to participate in the study. Pools of potential study participants have been created in UoP, MATERIA and INSERM's settings, which provide participants for immediate recruitment in the main stage of the study.

All three clinical centers have started the clinical study, and so far, until 20/05/17, 382 participants have been included in the study.

Further standardization of operational procedures and application of homogeneity measures go in parallel with the clinical studies clinical centers. In this direction check lists about the material and the procedures to be followed for all stages of the project have been elaborated. Moreover, we produced some forms for reporting each center's activity and the clinical study's follow up (periodic completion and centralization to INSERM), as well as a timetable indicating each participant's actions' schedule (planification of the clinical evaluations and FS sessions). Documents describing the procedure for declaration of undesirable events have been distributed to clinical partners. The unified eCRF (delivered in October 2016) for use by all 3 centers resulted in the substitution of paper CRFs by their electronic versions (paper to eCRF transition rates>90%).

Active interaction with all WPs for clinical guidance and feedback provision contributes to fruitful cooperation and system developments. Dissemination activities (WP8) and communication of the project to wider publics proceeds successfully.

Some ethical issues raised on the Review Meeting of M10, led to appropriate adjustments of informed consent forms and additional approval acquisitions from the local corresponding Authorities.

### 12.2.4 WP2 – Deviations and critical issues

The main deviation of the programmed tasks was the time schedule of the study which was supposed to start recruiting subjects in M4. The main reason for this delay in INSERM, Nancy, France, was the delay for obtaining approval from Ethical

Committees. This issue has long been settled and recruitment rates in Nancy managed to keep up with this of other clinical centers.

However, although the inclusions of all participants for groups A and B are accomplished, their clinical evaluations, first FrailSafe sessions and global follow up are still quite out of the original study's timeschedule and try to comply with the mitigation strategy plan proposed in the revised version of D2.1 and in the complementary report submitted to the Officer on M13. The current estimation of the actual delay from the mitigated plan is approximately 2-3 months.

The table below summarizes the progress of the inclusions, the clinical evaluations and the FrailSafe sessions up until M17, as well as the sex and frailty level analogy of the inclusions so far:

| *Updated to 20/5/17* | **Patras** | **Nicosia** | **Nancy** | **Total** |
|---|---|---|---|---|
| Inclusions | | | | |
| Number of inclusions | 120 | 126 | 136 | 382 |
| Number of valid participants (inclusions-withdrawals) | **108** | **114** | **120** | **342** |
| Sex distribution | | | | |
| Male (M) | 45 | 48 | 30 | 123**(36%)** |
| Female (F) | 63 | 66 | 90 | 219**(64%)** |
| Frailty and distribution (according to Fried) and sex analogy | | | | |
| nonfrail | 40 (15M+25F) | 14 (7M+7F) | 61 (14M+47F) | 115 (36M+79F) **(33.6%)** |
| prefrail | 37 (17M+20F) | 58 (26M+32F) | 44 (11M+33F) | 139 (54M+85F) **(40.6%)** |
| frail | 31 (13M+18F) | 42 (15M+27F) | 15 (5M+10F) | 88 (33M+55F) **(25.7%)** |
| Number of clinical evaluations performed | | | | |

| | | | | |
|---|---|---|---|---|
| Group A 1rst round | 80 | 85 | 90 | 255 |
| Group B 1rst round | 40 | 41 | 46 | 127 |
| Group B 2nd round | 0 | 0 | 9 | 9 |
| **Total** | **120** | **126** | **145** | **391** |
| Number of FS sessions performed | | | | |
| Group A 1rst round | 37 | 43 | 36 | 116 |
| Group B 1rst round | 38 | 31 | 38 | 107 |
| Group B 2nd round | 3 | 0 | 10 | 13 |
| **Total** | **78** | **74** | **84** | **236** |

Sensors and devices are gradually introduced as long as they were becoming available. Limited numbers of these, for instance one WWS strap per center led to having measurements from smaller number of participants. More detailed reports on the details on FrailSafe sessions' devices usage are provided in Section 3 of D2.6. Analysis of data collected by clinical parameters' monitoring has started and is also decribed in D2.6.

Another issue that is observed so far is the deviation of the desired analogy of non-frail/pre-frail/frail subjects by the evaluations made until now:

- non-frail: 33.6% vs 50% scheduled
- pre-frail: 40.6% vs 25% scheduled
- frail: 25.7% vs 25% scheduled

However, this analogy is already closer to the desired one in comparison to the one observed on M12 (29% non-frail, 43%pre-frail, and 29% frail).

### 12.2.5 WP2 – Use of resources

**i**- As far as **INSERM** is concerned, the allocated resources have been used so far for hiring one geriatrician who is responsible for:

-the communication of the study towards our partners and several associations of older individuals

- finalization with the other clinical research teams of the clinical protocol

- preparation of the documents for the different Ethical Committees

- participation to the teleconferences, live meetings and other discussions with the different other partners for the development of this project

-dealing with the majority of the administrative issues

- making of the clinical evaluations

and a nurse, responsible for:

-paying the home visits for the installation and retrieval of the FrailSafe system material

-following up the participants by telephone

-fixing the appointments

-assisting at the clinical evaluation sessions

-dealing with technical issues regarding material

-carrying out selected administrative issues.

**ii-**The allocated resources for the medical team of **UoP** have been used until now for hiring a neurologist and a nurse.

The neurologist is responsible for:

- the recruitment of the participants and making of the clinical evaluations

- participation to the teleconferences, meetings and discussions with the other partners for the development of the project and for solving the issues that arise during its course

- communication with the other clinical research teams in order to finalize the clinical protocol and resolve the problems that may arise

- dealing with the administrative issues

- preparation of the documents for the local Ethical Committee

and a nurse, responsible for:

-participation to the clinical evaluations sessions

- the installation and retrieval of the FrailSafe system material at participants houses

- fixing the appointments for the clinical evaluation sessions and the home visits

- phone follow up for the participants

-dealing with technical issues regarding material

**iii- Materia Group** in Cyprus has allocated resources so far in hiring a gerontologist, a nurse, and a part-time psychologist. Their responsibilities are:

Gerontologist: initial communication with participants, preparation of documents for the bioethics committee, communication with municipality senior centers, clinical evaluations, partners meetings, administration duties

Nurse: clinical evaluations, home visits for FS system trials, telephone follow-ups, technical training in using all devices

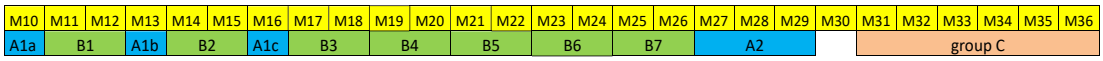
Psychologist: clinical evaluations, technical training in using all devices, telephone follow-ups, arranging appoitments with patients, participation in partner meetings, meetings with IT partners for development purposes.

### 12.2.6 WP2 – Corrective actions

INSERM has obtained the relevant Authorities' approval (6th October 2016) for the first half of the study (recruitment of groups A and B and for the use of the FrailSafe devices available so far). The clinical study has immediately started after that. Patras has obtained the relevant Aythoritie' s Approval ( 20th April 2016) to start and condact the study and renewed approval from local Corresponding Authorities ( 26th April 2017 ) obtained to deal the ethical and liability issues raised since M10's Review Meetting.

Renewed approvals from local corresponding Authorities have been made and achieved since M10's Review Meetting, dealing with ethical and liability issues raised there.

We have elaborated a proposed mitigation plan of a modified timetable for FS home visits in order to catch up with "lost" FS evaluations in group A, schematically depicted as following:




More analytically the plan proposes:

- The split up in three of group A's first cycle of FS session and its interference between the 1st-3rd sessions of group B
- The decrease of the duration of FS session for group A (3-5 days instead of 5)
- The decreasefor group B of the total number of FS sessions' cycles in 7 (instead of 9)
- No change in the conduction of the study for groups C and D (M31 and after).

Data provision to other WPs will be accelerated, thanks to immediate feeding in eCRF of the data collected by clinical evaluations and the intensified actualization of FrailSafe sessions. The applications of the FrailSafe system devices are realized with the material that we already possess in the present phase of the study and the

developed equipment will be integrated to the FrailSafe system, as soon as it is ready in technical terms.

Despite the mitigation plan proposed, the need for a prolongation of the study cannot be eliminated.

## *12.3 WP3 – Smart Sensing, data acquisition and signal processing*

### 12.3.1 WP3 – Objectives of WP3 during the period

In the frame of Task 3.1 "Design of FrailSafe Sensor Network" (started at the beginning of the project and closed at M6), a search for sensors had to be performed, on the base of functional and non-functional specifications, in order to monitor, within project monitoring phase, the parameters of interest.

In the frame of Task 3.2 "Development of FrailSafe wearable sensing systems" (started at M4, running) a wearable product (WWBS) have been fully developed able to monitor physiological parameters (cardiac and respiratory signals) together with information on user posture, activity and movement, in a comfortable way for the end-user.

In the frame of Task 3.3 “Feature extraction and low level signal processing” (started at M4, running), a number of algorithms for activity classification and behavioural monitoring during everyday life manifestations (given special consideration to both indoor and outdoor sensing scenarios) have been partially developed and tested separately in order to make them ready for the final integration.

In the frame of Task 3.4 "WWBS communication, protocol and integration" (started at M10, running) a number of communication tools for accessing the generated data streams from the set of different devices to the mobile device (which acts as a gateway) have been successfully developed.

In the frame of Task 3.5 "WWBS prototypes, assembly, testing, evaluation and production" (started at M10, running) a first series of tests have been performed on the first version of the WWBS product in order to evaluate its performances.

### 12.3.2 WP3 – Summary of progress

In the frame of **Task 3.1**, a set of different devices have been selected and purchased, in order to start the collection of data from the first clinical campaign. Specifically:

| Parameter | Sensor/device |
|---|---|
| Weight | FORA bio-impendence scale |
| Arterial stiffness | Mobilograph |
| Blood Pressure | FORA blood pressure monitor |
| Strength | Hoggan dynamometer |
| Electrocardiogram (ECG) | |

| | |
|---|---|
| Heart rate | Wearable WBan System (WWBS - a first version will be available from M15) |
| Respiration signal | |
| Respiration rate | |
| Posture | |
| Activity classification | |
| User localisation at home | Estimote™ iBeacon |
| User localisation outdoors | Mobile Phone |

On the base of aamendment to contract #1, some sets of commercial inertial platforms have been selected and purchased to start collecting data from older adults during the first campaigns, to let the consortium develop dedicated algorithms and improve overall knowledge on short- and long-term monitoring, on the basis of real data available before WWBS distribution to clinical centres.

Activity about security, safety and data protection issues in WBAN context has been conducted in Task 3.1, as preparatory to the activities that will be faced in Task 3.4. Particularly, activity dealt with:

- Analysis of EU Data Protection Directive, 95/46/EC EU Directive;
- EU General Data Protection Regulation (2016), in force form 25th of May 2016, and replacing the EU Directive 95/46/EC;
- Analysis of main security and data protection requirements in particular, identification of preliminary security and data protection requirements in WBAN.

Particular attention has been dedicated to WBAN weakness that is *data communication security* and *data storage security.* Security issues that have been mainly considered are:

- **Data integrity**: in order to ensures that no data changes have been done by any adversary before reaching the storage;
- **Data authentication:** hold guarantee that the data is sent by a trusted sender;
- **Data freshness:** in order to guarantee that all received data is fresh. This means that all data frames are in correct order, and not replicated for disruption purposes;
- **Data confidentiality**: in order to protect the data from a disclosure, the system requires data confidentiality. Particularly, during communication, there is a possibility of overhearing and eavesdropping the sensitive information by the adversary. Generally, encrypting the data with secret key and sharing the secret key through a secure channel is one of the ways to acquire confidentiality;
- **Availability:** to enable patient data to always be available to the physician, for example. In case of loss of availability of one node in the system, redundancy

that enforces switching operation from a disabled node to an available node can be used, remember to use forward and backward secrecy.

A first analysis of IEEE 802.15.6 standard (that formulates the physical and medium access for body area networks) has been performed and will be deeply faced in Task 3.4. Details about the above mentioned activity have been deeply described in D3.1.

Within the activity of **Task 3.2**, a first version of WWBS electronic device has been designed, developed, produced (8 units) and EC certified for electric safety and electromagnetic compatibility. The system is dedicated to the acquisition, pre-processing, storage and transmission of data from sensors present on the sensorised garment and an integrated IMU. In the first phase a careful selection of the electronics components has been performed, in particular the microcontroller used in the device is aARM Cortex M3 that guarantees an adequate computational power for all the features extracted from the signal acquired. A precise and appropriately filtered ECG analog front-end has been developed in order to get all the information from the heart signal and, at the same time, to remove as much as possible the noise. A dedicated circuitry for breath detection has been designed to power the piezoresistive sensor and to get the signal coming from it. Also in this case an appropriate filtering has been applied to minimise the noise coming from motion artefacts, a normal problem affecting this type of sensors. A 9 DoF (Degree of Freedom) IMU in a single chip has been chosen to be integrated into the electronic device: it will monitor trunk position and activity, as it will be placed in a pocket in a position to be defined but surely joined to the user body. To tests all these new circuitries, it has been developed a dedicated evaluation board (**Figure 2**).

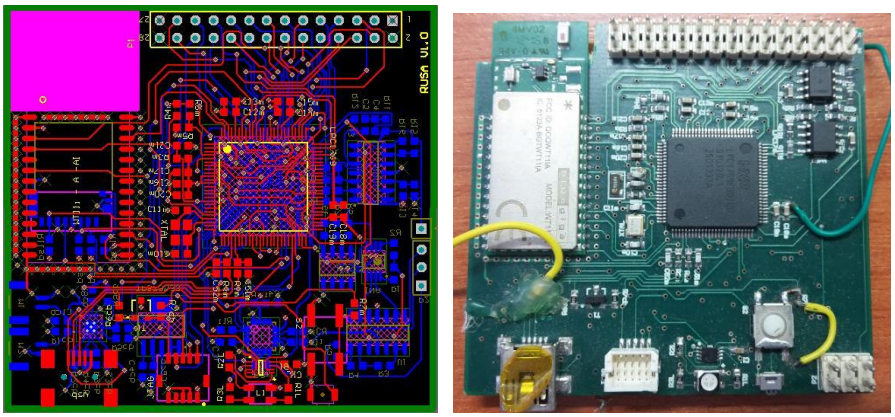


**Figure 2: Evaluation Board.**

A second phase of testing has been conducted concerning the power consumption of the device. The final electronic was able to record and send data wirelessly for several hours. This aspect has involved also the battery choice, because higher capacity of the battery means more weight and bigger dimension, so reducing user's comfort when wearing the WWBS system.

On the basis of the tests performed with the evaluation board, the design and development of a newer electronic device has been done. The major changes were done on ECG and breath analog front-end. Regarding the ECG front-end, it was

decided to move to a single chip, made by Texas Instruments, that includes all the characteristics designed in the previous device, but with a very low power consumption and moreover with a very small dimension. With reference to breath front-end, it was decided to select a solution that could allow some flexibility in managing the electrical property of the textile sensor: this solution has been considered preferable because at present there is no final decision on the garment, and the chosen design (which has improved comfort - e.g. a shirt with a frontal zip, easy to don and doff) requires that the breath sensor have a different shape and position on the vest. The rest of components are the same used in the evaluation board, but both dimension and power consumption have been strongly reduced. Chips of 9DoF IMU external modulesare the same of the one already integrated on the board: this solution gives the advantage to maintain signal compatibility. A PCB gerber and a picture of the most recent version of the device are shown below (**Figure 3**).

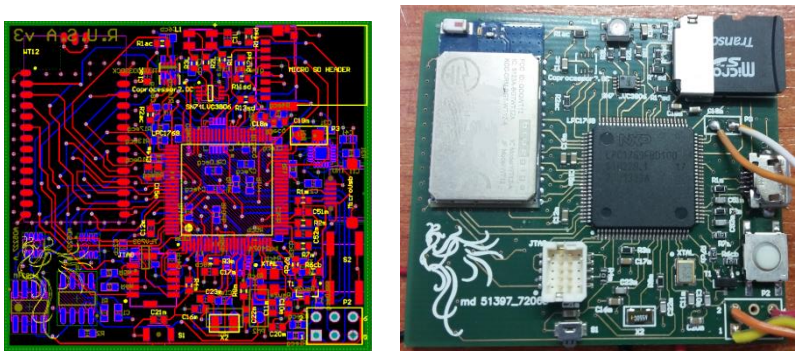


**Figure 3**: PCB gerber (left), most recent version of the device (right).

Schematic of the latest device is shown below.

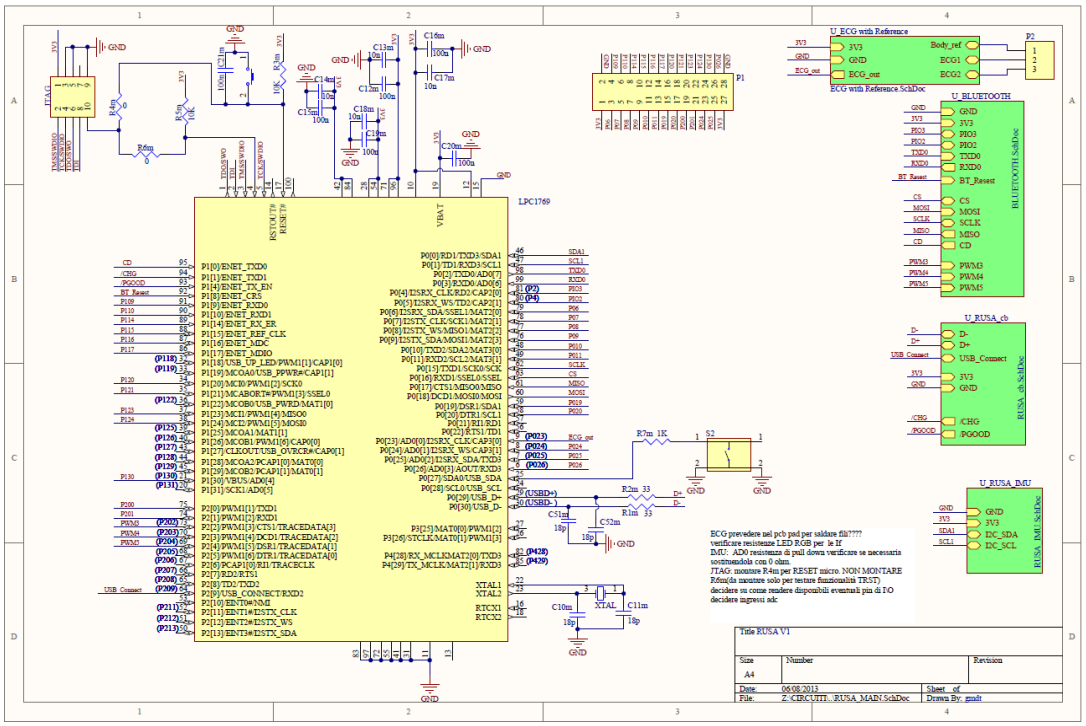


**Figure 4**: Schematic of the latest device.

After a second phase of tests it was decided to make a further new breath front-end to increase the dynamic of the signal. This has alloweda better amplification of the breath signal, also when the vest is not perfectly worn.
The results of new power consumption tests are shown below. In the first figure, it can see the charging phase of the battery with a capacity of 1000 mAh. The duration of this phase has been of about four hours. The second figure show the discharging phase in continuous streaming mode, so, with maximum power consumption. It can be seen that the battery is fully discharged in about 9 hours.

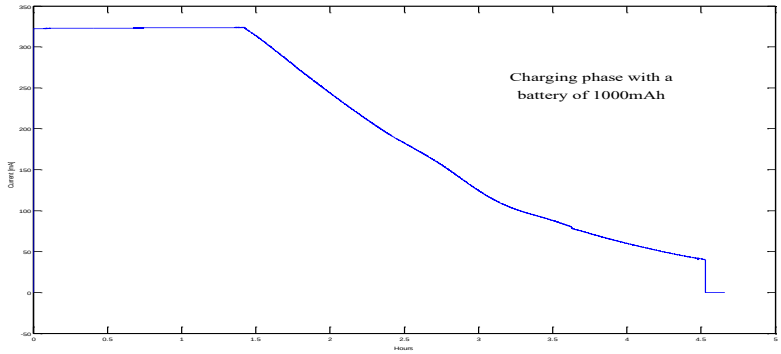



**Figure 5**: Charging phase of battery.

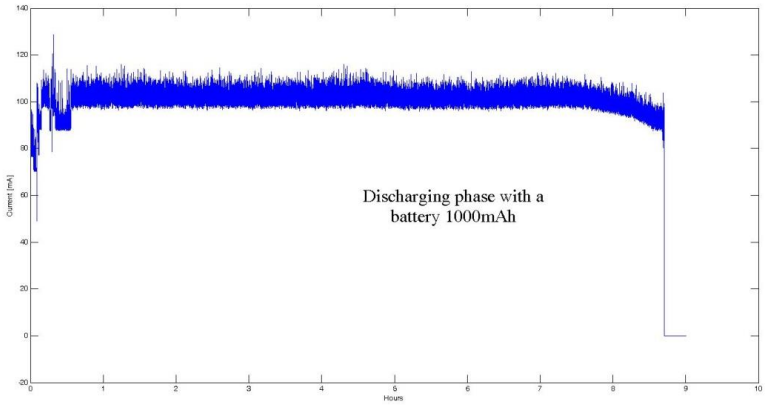



**Figure 6**: Discharging phase of battery.

Furthermore, another power consumption optimization has been developed in order to improve the battery duration as much as possible. A repetition of the test above has shown an increase in battery duration equal to 25%.

Regarding the tests for the external IMU's (on the limbs), a higher attention has been given on wired connection design in order to guarantee the correct communication with central device.

In February, 2017, a third version of the CAD file was sent to standard Smartex board producer, but when final boards with integrated components were tested in Smartex premises some malfunctioning appeared. Only after several tests (and 3 weeks of

work) it was discovered that those problems were due to a mistake of board producer: new board were then sent to us with due corrections, but this took other 3 weeks. After first tests, that were positive, 8 systems were produced and one sent to a certification laboratory for EC testing. 8 certified systems were finally delivered at the end of May, 2017.

In parallel, 8 shirts were produced, in 3 different sizes and unisex, in order to cover most patients: sizes distribution was studied on the basis of data obtained from each clinical centre. The shirt has a frontal zip, short sleeves with small pockets for IMUs placement and a larger pocket on the chest for the central unit. Please find below some pictures of the full system, full details are available in D3.2.

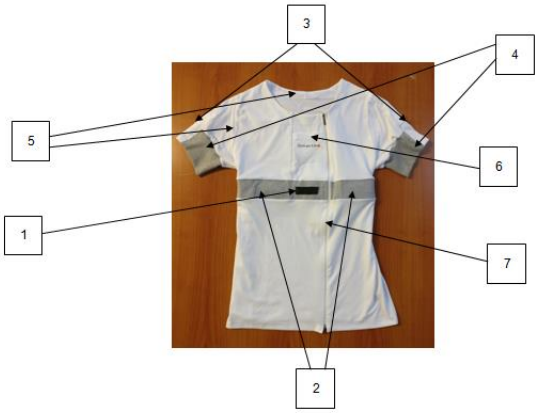



Figure 1. WWBS- sensorised garment: front view.

Legenda:

1. Fabric Piezoresistive sensor
2. Fabric Electrodes (in the inner side)
3. Pockets for IMUs
4. Elastic sleeves (to fix better IMUs to arms without reducing user's comfort)
5. Tubular solution for cable protection
6. Pocket for electronic device
7. Zip for easy don and doff

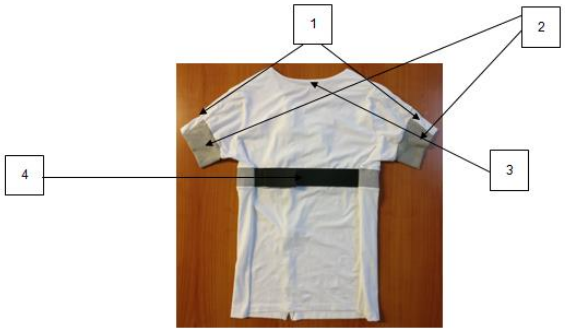
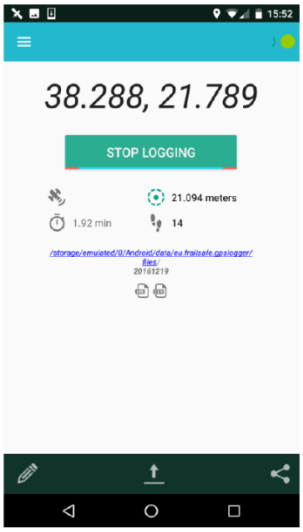



Figure 2. WWBS- sensorised garment: rear view.

Legenda:

1. Pockets for IMUs
2. Elastic sleeves (to fix better IMUs to arms without reducing user's comfort)
3. Tubular solution for cable protection
4. Strap solution to optimise the same garment to people with different sizes

During the first months of activity of **Task 3.3**, several algorithms for location acquisition and activity classification are being developed and tested.
In the case of outdoor sensing scenarios, the "**GPS Tracker App"** has been successfully completed; an application for Android smartphones that tracks and logs the position of the older person using it. More specifically, it stores the latitude, longitude and other location-specific measurements and auto uploads them (hourly and/or daily) via e-mail or FTP to remote servers, including a dedicated FTP server. In its final version, it will be integrated with the FrailSafe database framework when the latter is finally completed. A recent update includes an efficient step counting procedure. The main screen of this application is illustrated below.




Regarding the indoor localization process of older people, we are currently working on a **beacons-based** configuration system. Bluetooth beacons are small devices emitting a unique ID via the Bluetooth Low Energy (BLE) protocol. A smartphone can read the IDs of the nearby beacons and their approximate distances. Thus, beacons can be used to locate an older person carrying a smart device in his/her home. The Sensoro SmartBeacon-4AA beacons[5] have been ultimately selected Figure 7(a)), since

[5]https://www.sensoro.com/en/whyus

they combine relatively high quality with low price (so they will be used instead of the Estimote ones that were selected in the first six month of the project). Two applications have been developed, one to be used once by the nurse for the setup of the beacons inside the older person's house (Figure 7(b)), and one to be active while the person carries the smart device, in order to track him/her inside the house (Figure 7(c)). The applications are currently fully functional, providing room-level localization; however, they are under further modifications regarding improving the user interface. Furthermore, we are also investigating how to address the tracking of real-time coordinates in various environments, in order to be included in future versions.

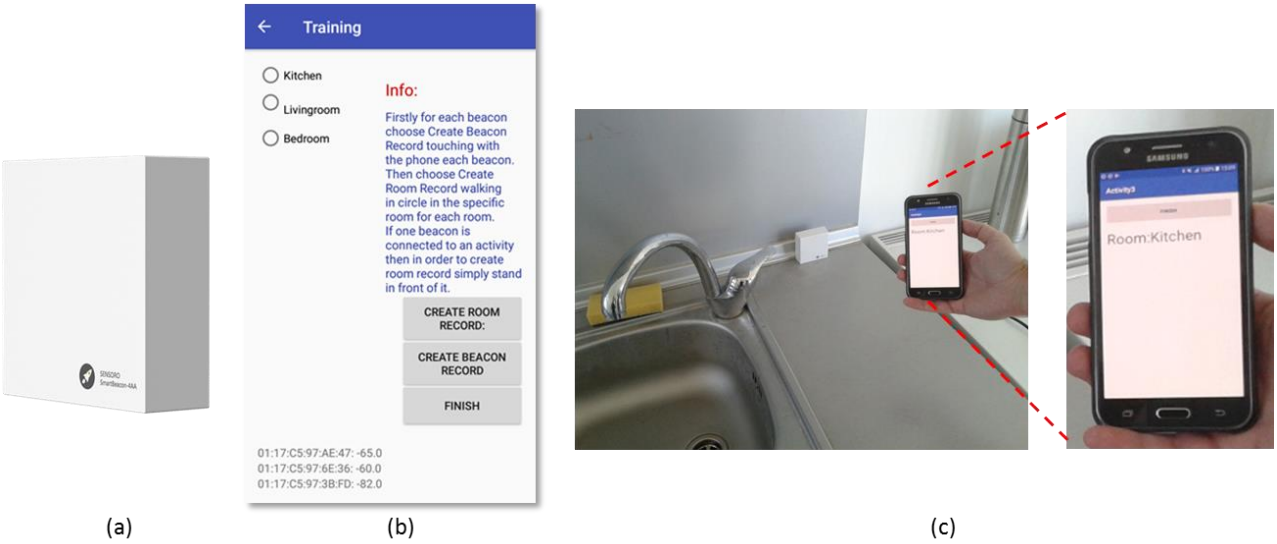
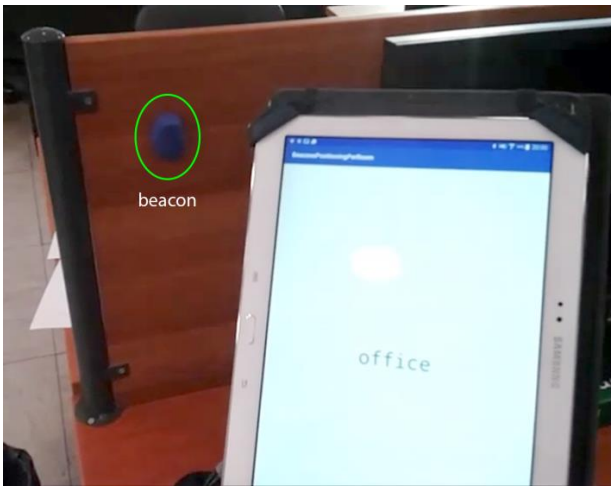



**Figure 7: (a) Sensoro beacon. (b) Screenshot of the beacon installation application. (c) Example of the indoor localization application.**

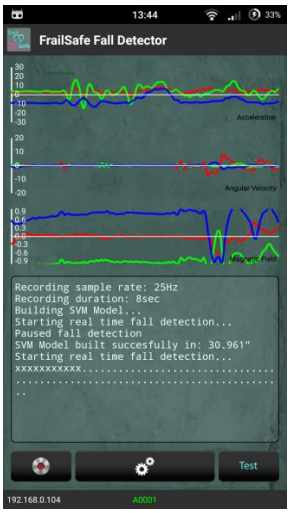



Regarding the problem of human **motion identification**, we have investigated a new classification methodology that can be used as a core module in order to discriminate the detected motions to six basic activities: *walking*, *walking-upstairs*, *walking-downstairs*, *sitting*, *standing* and *laying.* The presented workflow requires less

features but achieving equal accuracy in comparison to the one previously proposed for the dataset under consideration (multi-parametric sensor data acquired from accelerometers and gyroscopes using a large number of time-domain and frequency domain features). Note that the data extracted from the GPS Tracker App can further be exploited (task of offline analysis) for walking, driving or use of transportation activity classification or loss of orientation detector.

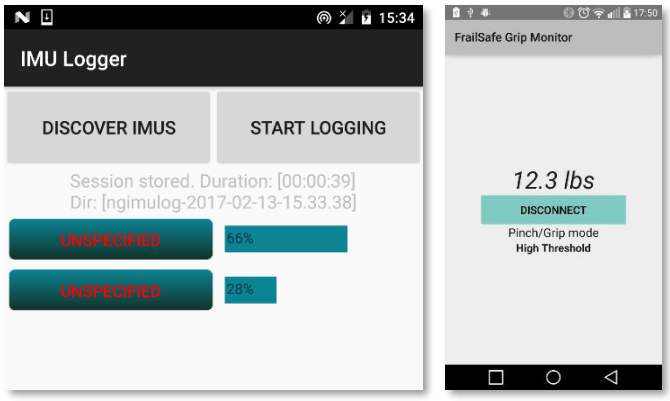
About all the so-called auxiliary devices, i.e. the FORA impedence scale, the FORA blood pressure monitor and the Mobilograph, the interactions among these devices and the FrailSafe system has been designed and finalized. The specifications to interact with the third-party software infrastructure has been documented and released to the WP responsible of this data import (WP4). The cloud resources needed for guaranteeing their integration has been allocated and setup.

Finally, yet importantly, concerning behavioral monitoring meaning risk events detection such as fall and instability metrics, we have developed an Android application (see Figure below) that uses sophisticated machine learning algorithms for real-time **fall detection** purposes by exploiting the accelerometer, gyroscope and magnetometer of a smartphone device. Acceleration data have been recorded using the smartphone and in our future directions is to test it under vest's IMUs hardware.

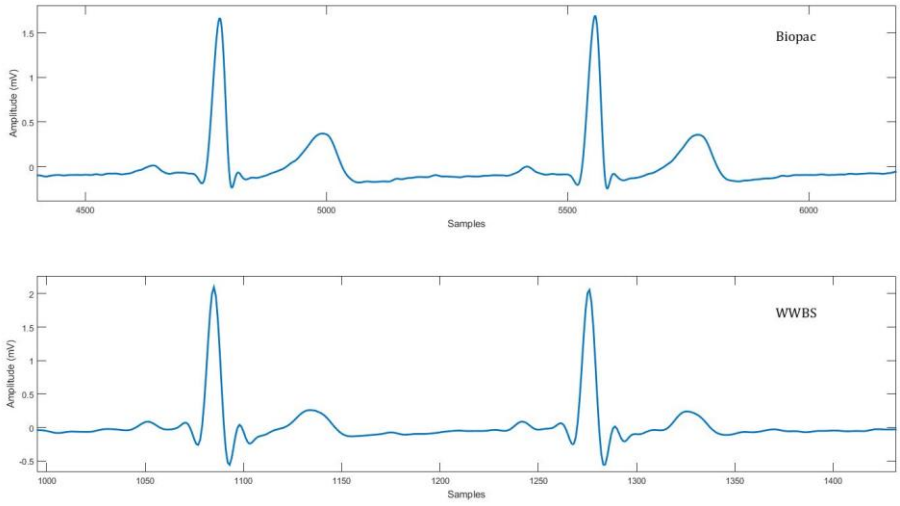


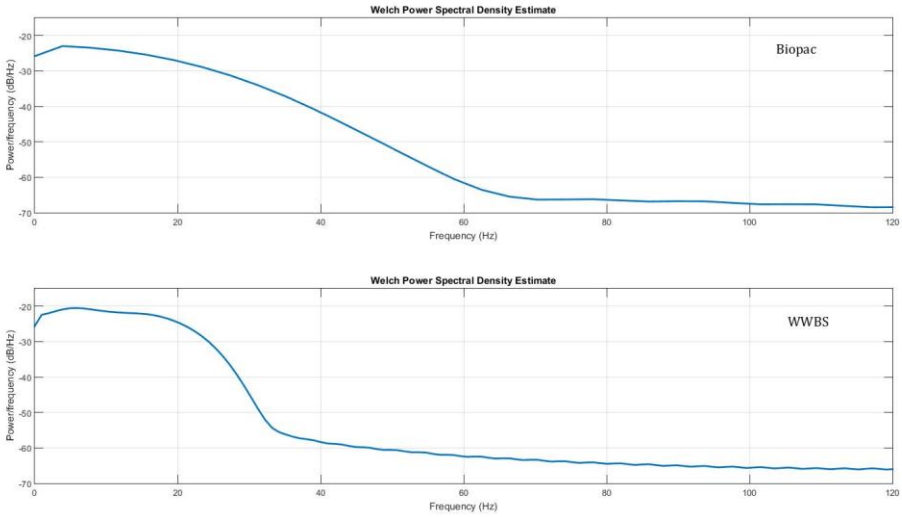

Regarding Task 3.4, a number of application programming interfaces (APIs) have been developed that makes it easier for developers to use certain technologies (reliable communication) in building applications by exploiting data from medical devices such as Beacons, IMUs and Dynamometer. Moreover, a set of graphical user interfaces for mobile devices (as Android applications) has been designed making it easier for people to calibrate, use and test the generated programs (see corresponding Figure below). Documentation for all developed connection interfaces is also provided in order to facilitate usage details. Finally, a primary discussion on the lightweight protocol for in WWBS communication and for WBAN to mobile device has been performed deciding that an energy efficient vital signal telemonitoring scheme that ensures reliable data transmission by exploiting compressed sensing (CS) for low-complexity signal

compression-reconstruction is the best solution. The integration of this solution in WWBS is under progress.




In the frame of **Task 3.5** several tests havebeen done with the device in comparison with a gold standard for physiological monitoring (i.e., Biopac system, produces by Biopac Inc.), showing interesting results. At present the attention has been focused on the ECG comparing the ECG wave and the spectral density (see figures below).






It is important to highlight the fact that WWBS in FrailSafe is intended to monitor only parameters related to the QRS peaks, like heart rate, R-R distance, heart rate variability.

The intermediate versions of WWBS and the one that has been certified and delivered (in 8 units) to FrailSafe partners have been duly tested in laboratory conditions in Smartex.

### 12.3.3 WP3 – Significant results and achievements

Decision on and purchase of sensors composing the FrailSafe network

Design, development, production and certification of WWBS

Purchase of commercial IMUs

Development of GPS Tracker/Pedometer Android Application for activity monitoring.

Development of indoor localization application using BLE beacons.

Development of Stability Detector Android application software.

Development of Fall Detector Android application software.

Resolve cloud connectivity with FORA Telehealth system.

Development of API for external IMUs communication.

Development of API for Dynamometer communication.

Protocol design for energy efficient & reliable signal transmission in WBAN hardware via compressed sensing mechanism.

### 12.3.4 WP3 – Deviations and critical issues

A potential issue was the decision to abandon the use of the sensitized ErgoGlove in favor of dynamometers, that was part of the discussion of a phone review and it was

accepted. In the same occasion, it was requested by PO to include in the sensor set a commercial device using IMUs to start collecting data useful for the development of dedicated algorithm by the consortium.

Deliverable 3.2 (prototype plus report) was due at M15, but, as already summarised above, two orders of problems forced Smartex to deliver both report and prototypes with delay:

- Smartex standard PCB supplier produced the WWBS main boards with small defects that were not detectable either by standard electric tests or before components integration. The time spent before to understand the reason of the problems and then for the production of new PBC (with integrated components) generated a 40-day delay;
- In Amendment 1 to project contract the number of devices to be delivered at M15 passed from 1 to 8, involving tests in real conditions (so with older adults using them at home without the presence of technical/clinical personnel). This step requested the certification of also this intermediate prototype, at least for safety regulations (electrical safety and electromagnetic compatibility), otherwise Ethical Committee would have not accepted its use.

**This delay has not generated major implications.** For instance, Group B3 will still use this device, with no reduction in the number of repetition, due to the delay in the WP2 planning (see above). Furthermore, as each clinical partner will have just two systems at this stage but 5 users per session, for 3 end users out of 5 there will be no difference in the planned protocol.

The indoor localization applications are currently deployed on a smartphone, which needs to be carried by the older person, while moving inside the house. This is considered as a temporary solution, in order to start collecting localization data as soon as possible. It was considered as feasible for the moment, supported by the fact that a mobile phone will be carried by the older person for other tasks as well, e.g. the pedometer, while the mobile phone can be attached to the vest (e.g. in a pocket). However, after the application is tested in real-world environments, the goal is to install it in smartwatch devices, to be distributed to the older persons.

### 12.3.5 WP3 – Use of resources

WP3 Resources have been used as expected in this first period of the project. They have been invested in the tasks outlined above.

### 12.3.6 WP3 – Corrective actions

Due to the delay in the delivery of D3.2 (prototype), test activity of this device were delayed: for this reason, Task 3.5 was not paused between M16 and M18 (as planned). This interruption was simply postponed to M18-M20.

## *12.4 WP4 – Data Management and Analytics*

### 12.4.1 WP4 – Objectives of WP4 during the period

The objectives of WP4 that have been achieved during the first period of nine months can be hereafter summarized:

In Task 4.1, the main aim is to create the database management system where all input data (from raw signals to questionnaires) will be stored. We decided to employ a NoSQL database, e.g. HBase, as it is part of the Hadoop ecosystem, which provides high scalability in data analysis and knowledge discovery algorithms as well. Additionally preliminary work towards the detection of patterns and associations between clinical indicators and frailty states was performed by analyzing the multidimensional time series acquired by the frailsafe system. The objective of the analysis is to reveil associations among signals and symptoms that are connected to the frailty syndrome.

Task 4.2 concerns the online data analysis where a special effort has been made on the identification of the device that will be used as a gateway to collect the sensor data. The main focus is to report on the usage of existing and new techniques for real-time online data pre-processing and data reduction. The techniques must be suitable for FrailSafe's streaming sensor data, where efficiency, scalability and effectiveness issues are of main importance. Furthermore, results from the offline multimodal data fusion are examined here to make online data preprocessing possible in real time. This will be available by adopting dimensionality reduction methods to the streaming nature of the data. Online data fusion is focused on maintaining the desired accuracy, while minimizing the overall processing time. Particular tasks involve the identification of loss of stability, tendency to fall, and loss of orientation of older people.

In Task 4.3 (which is completed), we employed an archetype relational mapping approach for building FrailSafe Virtual Patient Model (VPM) capable of efficiently generating relational databases using openEHR archetypes and templates. First, the data requirements of the VPM system were analyzed and organized into archetype-friendly concepts. The openEHR CKM was queried for matching archetypes; when necessary, new archetypes were developed to reflect concepts that were not encompassed by existing archetypes. Finally, a set of rules was designed to map the archetypes to data tables and provide data persistence based on the relational database. The final version of the VPM has been integrated to the core server database platform and evaluated by the technical and clinician teams.

In Task 4.4, elderly data from social media, e.g. social media analytics, which are used to monitor and capture user’s behavior as well as the social interaction of the older people, are collected. Concretely, we have proposed a set of questions plus a big five questionnaire to correlate (with use of machine learning approaches) the word usage and the social media behavior of subjects to frailty symptoms.

Task 4.5 aims at detecting signs of mental frailty and personality trait shifts by linguistic processing of a person’s written messages with use of LingTester, a Natural Language Component of the FrailSafe system. After further studying, state of the art methodology, a Language Model has started to be implemented with linguistic

information based on all predefined languages. The Language Model is composed by a Formal Component representing the lexicon, grammar and syntactic rules of the language, and a Statistical Component containing results of word and bigram frequencies which will be used.

Task 4.6 aims at extracting frailty-related indicators from signal processing and data fusion. Initially the clinician contributed by defining a set of relevant and informative indicators for frailty based on state of the art analysis of WP2. Flowingly, a preliminary work on signal processing and data mining techniques was performed. This work is focused so far in two directions: (i) model the multimodal data using tensors and (ii) mining multi-level association rules from multiple heterogeneous data sources. Finally, fueled by previous work on data fusion, three schemes were designed: (i) Early Integration scheme, (ii) Late Integration scheme with local (sensor dependent) training models, (iii) Late Integration scheme with global (sensor independent) training model. These schemes will be tested on FrailSafe data, once they are sufficient in volume.

In Task 4.7, an investigation of the role of inflammation in the pathogenesis of frailty has been made. Thus, recent studies support this association between inflammation, frailty, and age-related disease. As an objective, we have developed a novel platform that will aid the clinician to collect, analyze and report the relationships between biochemical and blood related markers to chronic inflammation and thereof the link between chronic inflammation and frailty of the elderly. Towards enhancing the risk assessment domain, the VPM that is designed for T4.3 is generating alerts towards clinicians in case it detects irregularities on heart rate, respiration rate, blood pressure. The clinicians can use the VPM to assess the risk of the older person and intervene accordingly.

### 12.4.2 WP4 – Summary of progress

#### T4.1 Offline Data Management and Analysis

Managing FrailSafe's multimodal data is a task of great importance. The huge data files that contain the raw sensor data generated by the devices, the medical records of the older people, the annotations generated by the experts (both clinicians and researchers), and the files that contain the analysis results need to be stored effectively, aiming to fulfill the data access requirements that arise during offline analysis.

After contacting all partners and the vendors that produce the devices, a summary of the expected input data was made. This summary was used as a guide towards the design of the database. Based on the nature of the data of the FrailSafe project, a NoSQL database was decided as more appropriate. Among the numerous NoSQL solutions the HBase was chosen. The motivation behind this choice is that HBase is part of the Hadoop ecosystem, which provides high scalability in data analysis and knowledge discovery algorithms as well.

The sensor data were aggregated in a gateway and then uploaded in the HBase database. The offline analysis using a cloud service by Amazon Web Services (AWS) will be the next step.

The contribution to the field of offline analysis of biomedical data mining has so far been twofold. A generic and adaptive architecture for multimodal biomedical data processing has been proposed in order to facilitate combined analysis of data originating from the beacons, the smart vest, the serious games, biochemical blood examinations as well as from standard clinical examinations.

Progress was made on the usage of existing and new developed techniques within the FrailSafe system towards offline data management, preprocessing and analysis. In particular, techniques for data pre-processing were examined involving data cleaning (handling of missing, noisy or inconsistent data, identification and/or removal of outliers), dealing with contaminated/noisy data segments, data integration, data transformation (normalization and aggregation), data reduction (production of reduced representations of data using dimensionality reduction (feature selection), discretisation and numerosity reduction techniques. New techniques for data reduction and summarization of streaming sensor data were also developed, in order to explore meaningful measuring units for frailty.

Additionally, the recordings from the vest/strap were analyzed offline for classification of activities of daily living. Analysis and evaluation of the accelerometer and gyroscope signals regarding the problem of motion identification were performed. Temporal and spectral features extracted from the sensor signals (accelerometer and gyroscope) and concatenated to a single feature vector were used to train motion dependent binary classification models. Each individual model was capable to recognize one motion versus all the others. Afterwards the decisions were combined by a fusion function using as weights the sensitivity values derived from the evaluation of each motion dependent classifier on the provided training set. The proposed methodology was evaluated using SVMs for the motion dependent classifiers and was compared against the common multiclass classification approach optimized using either feature selection or subject dependent classification. Since FrailSafe data ground truth annotations were not available, the above methodology was evaluated on multi-parametric data from the UCI HAR Dataset. The dataset consisted of accelerometer and gyroscope recordings from 30 volunteers within when performing six activities (walking, walking-upstairs, walking-downstairs sitting, standing, and laying). The classification accuracy of the proposed methodology reached 99% offering competitive performance comparing to the other approaches. In our newets work, the trained models were applied for automatic annotation of activities of daily living of the FrailSafe recordings from the vest/strap.

Furthermore, emphasis has been put into the statistical analysis of clinical measurements from eCRF. Specifically, lasso linear regression was applied to select a subset of variables and to estimate their β coefficients, in order to build predictive models having the best possible correlation with current classification criteria of frailty, such as the Fried's score.

**T4.2 Online Data Management and Analysis**

One of the FrailSafe project's aim is the real-time monitoring of the elder personstowards detecting frailty risks and triggering alarms in case of emergency situations (e.g., fall, loss of orientation, or suicidal manifestations in electronic written text). Incase of such an emergency situation, an alarm needs to be triggered updating theVPM (Virtual Patient Model) accordingly. Towards this direction, a system that collects the data streams and processes themwas developed.

Currently the online analysis algorithms are being developed and validated only inlaboratory environment. In the final FrailSafe product any event identified will betransmitted in real-time to the FrailSafe cloud. Additionally, in the FrailSafe cloudthere is a cluster running Apache Spark which has Spark Streaming module for realtime data analysis. This cluster is used in order to collect the data streams fromvarious sources and process them towards generating summaries and alerts.The data processing which has been identified as necessary to be performed in real-time for the FrailSafe project, is targeted in the areas of fall detection, instability, lossof orientation and suicidal manifestations in text. The first three areas lie in thescope of this task, while the last one is in the scope of the online mode of LingTester.

The most challenging aspect of fall detection is the distinction between falls and sudden movements that occur while performing activities of daily living (ADLs). Such movements are usually activites that include high acceleration (eg. walking orrunning) or transitions between activities (eg. getting up from chair). Weinvestigated the state-of-the-art on fall detection and evaluated wether it is feasible to detect falls using a single sensor. Then we extended our fall classification model and built an android application in order to detect falls in real-time. The app which used the sensors (accelerometer, gyroscope and magnetometer) of the smartphone managed to detect falls with high accuracy. In the final version, the app will be modified so that the smartphone will collect the sensor data directly from the wearable sensorized vest and perform the fall detection algorithm based on them.

Towards identifying loss of stability, we have developed an algorithm based on PCA (Principal Component Analysis) decomposition of the raw acceleration signals. The processing pipeline starts by filtering the raw data using a high-pass filter. In the second step, we eliminate the principal component of acceleration and instead use the secondary gait component of PCA. Then we reconstruct the decomposed secondary gait signals, from the separated Euclidean coordinates into a 3D signal that enables us to study secondary dynamics to the participant's gait.

Finally, we have analyzed the state-of-the-art on loss of spatial navigation and Loss of Orientation (LoO) which has gained much attention from both the research community and the industry, lately. The majority of the systems proposed are based on tracking information, geo-fencing, i.e. predefined boundaries of where the participant is supposed to be, and alerting systems aimed to inform the caregiver that a participant is probably wandering. In the next period, we will develop our loss of orientation application based on the current detection techniques.

### T4.3 Dynamic User Profiling Models

In this task, we present how virtual user modeling (VPM) research has attempted to address critical issues of FrailSafe human-computer interaction through a large number of analytic, usability-oriented approaches by providing older adults and caregivers with interface and tools fitting to their specific needs. More specifically, we provide a detailed definition of the patient model representation format adopted within the FrailSafe project. To this end, openEHR; a reference model for building VPM via archetypes (supported by an open source community and a variety of tools), has been adapted due to its clear benefits against its competitors and has been extended to fulfill the goals and functional requirements of the FrailSafe system. The identification and classification of the entities/concepts of interest relevant to FrailSafe is initially offered including monitored parameters, clinical data, diagnosis results, risk factor, action plans, interventions, patient record, etc., in order to meet the defined requirements. These entities are categorized into data related to the user identification, data essential to the clinician and data recorded from the integrated sensors as well as the games analysis. In addition to these, a list of parameters that are related to the statistical offline and real-time processing is also introduced, Exploiting the openEHR reference modeling, the most highly related open-source existing archetypes, downloaded by the openEHR Clinical Knowledge Manager repository, have employed or adapted to the ones that fits for each one of the identified monitoring parameters. For the rest parameters, entirely new archetypes have been designed and created. Furthermore, the final relational model and the corresponding SQL databases have been developed and successfully tested using artificially generated data since real data from all modalities were not available until recently. Finally, an alpha version of a web visualization platform, decision support and notification system has been created using modern web technologies. An advanced version of this platform is going to be designed jointly with task T5.4.

### T4.4 Sensing Social Media

We have concluded deliverable D4.7. In particular, we have conducted detailed experiments for the Big Five Personality Traits Extraction for Greek, Cypriots and French participants. The questionnaires are transferred to .csv in format (id_qi, Ai) where id_qi is the id of question i and Ai is the score of question i. The name of each .csv is the id of the subject. Each trait is calculated by the average of the score (scale 1-5) or reverse score (6 –score) of certain questions in the questionnaire as it is implemented in our code.

Moreover, utilizing eCRF API, we were able to retrieve all available raw data, stored by each medical team, containing detailed answers to the questionnaire, along with uploaded files of present and past text.

The corresponding data are till now the following:

Greece (UoP): 120 Users with 248 Texts where

- Image: 118Texts
- Important Life Event: 120Texts
- Past Written Text: 10Texts

Cyprus (MATERIA): 75 Users with 138 Texts

- Image: 61Texts
- Important Life Event: 54Texts
- Past Written Text: 8Texts
- Facebook Posts: 15Texts

France (NANCY): 86 Users with 262 Texts

- Image: 39Texts
- Present Text: 73Texts
- Past Written Text: 150Texts

Furthermore, we finalized and tested of

- Twitter crawler in PHP and alternative implementation in Java.
- Facebook crawler in PHP (for Facebook pages). Currently it is in development state and a submission has been made according to the Facebook App approval process.
- Design of IMAP client for e-mail collection. It will be deployed once privacy concerns are resolved.
- Design and implementation of Web interface for the execution of the social crawlers and the IMAP client.
- Implementation of SQL database for storing texts collected by the above social crawlers.
- Anonymization procedure to remove user identifying data, like for instance credit cards, social security numbers and phone numbers
- In order to obtain the first test results for the LingTester online tool, four artificial user accounts have been created simulating the potential participants according to prior data (knowledge) collected by the clinical trials of FrailSafe project.
- A series of tests have been conducted using the test user accounts, the evaluation of the test results has shown sustainable good functioning of the tool.

In the framework of T4.4, big-five profiles are produced, providing emotional "fingerprints" for each individual.

This set of crawlers could help to download the social media interaction of the users. However, we had few information concerning the social media interaction, hence we enriched the data collection phase with data from anonymous users that could help to detect overfitting in the LingTester built in phase 4.5.

Data retrieved from Twitter for anonymous users for the 3 different languages are:
English: 30756 Tweets from 9917 Users

- 4 Users with 5 Tweets
- 997 Users with 4 Tweets
- 8916 Users with 3 Tweets

French: 18656 Tweets from 8531 Users

- 1594 Users with 3 Tweets
- 6937 Users with 2 Tweets

Greek: 8090 Tweets from 5717 Users

- 2372 Users with 2 Tweets
- 3344 Users with 1 Tweet

Moreover, we have completed the preliminary version of deliverable D4.8 LingTester Test Results – Active (on-line) mode. More analytically we initiated the development of the online mode of the LingTester tools, which covers all steps needed to support all necessary user actions while also removing any sensitive information, and thus, protecting participants' data. The LingTester online mode is constructed based on two main sub modules, frontend and backend. Each submodule is also based on different layers of processes which interact altogether through predefined APIs, existing or custom ones. At this point, the prototype is in early alpha stage, but still it is able to perform classification according to levels of frailty.
As this is still a preliminary version of the online LingTester software tool, it was imperative to have a first testing and debugging procedure with a set of four artificial users. The results we obtained were generally in line with the FrailSafe dataset. The overall accuracy was 83.33% with a few of the predicted classes being wrong. This is an expected outcome as the integrated model is nearly the same with that of D4.10 but not exactly the same because of the restrictions and the reduction of information the whole flow of the online software tool introduces (e.g. some of the model feature values are not always available by the online users).

On the final version of the online LingTester tool a series of tests will be performed on real world case scenarios.

### T4.5 Processing Social Media

LingTester is the Natural Language Component of the FrailSafe system that will be able to detect signs of mental frailty and personality trait shifts by linguistic processing of a person's written messages. It will be able to act either passively (i.e. respond to a text input on demand) or actively (i.e. buffering every e-mail, Facebook post, twitter message, etc.).

The LingTester module includes four computational linguistic components: a Word Speller, a Morphological Processor, a Readability Parser, and a Misspelling Processor. In order to optimize results, and in cooperation with the teams involved, questionnaire undergone further evaluation.

After further studying state of the art methodology, a Language Model has been started to be implemented with linguistic information based on all predefined languages. The Language Model is composed by a Formal Component representing the lexicon, grammar and syntactic rules of the language, and a Statistical Component containing results of word and bigram frequencies which will be used.

For this architecture to work, initial sample user writings were used in order to build a user model for each individual. This user model includes two kinds of information concerning the individual's use of language: (a) static information, i.e. how the user's use of language differentiates from the norm (the average user), and (b) dynamic information, i.e. how the user's use of language changes over time. The book-keeping of this information to all user models contained in the system will be performed by the User Model Update Process. This process will first train the user models from the initial data, and later on, it will use any new text written by the same user to update the model and keep track of his language use evolution. If the change in language use happens to exceed what is expected from normal time-evolution, an Alert Process will initiate responses targeted to the designated individuals.

The classification method based on the proposed extracted features was tested using texts from the aforementioned 155 participants showed low accuracy (~64%). A further investigation on the appropriate features is undergone and to this direction additional raw data are being collected.

Concerning T4.5 (Processing social media) work is proceeding as reported in "D4.12 LingTester (Prototype) (vers a)". The LingTester prototype is in beta stage, but still it is able to perform classification according to levels of frailty. The D4.12 deliverable describes the updated architecture, the initial data analysis, the construction of the local database, the preprocessing stage, the feature extraction process and the experimental results of the machine learning component. We are currently scheduling a series of improvements in order to advance the overall performance, add more predictive capabilities and improve the LingTester user experience. More specifically, on the subject of data collection, management and dataset exportation, a number of actions like the offline database population with new collected data, the features evaluation against a different input language (French language) and the optimization and bug fix of current features and feature extraction methodology is expected to improve the quality of the train dataset. In addition, internal database will be absorbed by the FrailSafe cloud storage for easy access by other modules. On the subject of the classification task, the future research includes the exhaustive research on feature selection methodologies, the experimentation on supervised ensemble classifier models and the deployment of semi-supervised techniques in order enhance the small available dataset with a bigger unlabeled dataset. Moreover, two new areas of research are being explored. For the detection of suicidal statements an initial corpus has been constructed, manually tagged and experiments are being evaluated. Furthermore, patient mental state transition over time has been designed and we are in the process of implementation.

In the framework of T4.5 a machine learning model is produced linking its language usage to his/her frailty level. We intend to check if these two outputs can be combined and produce more elaborate results. For this reason, when big-five profiles are available for all individuals, we intend to retrain the LingTester with the additional big-five features and compare the results to the initial ones (without the big-five features). Moreover, for individuals where an indication for mental frailty stage is available from their medical records, this information will be used instead of the general frailty indication, in order to produce even more accurate results, and for individuals who have completed the social media questionnaire, selected answers will be used as potential features as well.

**T4.6 Signal Processing for extraction of frailty-related indicators**

One of the key objectives of the FrailSafe project is the better understanding of frailty and the development of new quantitative and qualitative measures to define it. Towards this direction, the current state of the art of frailty definition was analyzed in order to discover the strengths and limitations of each method. A special attention was given to the electronic Frailty Index which can be generated automatically by health record data. As part of deliverable D2.1 a new combined index (Combined Frailty index: CoFI) was defined, that will be used to express frailty status relevant to the study's measurements. This index will be created by adding up two other frailty indices derived from the study, the Clinical Frailty Index (ClFI), corresponding to the results of the clinical evaluation, and the Technical Frailty Index (TFI), corresponding to the metrics derived from the FrailSafe system devices. Additionally, we plan to link and associate FrailSafe parameters to the eFI parameters at a higher level of abstraction at this stage so that we will be able to evaluate our population using their scoring system. This will help us exploit the results of the eFI which were based on 900k+ health records and validated in large international studies. This way, we will be able to strengthen the statistic viability of our study, whilst at the same time being able to assess the added value of the FrailSafe system to our participants.

In our recent work, we used clinical measurements from eCRF for multivariate statistical analysis. Specifically, after preprocessing and conversion to numerical data their predictive ability towards the development of a frailty index was examined. Two different frailty indexes (*FI*) were computed, one aiming to predict the discrete Fried classification score ($FI_1$) and one trying to estimate a continuous score as a linear combination of the 5 criteria related to Fried classification ($FI_2$). The ultimate goal is to investigate whether the proposed frailty indexes are more reliable predictors of frailty transition than standard classification scores and also assess their correlation to the multi-channel recordings from the FrailSafe system. For the latter purpose, all sensor data were time synchronized to allow multichannel analysis. The frequency of 25Hz was selected as reference space, since several of the sensor data are sampled at this rate. The recordings of ECG signal were downsampled from 250Hz to 25Hz, whereas other recordings (Breathing Amplitude, Breathing Rate, Heart Rate, R-R intervals, Heart rate variability, Activity classification) were upsampled. Some of the recordings were slightly time-shifted (~15msec) in order to be synchronized with the rest.

In the following, the analysis followed two directions. First is the modelling of the multimodal data that are being collected in FrailSafe, using tensors. By doing so, we can use their strong mathematical background and achieve several advantages such as data compression, identification of clusters and exploitation of patterns. More specifically, each data source can be thought of as a dimension (a mode) in a N-dimensional tensor (where N is the number of the different kind of data sources). For each different sample of the data collected (a sample can be a set of data coming from a specific time course), there is a distinct tensor created, which in fact belongs to a set of K training tensors. For each of these samples we suppose that the knowledge about the frailty condition exists (aka the class to which a training tensor belongs to). The second direction aims to discover a novel way of mining multi-level association rules, in a distributed environment, from multiple heterogeneous data sources. As preliminary work, the state of the art in multi-level association rule methods has been explored. Motivated by the related work, the basic architecture and packet layout have been designed and the source codes for a number of functions (retrieving hierarchy data and creating the corresponding xml files, reading hierarchy data from xml files, creation and reading of the xml configuration file) have been developed in java. Furthermore, existing algorithms in Mahout, from the Hadoop framework stack, are examined in order to generate the frequent itemsets. As a secondary choice, an Apriori implementation based on the main map-reduce Hadoop framework stack could be used. The proposed model is going to be tested using FrailSafe's multimodal data. In the following period, our efforts will be focused on developing, implementing, and testing our model.

Finally, fueled by previous work on data fusion, three schemes were designed: (i) Early Integration scheme, (ii) Late Integration scheme with local (sensor dependent) training models, (iii) Late Integration scheme with global (sensor independent) training model. In the Early Integration scheme, each one of the available sensor units from each frame is processed in parallel by the feature extraction algorithm. In the LI with global (sensor independent) training model fusion scheme, a common classification model is used for the feature vectors extracted from the different sensor units. The data matrix of the training set is constructed by merging all training sets from the LI with local models fusion scheme.

Previously, existing methods for classification or modeling generally relied on the usage of domain specific features normally selected by human experts. Finding the best features was the subject of a lot of research and the performance of the classifier was heavily dependent on their quality. In our future work, when more data will be available, we aim to investigate deep neural networks and especially convolutional neural networks (CNNs). The advantage of the deep architectures is that they can learn the features by themselves, reducing the need for human experts. By employing convolution and pooling operations they have shown to be able to capture the salient patterns of the multi-channel time series data at different timescales.

**T4.7 FrailSafe clinical state prediction engine and risk assessment**

The role of inflammation in the pathogenesis of frailty has been hypothesized, and so far many studies have been performed in order to understand the mechanism of

action underlying this association. Recent studies support this hypothesis and show a clear association between inflammation, frailty, and age-related disease. Chronic inflammation is key pathophysiologic process that contributes to the frailty directly and indirectly through other intermediate physiologic systems, such as the musculoskeletal, endocrine, and hematologic systems. The complex multifactorial etiologies of frailty also include obesity and other age-related specific diseases. This has a semantic effect on quality of life in the later years. In this direction, we have developed a novel platform that will aid the clinician to collect, analyze and report the relationships between biochemical and blood related markers to chronic inflammation and thereof the link between chronic inflammation and frailty of the older people. The role of cytokines, interleukins, cardiovascular abnormalities in combination with chronic high blood pressure, hyperlipidemia and diabetes has been extensively researched in a systematic review article that has been already submitted to an international, peer-reviewed journal in the biomedical domain. The editor's initial reply was encouraging and we are now at the stage where we are awating the reviewer's feedback in order to proceed to the next stage.

Towards enhancing the risk assessment domain, the VPM that is part of the Task T4.3 is designed to monitor the older person's vital signs and generate alerts towards clinicians in case it detects irregularities on heart rate, respiration rate, and blood pressure. The VPM will contain an overview of all spatiotemporal data as well as an overview of the full user activity and physiological classification. Thus, the VPM can serve as a risk assessment platform, which the clinicians can use to monitor the older people and intervene accordingly in case of risks.

### 12.4.3 WP4 – Significant results and achievements

The achievements for the first six-month period of the project can be summarized in the following:

- A thorough analysis of the state of the art for all the tasks in WP4.
- Selection of the data management system and the data analysis framework for FrailSafe.
- Design and development of FrailSafe's virtual patient model.
- Data collection from clinical partners and storage in the data management system.
- The VPM has been completed and is getting filled with data so that it will serve as a high efficient risk assessment tool for the clinicians.
- Real-time adaptation of the fall detection algorithm developed for T3.3.
- Preliminary work beyond the state of the art in multimodal data analysis and activity recognition.
- A systematic review article has been prepared to be submitted to an international, peer-reviewed journal in the biomedical realm.

### 12.4.4 WP4 – Deviations and critical issues

No deviations have been produced during this period in WP4.

### 12.4.5 WP4 – Use of resources

WP4 Resources have been used as expected in this first period of the project. They have been invested mostly in the state of the art regarding the database design, the investigation of the classification algorithms that will be implemented for the analysis, the analysis of the patient model representation as well as the social interaction of the elderly aiming at relating the social characterization with the mental disorders trace frailty.

### 12.4.6 WP4 – Corrective actions

No corrective actions were needed for this period.

## *12.5 WP5 – Dynamic Intervention Services*

### 12.5.1 WP5 – Objectives of WP5 during the period

In the present reporting period, the principle objective in WP5 has been to improve and add new modules to the FrailSafe framework, as well as the creation of a gaming platform that is going to include all the games developed within FrailSafe framework.

Furthermore, the improvement of the existing games has been pursued, as a result of the answers from volunteers and clinicians and the first test results.

In collaboration with the clinicians, the different new game proposals have been analysed with the main goal of defining a final list of games to be implemented.

### 12.5.2 WP5 – Summary of progress

*T5.1 – Analysis of hardware devices and software tools*

The analysis of hardware devices has finished. A model of tablet, Google Pixel C, and a model of Smartphone, Nexus 5X, have been selected as devices of reference in FrailSafe. This does not mean that FrailSafe developments would not work in other devices, but having a common hardware platform for development and validation will speed up the process.

The analysis of software tools is now also finished. The game engine, Unity, has been selected and is currently analyzed in detail for the development of FrailSafe games. Other libraries will give access to Internet, Databases, Sensors, Bluetooth, SD memory, or will allow creating the framework menu, and the interfaces of the game applications. These libraries are still being analyzed and will remain under analysis during the development phase where a more in depth knowledge on them will be acquired.

*T5.2 – Games framework development*

This task comprised the development of a general platform, connected with the framework through which the different games will be accessed.


**Figure 8: FrailSafe gaming platform main screen.**

On a first phase of the project, some sample applications were developed making use of Unity graphic engine. By using the connection library provided by CERTH, a plugin for Unity was developed, connecting the handgrip MicroFET device via Bluetooth to the tablet which enables to obtain the data from it in real time in order to be used in the games. The user interface implemented for the plugin was extended to allow the user to have better control on the Bluetooth devices he wants to use in the game.

In the last months, unlike in previous versions, in which the user´s login module was implemented independently in the two game applications developed by Brainstorm, from now on it is included within the framework. The existing games and the next to come will make use of the functions integrated in the framework for their execution and configuration.

Furthermore, these three modules have been definitely included within the framework, that is, the connection and data reception module, the HandGrip and the game data register module.

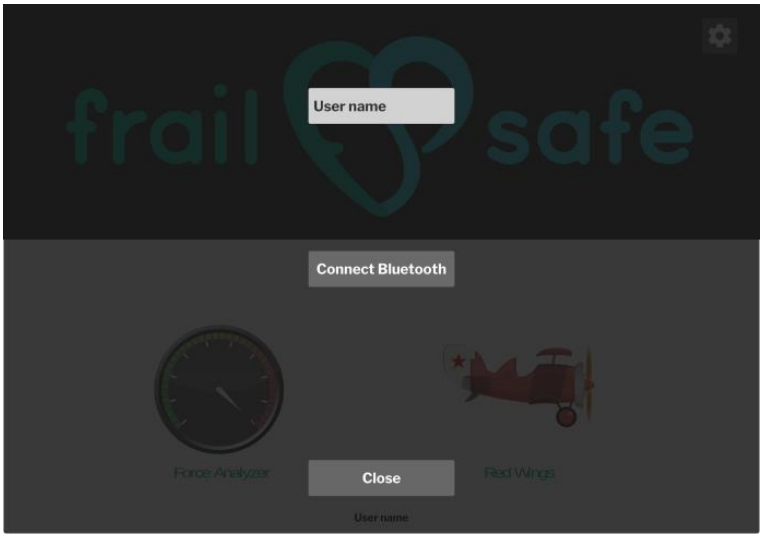



**Figure 9: FrailSafe gaming platform configuration screen.**

For this last module, an analysis is being carried out in collaboration with the clinicians and the rest of partners in order to determine which parameters are the most appropriate and required for evaluating the older person´s condition and progress.

In addition, the possibility of including third party games into the platform, is being considered besides the option that these games can register data. Hitherto, two options are being considered:

- Games which their source code and license enable the integration in the platform. That fact would enable adapting those games for FrailSafe framework making them compatible with the rest of the interaction devices, apart from getting a detailed log with the game´s events.
- Those games that either their source code isn´t available or their license doesn´t enables their inclusion in the platform. Under these circumstances, the system will try to launch these games from the FrailSafe´s interface. The game operation won´t be connected with the standard devices in FrailSafe and the data register will be poor, being only limited to the duration while the game has been active.

This period has also included the development of a tool that enables the visualisation of the results and the logs from the different games, making possible to compare them based on the parameters registered in each game. This application allows us to select one or several sessions from the same game and compare them by means of charts, giving the opportunity to assess the player´s performance throughout the session. This app has contributed, from the technical side, to identify the weaknesses (those phases with a high failure average) and their causes, and thereby solving those problems and improve the playability.

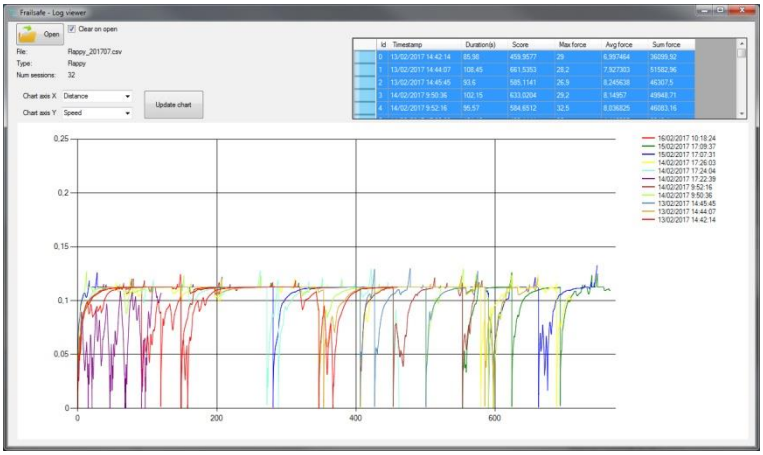


**Figure 10: User interface of log analysis application.**

*T5.3 – Games development*

Regarding the game development, in the first year of the project, small examples were programmed and tested their functionality verifying that sensor access is granted, or loading of 3D models and rendering them on screen, for example. This tests objective is to assure that each technical difficulty is overcome before the proper development begins, preparing the path for the framework design and for its development. A preliminary version of a game using the MicroFET handgrip device were developed and tested to verify its usability.

In the last months, a deep analysis about several games was conducted by technicians, experts and clinicians in order to assess the different options and determine the next games that will be included in the FrailSafe platform. To do that, a series of surveys have been conducted about different game proposals defining their own features and capacities, as well as describing in which physical and cognitive aspects will focus on.

Also, some validation tests have been designed to be completed by older people and clinicians in order to assess the results after the trials over the first prototypes and, thereby to adapt accordingly in order to improve the playability and the acceptance in their subsequent versions.

Taking into consideration those results, new versions of the games have been developed based on the prototypes developed at first instance.

- Red wings: Regarding the game known in its first version as Flappy (Bird Game), it has been implemented several improvements both at a graphical and usability level, since the prototype version was based on a commercial game, offering now a new appearance and designing the game logic so that the game gets to adapt the level of difficulty according to different variables and skills (reflexes, strength, fatigue, etc.). On top of that, this game has been integrated in the framework and connected through the global platform with the HandGrip and the data login management.

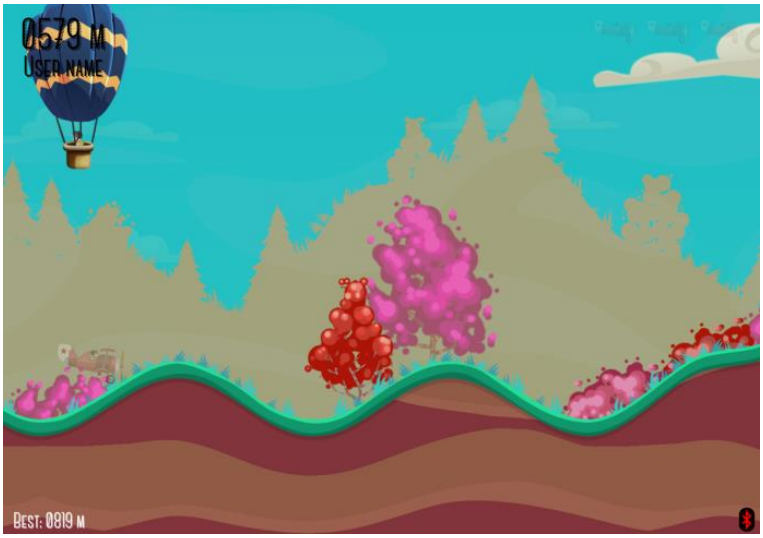



**Figure 11: Red Wings game appearance.**

- Force analyzer: not only the integration of this application within the global platform has been achieved, but also some improvements speaking mainly about the analysis of the collected data, what enables to store as well new parameters as the muscle fatigue.

During the past months, it has been undertaken the development of the game that will be connected with the Vest sensor. This game will assess the older person´s capacity and freedom of movement in arms and torso, as well as the agility and reflexes. The game is being developed in a way that from the very beginning will allow adjusting the level of difficulty according to the older person´s capacities.

**Figure 12: Sensor vest game design**

Furthermore, two augmented reality demo games are currently under development on both tablet and glasses, testing the ergonomics, user-friendliness, compactness and unobtrusiveness. First, “Gravity Ball” is a marker-based Augmented Reality game, targeted for mobile devices. As illustrated in Figure 13, the goal is to guide a virtual

sphere into the level's hole, the finishing point, as fast and as steadily as possible by moving the tangible handheld marker (virtual textured terrain) accordingly.

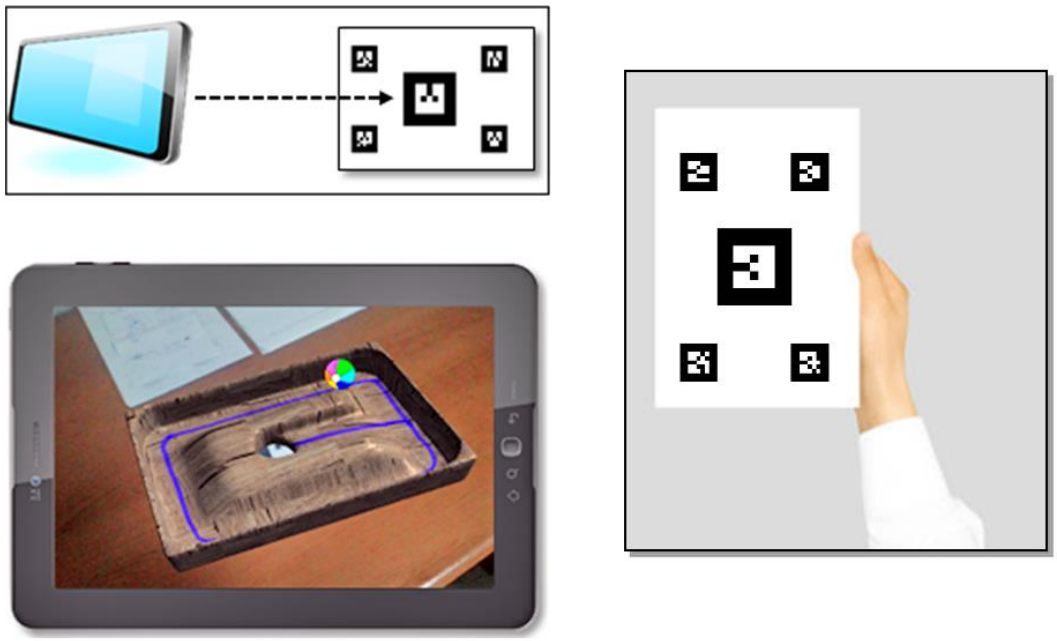


**Figure 13: Gravity Ball gameplay guidelines. (left) By scanning the tracking marker using tablet printed on a paper, the tablet will show an AR sphere and a terrain of different difficulty. (right) Rotate the terrain (the tracking marker) to guide the AR sphere**

Second, the "Floating Archery Target" is a hands-free and markers-free augmented reality game targeted for AR glasses devices. The goal is to track as fast as possible a virtual object, rendered through the optical see-through device, which floats randomly around him using a colored tag (see Figure 14).

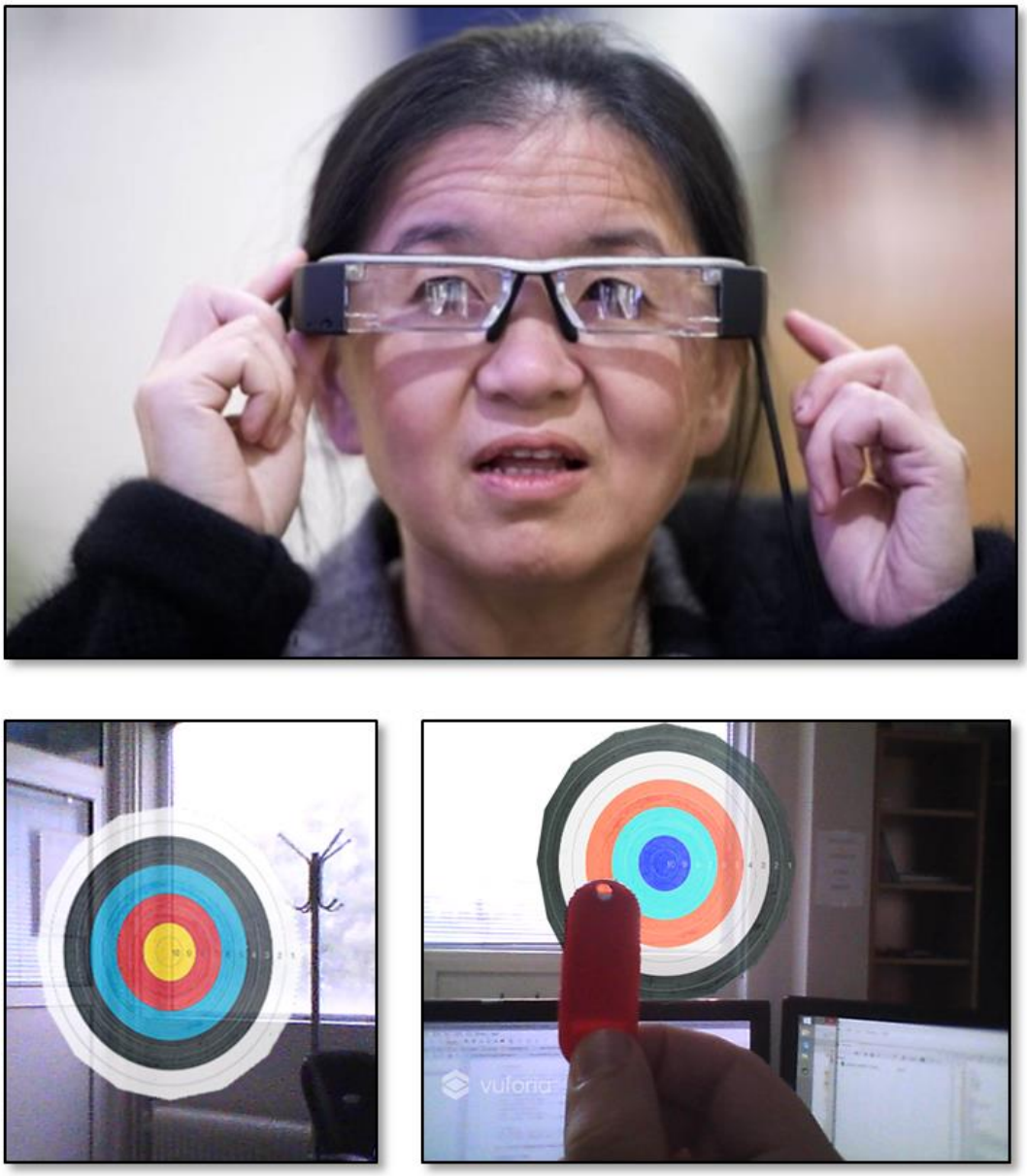



**Figure 14: Floating Archery Target gameplay guidelines. (top)The participant wears the AR glasses and then (bottom) tracks a virtual 3D object that floats around him in space using a colored tag.**

Last but not least, the virtual supermarket game is a cognitive training game that helps in detecting mild cognitive impairment, by asking the user to navigate in a 3D virtual supermarket environment and buy the products in the shopping list. The game has been improved in terms of graphics quality (visually appealing environment with more realistic 3D product models and sound effects, see **Figure 15**), multi-lingual support and capability of stable communication with the mobile gateway of the FrailSafe architecture.


**Figure 15: Visual enhancement between initial (left) and updated (right) versions of Supermarket game.**

Moreover, the Virtual Supermarket game has been enhanced with respect to user-friendliness and ease of learning. The time-consuming login procedure has been bypassed by allowing the clinician to lock the game for a specific older person, so that the game can be started instantly by the latter. At the same time, a set of tutorial levels have been added, in order to allow the older person to learn how to play the game, in an effort to reduce the need for a clinician to be present while the user plays the game (see Figure 16).


**Figure 16: Enhancement of the Virtual Supermarket game targeting ease of use and learning. The time-consuming user login can be bypassed, so that the game can start instantly (left). Tutorials with on-screen instructions can be started, to make it easy for the older person to learn how to play the game (right).**

*T5.4 –Personalised context-aware, information visualization and DSS.*

A preliminary dashboard has been developed, where FrailSafe data can be visualized. The dashboard supports two modes of operation: older person and clinician. When an older person logs in, the dashboard presents information related to the specific older person, such as historical measurements of blood pressure and activities, in the form of histograms, pie charts, etc (Figure 17). When a clinician logs in, the dashboard collectively presents information related to all older persons under the supervision of the clinician, in the form of tables, histograms, pie charts, etc. (Figure 18). In this mode, more sophisticated visualization methods are also under development, such as

multimodal graph-based visualizations of user similarities, which allow the clinician to have a more comprehensive overview of various parameters or combinations of parameters (Figure 19).

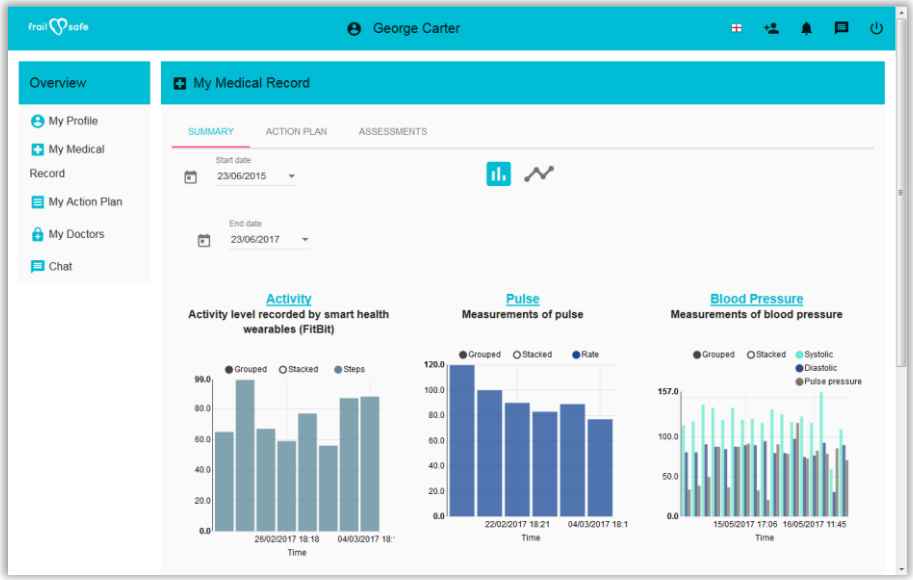



**Figure 17: FrailSafe dashboard displaying information for a specific older person.**

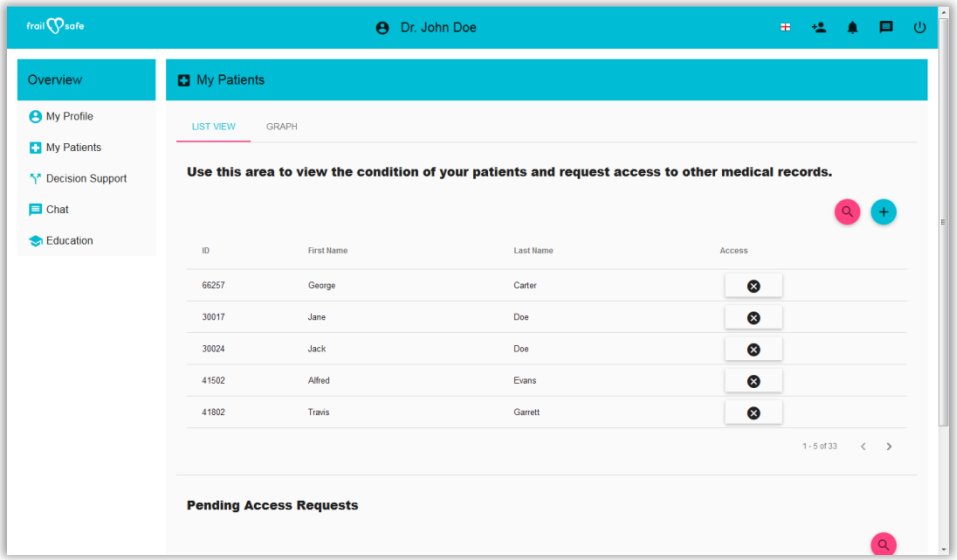



**Figure 18: FrailSafe dashboard collectively displaying information regarding the older persons under the supervision of a clinician.**

For the development of the dashboards, artificial data as well as real data collected through the Virtual Supermarket game, have been used to test the various visualization types. The dashboards are under development, in order to try various visualization types of parameters or their combinations, and in order to integrate them to the FrailSafe databases, so as to use actual data collected during the project.


**Figure 19: Histograms and graph-based visualizations of data collected through the Virtual Supermarket game. Such visualizations allow the recognition of patterns in user behaviour (e.g. the distribution of game completion time), and the detection of outliers (e.g. the disconnected points, i.e. users, in the graph-based visualization).**

### 12.5.3 WP5 – Significant results and achievements

The results achieved during this period are set out in several deliverables, both in documents and in prototypes. Below, the most relevant results are listed.

The deliverable D5.1 which details the results of the hardware devices and software tools analysis.

The results coming from the consultations conducted with older persons and clinicians as well as the game progress and the developments carried out were described in detail within the deliverable titled Dynamic Intervention Services corresponding to WP5.

The first version of the FrailSafe game platform has been published with the Force Meter and Red Wings applications integrated in it, having started the trials over this version with some volunteers. The virtual supermarket game has been upgraded including graphics quality and graphic user interface improvements as well as the core framework for developing augmented reality games has been implemented for both tablet and glasses devices.

During this period, it has been carried out the implementation of the first version of an application that allows us to monitor and assess the evolution and the results obtained during the sessions, with the main purpose of identify potential weaknesses in the games and thus performing the required corrective actions.

Preliminary older person- and clinician-oriented dashboards have been implemented and are under further development, with the goal of allowing the older person and

the clinicians to have a visual overview of the data collected throughout FrailSafe, using intuitive and comprehensive visualizations.

### 12.5.4 WP5 – Deviations and critical issues

No deviations were found during this period under WP5.

### 12.5.5 WP5 – Use of resources

The use of resources has been according the planification.

### 12.5.6 WP5 – Corrective actions

No corrective actions will be required.

## *12.6 WP6 – Integration and FrailSafe Application and Services*

The overall objectives of WP6 (M3 – M32), that aims at creating FrailSafe integrated system as well as the guidance platform, can be summarized as follows:

- implementation of FrailSafe Application and Services;
- implementation of the Virtual Community Platform;
- orchestration of the system development tasks of WP2 – WP5 in order to produce the FrailSafe integrated system, explicitly taking into account security and privacy issues.

In order to perform the abovementioned activities, WP6 takes input from WP1, WP2, WP3, WP4, WP5 and channel information about progress and system capabilities to the outside world.

Tables hereafter proposed, synthetically explain the WP6 activities' organization, that means, tasks, leadership, tasks' scheduling, effort (M/M), deliverables and milestones:

**Table 4 WP6 Tasks**

| Tasks | Effort (M/M) | Leadership |
|---|---|---|
| T6.1 FrailSafe Virtual Community Platform | 12 | UoP |
| T6.2 Security and Privacy subsystem | 11 | SIGLA |
| T6.3 System integration | 48 | SIGLA |

**Table 5 WP6 Deliverables and Milestones**

| | | |
|---|---|---|
| **Deliverables** | D6.1 FrailSafe Virtual Community Platform | M28: preliminary version<br>M32: final version |

| | | |
|---|---|---|
| | D6.2 FrailSafe mHealth Integrated version | M18: first version<br>M25: second version<br>M32: final version |
| | | |
| **Milestones** | MS8 First Integrated System Prototype | M20 |
| | MS9 Second Integrated System Prototype | M24 |
| | MS10 Final Integrated & Optimized System Prototype | M32 |

### 12.6.1 WP6 – Objectives of WP6 during the period

The main objectives of WP6 that have been achieved during the first period can be hereafter summarized:

- Worked on M4 trials technical solution proposal, in collaboration with WP1;

- Discussed and deployed first release of the Clinical Web Platform (including the Authentication UI and the so-called e-CRF), in collaboration with WP2 and WP4;

- Definition and finalization of the interactions, the features and the processes of the system based on the designed front-end and back-end integrated architecture, based on Data Flow, User requirements and Use cases, in collaboration with WP1;

- Deeply investigating Data Security and Privacy EU Directives and Regulation and how they affect the Cloud Host choice. Particularly:

    - production of documentation for the Project Officer and the D1.3 deliverable supported by a legal consultant in matter of privacy matters;
    - production of a legal opinion by a specialized law firm on the matter, reception of official documentation from the chosen cloud provider;

- Deployment of pre-α version of Clinical Web Portal for ECRF (Electronic Case Report Form) features first test run to be performed by WP2 (this activity, belonging to T6.3 has been anticipated at M6 respect, as stated in Project Proposal, the scheduled start time that is M16). This kind of activity has been moved up in order to provide WP2 the possibility to collect digitalized data (instead of the paper one) since the beginning of the project to better

rationalize the data collection;

- Deployment of intermediate (M13) and final version (M17) of the ECRF module wrapped into the Clinical Web Portal; all the final functionalities, except for a few evolutive minor updates, have been implemented, deployed and released;

- Implementation, deploy and release of ECRF APIs for the data exchange with other modules of the system;

- Release of user-guides for ECRF and its APIs, with needed updated at each evolving release;

- Implementation, deploy and release of the first version of the IAM module – i.e. the security system (T6.2) – and integration of its components into a uniform system infrastructure;

- Release of documentation for the IAM module's APIs;

- Started integration task (T6.3) at M16 and release of a first integrated system prototype at M18, as scheduled by DoW;

Activities of WP6 started in the first period but currently ongoing are:

- Implementation of the Virtual Community Platform (T6.1);
- Testing, debugging, updating, modifying, completing the IAM system (T6.2);
- Actively progressing with the integration task (T6.3).

### 12.6.2 WP6 – Summary of progress

Hereafter, the summary of progress of each task of the WP6 (T6.1, T6.2, T6.3) is described.

**T6.1 FrailSafe Virtual Community Platform**

T6.1 concerns the development of a platform for caregivers, older people, and their families. This platform will serve as a space for older people to ask and answer questions about diagnoses, etiology, and treatment and to exchange disease and health related information. By using this platform, the older people will be able to monitor their status, get updated about medical issues but also socialize with others. A special attention has been given in forming communities among the VCP users and evaluate their effectiveness. The idea is to group users into several communities based

on their frailty fried index, the FrailSafe frailty index findings, and their geographic location.

Activities of T6.1 performed during the first period were firstly focused on the following issues:

- Identification of security and privacy platform design needs;
- Identification of personalized data that will be imported in the platform and which data will be available to caregivers and elderly families;
- Analysis of the personalized interactions among older people;
- Investigation of data that will be stored in the database management system;
- Visualization techniques for presenting data to the end users.

### T6.2 Security and Privacy subsystem

Activities of T6.2, performed during the first period, were firstly focused on the following issues:

- Identification of security and privacy system design needs;
- Analysis and good understanding of data security and privacy EU Directives and Regulation we must comply with, particularly:
    - EU General Data Protection Regulation (2016), in force form 25$^{th}$ of May 2016;
    - EU Directive 95/46/EC (1995), replaced by the EU General Data Protection Regulation.
- With the aim of having a more complete understanding of the new European General Data Protection Regulation and the implications of its coming into full force for the platform, in particular for what concerns the selection of a convenient cloud provider, the following steps have been followed:
    - Analysis of the available documentation provided by the cloud provider;
    - Consultation of a legal expert on privacy matters;
    - Contacts with cloud provider's support teams;
    - Production of a legal opinion by a law firm specialized in regulations and privacy for IT and data treatment;
    - It is on-going the production of an opinion on this matter by a third-party ethical expert;
- Design of a technical security checklist and of how to apply security measure to system's architecture;
- Design, implementation, deploy, release and test of the security system and of all the sub-systems composing it; in more detail:

- The Authentication sub-system
    - The LDAP data storage infrastructure for storing the users', the roles and their relations has been implemented;
    - The library for connecting to the LDAP data storage;
    - The proper Authentication service that implements all the logics providing the features of registration, authentication, credentials provisions and verification, password management and more;
    - The REDIS data storage needed for the management of the credentials has been implemented;
    - The implementation of the unit tests for verifying automatically the correct working of the library for the LDAP storage and for the Authentication service;
- The API Gateway
    - For limiting and securing the access to the resources of the platform a module, called API Gateway, has been designed, implemented, deployed, released and tested;
    - The MongoDB data storage needed by the audit and logging features of the API Gateway has been implemented;
- A Log library has been implemented for uniformly managing the logging infrastructure of the security system;
- A secure cloud infrastructure has been designed and implemented to strongly isolate and protect the resources of the system – i.e. data and applications - from any unauthorized access;
- A VPN server has been configured to provide restricted and authorized access to the internal resources of the system, through the usage of credentials with limited access to the set of resources required by each specific partner and only to those ones;
- Several security means have been put in place to protect data in transit – i.e. encryption HTTPS – and at rest – i.e. encryption, auditing, backup policies;
- SSL private certificates has been produced and provided to the partners in need of securing the communication with their components;

Furthermore, all the activities already realized and listed here above are under test and evolution for what concerns the engineering ones and on revision and further progress for all the others.

**T6.3System integration**

Activities of T6.3 are scheduled, as stated in the Project Proposal, to start at M16. However, as already mentioned in paragraph 10.1.6.1, the deployment of first version

of Clinical Web Portal for ECRF (Electronic Case Report Form) features first test run to be performed by WP2, foreseen to be developed within T6.3, has been anticipated at M6.

After the official start of the T6.3, at M16, the activities performed were firstly focused on the following actions:

- *Integration activities*
    - completing the overall understanding of FRAILSAFE architecture:
        - how each module of the system interacts with other ones;
        - mapping the security/privacy features to be implemented;
        - Identifying eventual missing modules / features to be implemented;
        - Working together with WP1 to achieve a Service Oriented Architecture, and where possible a micro-service one;
        - Defining a unified Data Model and data storage infrastructure for the system to ease the data exchange in strong collaboration with WP4;
        - Finalizing cloud provider selection – i.e. Amazon AWS – and verification of its compliance with the EU regulation framework;
    - Cloud infrastructure setup
        - Collection and configuration of cloud resources requirements about all the platform's sub-systems;
        - Provision to all the partners of the instructions and the means to access the configured resources they need in order to let them autonomously progress on the deployment of the modules they implement;
        - Deployment of the first set of software modules of the system required to setup the basic back-bone of the platform – i.e. Authentication module, API Gateway, VPN server and more;
        - Deployment of a second set of software modules in order to have a first version of integrated system;
        - Release and test of the First Integrated System prototype at M18, as in MS8 and writing of the report of such activities (D6.3);
    - Clinical Web Portal
        - Authentication UI

    - Implemented First version of the Authentication UI, wrapped into the Clinical Web Portal, to manage the system's users;
    - A further evolution of this component is in progress;
- ECRF
    - Passing through some progressive releases (at M13 and at M17) the final version of the system with full functionalities has been implemented, deployed, released, integrated and tested;
    - The APIs to provide data to other sub-systems have been implemented, deployed, released and tested;
    - The documentation for the ECRF and its related APIs has been prepared and provided to the partners in need of them;
    - unit tests for testing some of the APIs provided have been implemented;
- The means for wrapping the third component of the Clinical Web Portal, that is the DSS UI, has been discussed and designed in collaboration with the WP5.

- In reference to the games integration, a common framework for the games has been implemented in which all the games developed by Brainstorm will be included and also is being studied to include some of the games of CERTH. Currently the functions to connect with the database for user secure login are in development.

- As well regarding the games integration, the module to upload the game files – the game results summary and the game raw data – to the file server for further analysis is being implemented.

Moreover, the work of the task is ongoing and a relevant evolution of all the listed activities is expected for the months to come. Particularly, the evolution of the integrated platform is expected to evolve significantly, strictly in dependence of the progresses performed by the other WPs involved in the developments of the sub-systems.

The following official release of the integrated system is scheduled for the M24 of the project.

In order to guarantee the release of the integrated system at M24, a number of informal releases (module per module) will be requested to all the partners working

on implementation and committed to the integration activities of the sub-systems of their responsibilities, between M18-M24.

### 12.6.3 WP6 – Significant results and achievements

The first results achieved during the first project's period can be summarized in:

- State of the Art of Data security privacy and regulation;
- Analysis of Privacy by Design and by Default;
- Designed architecture, based on Data Flow, in collaboration with WP1;
- Deployment of first, second and final version of the ECRF (Electronic Case Report Form) features to support medical assessments' data collection performed by WP2;
- Analysis of the Virtual Community Platform specifications regarding the data that will be imported and stored in the Database Management System as well as the data that will be available for elderly families and caregivers;
- IAM system implementation and deployment as result of T6.2 modules' design and development;
- Cloud infrastructure design and implementation;
- Implementation of the first version the integrated Clinical Web Platform, including the Authentication UI and ECRF features;
- First release of the integrated system prototype.

### 12.6.4 WP6 – Deviations and critical issues

No critical deviations from the plan are arisen.

Instead, activity related with the Clinical Web Portal (within T6.3 which starts, as stated in Project Proposal, at M16)), concerning the ECRF features, has been anticipated and GS Survey has been already deployed for the first test run by WP2.

### 12.6.5 WP6 – Use of resources

Resources have been used according with the DoW and no deviation from the plan has occurred.

The effort on the Task 6.3 – planned to start at M18 – has been partially anticipated for providing a platform (i.e. the eCRF features of the Clinical Web Platform) for enhancing the data collection performed by WP2 partners.

### 12.6.6 WP6 – Corrective actions

Currently, no corrective actions are needed.

## *12.7 WP7 – Testing and Evaluation*

The objective of WP7 is the extensive testing of the FrailSafe integrated system in several validation scenarios while ensuring compliance with ethics standards. The specific goal of the latter is to evaluate whether FrailSafe effectively encourages self-care support of frailty.

WP7 has just started, in M18.

List of deliverables

| **Deliverable** | D7.1 | D7.2 | D7.3 | D7.4 |
|---|---|---|---|---|
| **Title** | Assessment protocol (vers a) | Assessment protocol (vers b) | Small scale evaluation report | Field trials report and socio-economic status |
| **Leader** | MATERIA | MATERIA | INSERM | MATERIA |
| **Due month** | 20 | 26 | 22 | 36 |

Schedule of relevant Milestones

| **Milestone number** | MS11 | MS14 |
|---|---|---|
| **Title** | Definition of evaluation scenarios and applications | Frailsafe outcomes evaluation |
| **Leader** | MATERIA | MATERIA |
| **Due Month** | 32 | 36 |

Participation per partner

| **Partner number and short name** | **WP7 effort** |
|---|---|
| 1- UoP | 14.00 |
| 2- BRAINSTORM | 8.00 |
| 6- MATERIA GROUP | 20.00 |
| 7- GRUPPO SIGLA | 3.00 |
| 9- INSERM | 14.00 |

An overall of 438 individuals will be evaluated with “FrailSafe”. Predictions on outcome events and on transition of frailty rates will be evaluated, together with

rehabilitation effect of the “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.

This WP started on M18. We report its objectives and some progress here. Extensive testing of the FrailSafe integrated system in several validation scenarios while ensuring compliance with ethics standards. The project validation activities will consist of: a) Evaluation in semi-controlled environments carried out in small-sized (n=30), carefully-controlled case studies, aimed at testing the feasibility of the proposed platform; b) Evaluation with older people through a longitudinal demonstration involving a larger sample of participants consisting of 75 older people recruited in the first study with a range of severity of disease, 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 of frailty.

An overall of 438 individuals will be evaluated with “FrailSafe”. Predictions on outcome events and on transition of frailty rates will be evaluated, together with rehabilitation effect of the “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.

### 12.7.1 WP7 – Objectives of WP7 during the period

Quantification and evaluation of metrics that characterize frailty are the main objectives of the corresponding work package. The work packages WP1, WP2 and WP7 are related to the following Mos:

MO1. Better understand frailty and its relation to co-morbidities MO2. Develop quantitative and qualitative measures to define frailty MO3. Use these measures to predict short and long-term outcome MO4. Develop real life tools for the assessment of physiological reserve and external challenges MO5. 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. MO6. 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 MO7. Achieve all with a safe and acceptable to older people system.

### 12.7.2 WP7 – Summary of progress

In the context of Task 2.3 – Clinical guidelines for system development, a review of the literature was conducted in order to investigate the current and most well-based recommendations referring to frailty related conditions. A preliminary version of the analysis of data was conducted and some preliminary results were calculated. All these together with the measurements of D2.2 will ground the WP4 models with experimental data, gradually providing sufficient data for the quantification of the patient models and prediction framework.

Questionnaire, surveys and focus groups were conducted to investigate the FrailSafe metrics and get feedback from end users. Questionnaires regarding game activity were also conducted. Collection of feedback is an on-going and continuous task in this project. This feedback is very vital as it is one of the parameters taken into account when designing and planning the way the pilot studies will be organized, supported and managed throughout the duration of the project in order to ensure reliable and ongoing feedback as part of the co-design method, as well as a safe and ethical procedure for the participants.

The goal of Frailsafe at the end of the clinical assessments and trials, is to be able to distinguish the metrics which are significant in predicting and preventing frailty, and to assign weights to each one so that a new metric is created, which will integrate all the significant variables found through the data analysis.

Questionnaire, surveys and focus groups are in progress to investigate the FrailSafe metrics and get feedback from end users. Thus, at the end of the clinical assessments we will be able to distinguish the metrics important for investigation and that are related to frailty.

### 12.7.3 WP7 – Significant results and achievements

No significant results and achievements yet since the WP officially started on M18.

### 12.7.4 WP7 – Deviations and critical issues

No deviations or critical issues to report.

### 12.7.5 WP7 – Use of resources

Allocation of resources is in initial stages. Preliminary review and preparation of main areas of D7.1 have been undertaken by the gerontologist and the geriatrician of the team.

### 12.7.6 WP7 – Corrective actions

No corrective actions took place.

## *12.8 WP8 – Dissemination and Exploitation*

### 12.8.1 WP8 – Objectives of WP8 during the period

The objectives of WP8 were to raise public awareness of the project developments among key user groups, the scientific community and the general public through different communication channels. Moreover, another important action was to facilitate sharing of knowledge inside the consortium.

### 12.8.2 WP8 – Summary of progress

**Task 8.1: Dissemination activities, material and publication policy (M1-M36)**

Website: The project website has been created and made available at the end of M3 to enable the public to access the information on FrailSafe: http://frailsafe-project.eu/. An internal tool (the repository) has been set up to allow consortium partners to share knowledge and documents related to the project. The website has already started to gain interest, as during the last six months (January-June 2017), it attracted around 200 distinct visitors per month, recording more than 250 sessions per month and, in average, six (6) page views per session. These figures are expected to grow as the project evolves and the website is enriched with new content and results.

Logo: The heart, symbol of good health, is formed by the F of "frail" and the S of "safe". The colors were chosen to give a dynamic and fresh image. The typo aimed to be modern and representing strength at the same time, as opposed to frailty.

Press releases: A first press release was published in February 2016 to announce the launch of the project and communicate the general information about the objectives and its partners. A second press release was created in April 2016 to announce the official launch of the website, while a more recent one (February 2017) presented the system architecture of FrailSafe (check here). It was decided with the consortium partners that the milestones and deliverables due at the same period as the newsletters would make the object of an article, instead of a press release (contrary to what has been decided in the dissemination plan).

Leaflet: To ensure the dissemination of the project at various conferences and events, FrailSafe partners are invited to bring along the general FrailSafe leaflet, available on the website in English, French and Greek language to be downloaded by visitors. A second leaflet was created to be displayed in medical centers that will help clinicians explain the project to older people and convince them to take part as volunteers in the FrailSafe study (again available in English, French and Greek). An updated version of the general leaflet was made in June 2017, with a modern touch. It is available on the website for readers to upload.

Poster: A FrailSafe poster is pending as the consortium partners are still thinking about the moto that best describes the project.

Presentation: A PPT template is available to FrailSafe partners for presentations to be made to external partners. A short PPT version for a general public has been approved by all partners. It has also been agreed by the partners that a more detailed PPT version will be adapted according to the target audience (medical or technical) by using the FrailSafe PPT template.

Twitter: A Twitter account (@EUFrailSafe) was created to share FrailSafe information but also information linked to frailty (47 tweets since December 2016, 87 followers currently compared to 44 in December 2016).

Facebook: A Facebook account (@frailsafe, 130 followers so far) was created to target an audience that doesn't use Twitter. The information posted on Facebook is in principle the same as the one posted on Twitter.

Newsletter: The first newsletter was published by the end of June. It focuses on the objectives of the project from a technical and medical perspective. Information from other EU projects and EU events linked to frailty are also part of the newsletter information. The second newsletter was published in December 2016 and narrated the most recent outcomes and deliverables of the project during those last 6 months. (check here). The next one followed in mid-July 2017, encompassing the latest achievements of the project.

Scientific publications: Partners are invited to publish scientific papers about FrailSafe in order to disseminate the information about FrailSafe to a target medical or technical audience. There are already seven (7) related publications available on the website, which could be found here; however, other scientific publications are available and listed above (see section 6.1).

Data Management Plan: The first version of the Data Management Plan (DMP) (deliverable D8.12) was submitted by the end of June. It summarizes the scientific, technological and personal data expected to be produced in FrailSafe and also the strategy adopted to achieve open access to FrailSafe results. Further details concerning the DMP are included in section 16.

**Task 8.2: Exploitation and FrailSafe business models (M14-M36)**

Officially, the task has in M14, but due to its critical importance, preliminary research and discussions have started even earlier related to the business potential of FrailSafe, its innovative aspects and the added value compared to the current market state (see Section 15formore).

**Task 8.3: IPR management (M1-M36)**

During the reported period, the Intellectual Property Rights (IPR) Working Group was defined to work towards the compilation of the IPR agreement. Also, the Advisory Stakeholder Board (ASB) was formed with industrial members as well as stakeholders from outside the consortium. A first version of the IPR protection plan was issued in M12 (Deliverable D8.8). Further details concerning the IPR management are included in section 6.3.

**Task 8.4 Standardization and concertation actions (M1-M36)**

The first step of this task dealt with the EU directives and regulations on data protection, privacy and security as well as the US HIPAA. Results coming from this activity have been shared with WP1, WP3 and WP6 so as with the FrailSafe Ethics leader for the writing of the FrailSafe Ethics Manual. Moreover, FrailSafe partners came in contact with ETSI (European Telecommunication Standard Institute) and our presentation proposal "FrailSafe, a prevent frailty platform.

Standardization activity dealt, in the first period, and currently deals with the drafting of the State of the Art of standard working groups in mHealth and their progress in the analysis of gaps of standards devoted to *Personal Health Device Communication* and, in particular, related with the safe integration of wireless medical devices of all types, both those capable of information provision (measurements) and those requiring computer control from external health systems.

This activity is introductory to the next one that will address the comparative analysis of the standards impacting the solutions developed in the FrailSafe project.

To date, state of the art has been conducted on the following standard working group:

- CEN/TC 251;
- ITU-T Multimedia Framework for E-Health Applications (Question 28/16 which coordinates the technical standardization of multimedia systems to support eHealth applications), Study Group 16 (Multimedia coding, systems and applications);
- ISO/TC 215;
- ISO 11073 (ISO 11073-20601, ISO/IEEE 11073-10404, ISO/IEEE 11073-10407, ISO/IEEE 11073-10408, ISO/IEEE 11073-10415, ISO/IEEE 11073-10417, ISO/IEEE 11073-10471);
- ISO/TS 25237:2008.

"Research and standardization issues" has been accepted within the "From Research to Standardization" workshop. Unfortunately, due to some unexpected duties, SIGLA could not participate to the workshop at the end.

Activities of concertation has been done with some other projects, in particular:

- Projects funded within H2020 - PHC-21-2015: Advancing active and healthy ageing with ICT: Early risk detection and intervention:
    - My – AHA, My Active and Healthy Ageing
    - City4Age – Prevention of MCI and Frailty
    - PreventIT - Early risk detection and prevention in ageing people by self-administered ICT-supported assessment and a behavioural change intervention delivered by use of smartphones and smartwatches
    - iPROGNOSIS - Intelligent Parkinson eaRly detectiOn Guiding NOvel Supportive InterventionS

- Project funded by the *Italian Ministry of University and Research* within the Call “Smart Cities and Communities and Social Innovation”):
    - OPLON Care & Cure - OPportunities for active and healthy LONgevity

**Advisory Board**

Brainstorm holds the responsibility for the management and structure of the Advisory Stakeholder Board (ASB), having started its creation on December 2016. The Board´s responsibilities consist of: the project assessment, steering, revision of deliverables, and consultancy. It should mainly monitor and control that the project outcomes keep in line with the commercial exploitability of results.

The first step was to clarify, among FrailSafe partners, the characteristics to be present in the ASB advisors and stakeholders from outside the consortium. Afterwards, three actions were taken before holding the conferences with the advisors:

1. Recruiting and selecting six advisors: asking the partners for candidates, learning about their profiles, knowledge and expertise, availability, etc. Several lists were discussed and later, FrailSafe partners reached an agreement of a group of six advisors.
2. Inviting and convincing them to become members of the Advisory Board, providing them with information about the Project and their role as advisors. Two documents were created: Terms of Reference and Statement of Interest.
3. Compiling all the questions that FrailSafe partners wished to formulate to the advisors. Finally, a list of 56 questions concerning exploitation, games, clinical aspects, ethics, etc. has been collected.

The above work was done during the period comprised between December 2016 and March 2017. Planning the meetings and matching topics and questions for each advisor was a work conducted in parallel while talking with partners and advisors.

After having created the Advisory Board, a second phase started. Brainstorm has managed, scheduled and created the agenda for each meeting. So far (June 2017), three meetings took place. The information about the topics and questions to be discussed with each advisor was sent by email. As a reference, the agenda usually contains a total of 10 questions to discuss with each advisor.

### 12.8.3 WP8 – Significant results and achievements

The first results achieved during the first project’s period can be summarized as follows:

- FrailSafe website launched, as reported in deliverable “D8.5: Project Web Presence” (M3). Additionally, the corresponding project milestone (“MS1: Web site available”) was reached.

- First and second version of the FrailSafe Dissemination Plan created, as illustrated in deliverables "D8.1: Dissemination plan and FrailSafe dissemination material (vers a)" (M3) and "D8.2: Dissemination plan and FrailSafe dissemination material (vers b)" (M12) respectively.
- First version of the FrailSafe Data Management Plan compiled (Deliverable "D8.12: Data Management Plan" (M6)).
- First version of the IPR Management presented in deliverable "D8.8: IPR Protection Plan (vers a)" (M12).
- First version of the FrailSafe Exploitation Plan drafted in deliverable "D8.6: Exploitation Report and FrailSafe Business Models (vers a)" (M18).
- Scientific dissemination activities took place both to scientific communities and to stakeholders through the participation at events listed in section 6.2.3.
- State-of-the-art of EU Directives and Regulations on privacy, data security and protection created.

### 12.8.4 WP8 – Deviations and critical issues

Currently, no deviations from the project plan occurred, so as no critical issues came to light.

### 12.8.5 WP8 – Use of resources

Resources have been used according to the plan and no deviation has been occurred.

### 12.8.6 WP8 – Corrective actions

No corrective actions required.

## *12.9 WP9 – Management and Ethics*

The main objectives of this work-package are to guarantee the efficient functioning of the project, the resolution of possible conflicts that may arise and the timely completion of deliverables and milestones. In particular, the efforts here focus on: ensuring the delivery of the project on time and within the budget, coordinating the technological and scientific aspects of the project, guaranteeing high-quality standards at all levels, guaranteeing the accomplishment of the objectives, ensuring that the project maintains its relevance towards the objectives of the program, managing resources and monitoring the overall project performance, managing ethics and safety issues, as well as establishing appropriate relationships and communication channels with the funding actors as well as between consortium partners.

WP9 is split into three ongoing tasks, as presented in the following table:

| WP9 Tasks | Effort (PMs) | Leadership |
|---|---|---|
| T9.1 Project Management | 18.5 | UoP |

| | | |
|---|---|---|
| T9.2 Risk management and contingency planning | 5 | UoP |
| T9.3 Ethics and safety | 4 | UoP |

The outcomes of WP9, in terms of deliverables are presented in the following table:

| | | |
|---|---|---|
| **Deliverables** | D9.1 Project reference manual and quality plan | M3 |
| | D9.2 Project Quality Plan | M3 |
| | D9.3 Periodic Management Reports | M6: 1st periodic report<br>M12: 2nd periodic report<br>M24: 3rd periodic report<br>M30: 4th periodic report |
| | D9.4 Project First Report | M18 |
| | D9.5 Project Final Report | M36 |
| | D9.6 Ethics, Safety and mHealth Barriers (regulation, legislation, etc.) Manual | M5: preliminary manual<br>M36: final version |

### 12.9.1 WP9 – Objectives of WP9 during the period

The main objectives of WP9 during this first 18 month periodic period were the following:

- The development of the project reference manual that includes the project's work breakdown, inter-dependencies, timetable, responsible partners and management structure
- The development of the project's quality plan and definition of the project's quality policies, procedures, criteria for and areas of application, and roles, responsibilities and authorities
- The development of preliminary version of the Ethics, Safety and mHealth Barriers Manual and maintenance of it to stay current with projects' development
- The assembling of the1st and 2nd periodic progress reports

### 12.9.2 WP9 – Summary of progress

The progress in the three tasks of WP9 during this period is summarized in the following.

#### T9.1 Project Management

This is an ongoing task that deals with the daily management and control of the project, as well as the liaison with the Commission and external organizations. For this period, it includes reporting (this 1st periodic report), coordination of actions, organization of periodic Project Board meetings, decision making, conflict resolution, maintaining financial records, coordinating cost submission, distribution of EC

payments. Outcomes of this task for the reporting period are the project reference manual and the quality plan.

The project reference manual [D9.1]:

- summarizes the project facts and objectives, namely the project's work breakdown, the work package inter-dependencies, the task dependencies, the project timetable regarding deliverables and milestones, along with the respective responsible partners and the project measures and indicators
- defines the organizational management structure of the project, the coordination among the partners, the project management tools and reporting, the information flow and exchange and the risk management and contingency plans
- summarizes the project's quality plan, the quality system review and defines the project's quality board

The Project Quality Plan [D9.2]:

- provides the general quality control measures and actions, such as success criteria, corrective and preventative actions, contingency planning and risk management;
- provides the quality control of deliverables and documentation, including document types, documents naming, and document templates;
- provides the quality control of the whole project, including the peer-reviewing evaluation of project's deliverables.
- provides various templates useful for the project' quality management

**T9.2 Risk management and contingency planning**

It is an ongoing task that:

- continuously monitors the progress of the project and its alignment with the initial objectives
- performs risk management activities and applies contingency actions when necessary

The progress achieved towards the main objectives has been already reported in Section 9.2 of this report. The critical Implementation risks and mitigation actions have been reported in Section 5 of this report.

**T9.3 Ethics and Safety**

This ongoing task focuses on the appropriate ethical and safety approvals of the proposed applications at the pilot sites and for supervising the implementation of all evaluation studies and data. A preliminary version of the Ethics, Safety and mHealth

Barriers Manual (D9.6 (a)) has been delivered. This is a living document and is being kept up to date. This manual provides:

- overview of health, safety and well being
- legal framework for privacy protection including EU and national frameworks, data quality and security issues
- legal and ethical framework for involvement of human subjects in the study
- cloud computing privacy and data protection issues and compliance to GDPR
- ethics guidelines for protection of personal data, technical approaches, ethics approvals, biological samples for research protection of geolocation data, web and social media mining issues, and right to be forgotten
- The Ethics manual has been reviewed by an independent Ethics expert and her report is attached in the Appendix. In addition, the Ethics manual has been revised to include sections on incidental findings, analysis of telomeres and clarifications regarding emergency situations.

Recently we obtained a legal opinion regarding the compliance of the selected cloud provider service to the GDPR as well as a support letter from the Independent Ethics Supervisor (included in the Appendix).

The PO has asked that the reviewers and himself would observe participants using the FrailSafe system during their on-site visit in UoP. The compliance with the Ethics and the Data Protection Directive has been discussed during the plenary FrailSafe meeting in Cyprus. Concerns have been raised about violating anonymity of participants, whose identity is known only by the local clinical team. The PO assured the consortium that this is common practice in Horizon projects and thus, it was decided to put it to the attention of the Local Ethic Committee of UoP by submitting amendment of the consent with application number 13632 / 08.06.2017). The approval is awaited.

### 12.9.3 WP9 – Significant results and achievements

The most significant results and achievements regarding WP9, in this first period, following the above summary, are the following:

- The project reference manual [D9.1]
- The Project Quality Plan [D9.2]
- The preliminary version of the Ethics, Safety and mHealth Barriers Manual [D9.6 (a)]
- The progress reports [D9.3] for M6, [D9.4] for M12 and the periodic report [D9.7] (this document).

### 12.9.4 WP9 – Deviations and critical issues

There are no critical deviations from the plan. All deliverables have been delivered on time.

### 12.9.5 WP9 – Use of resources

These are summarized in Table of Section 17.1.

### 12.9.6 WP9 – Corrective actions

Currently, no corrective actions are needed.

# 13 Impact

No significant impact yet to be reported. This is the first 18 month periodic report.

# 14 Summary of Actual PMs Allocation for the Reporting Period (cumulative M1-M18)

| | Person Months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Partner short name** | **WP1** | **WP2** | **WP3** | **WP4** | **WP5** | **WP6** | **WP7** | **WP8** | **WP9** | **Total** |
| **UoP** | 6.91 | 8.42 | 3.36 | 22.78 | 4.48 | 1.62 | 0.65 | 0.285 | 6.51 | 55.015 |
| **BRA** | 1 | 4.92 | - | - | 17.92 | 2.95 | - | 2.35 | - | 29.14 |
| **SMARTEX** | 3.48 | 0.53 | 37.81 | - | - | 1.41 | - | 0.16 | 0.83 | 44.22 |
| **AGE** | 1.42 | - | - | - | - | - | - | 5.32 | 1.07 | 7.81 |
| **CERTH** | 9.9 | - | 4.94 | 3.03 | 7.24 | - | - | 1.15 | 0.27 | 26.53 |
| **MATERIA** | 11 | 9.1 | - | - | 1.9 | - | 2.1 | 2.86 | - | 26.96 |
| **SIGLA** | 10.61 | - | 3.57 | - | - | 16.34 | - | 1.45 | 1.12 | 33.09 |
| **HYPERTECH** | 3 | - | - | 2.41 | 1.52 | 1.22 | - | 7.62 | - | 15.77 |
| **INSERM** | 5 | 13 | - | - | 1 | - | 1 | 3 | 1 | 24 |
| **Total** | 52.32 | 35.97 | 49.68 | 28.22 | 34.06 | 23.54 | 3.75 | 24.20 | 10.80 | 262.54 |

# 15 Updates of the exploitation and dissemination plan

The dissemination activities are going according to the envisaged plan (deliverable D8.1) submitted in M3.

Important European conferences and events related to frailty and geriatry are selected progressively in time. These events are an opportunity to have a greater visibility about the project and approach relevant stakeholders for future collaborations.

Officially, the exploitation and business model creation task (T8.2) has started in M14, but due to its critical importance, preliminary research and discussions have started even earlier related to the business potential of FrailSafe, its innovative aspects and the added value compared to the current market state, also taking into account FR18 from the 1st Interim Review Report. In this respect, the definition of the technical architecture of the FrailSafe platform currently underway, is primarily taken into account, since it includes, among others, the definition of the various exploitable components expected to be developed during the project lifecycle (WWBS, games, data analysis and visualization tools, Virtual Patient Model, clinical and community platform etc.).

Relevant discussions are currently taking place within the IPR management task (T8.3), by trying to distinguish contribution of partners to individual modules and to the final integrated FrailSafe system, indicating IPR restrictions, licenses required and target markets-audiences for the exploitation of the FrailSafe solution as a whole or partially.

In this direction, the consortium has already been asked to declare its initial intentions regarding exploitation, i.e. if there is an interest in participating in a company or a scheme that will manage the exploitation of FrailSafe (active exploitation), if partners prefer to sell or license the solution (passive exploitation), if they prefer to offer services (solely or in conjunction with another type of exploitation) (added-value services) and finally, if they are interested only in sustaining the solution (not commercially exploit it).

All relevant aspects are presented in detail in the first draft Exploitation Plan (D8.6) submitted on M18.

# 16 Updates of the data management plan

The first version of the Data Management Plan (DMP) (deliverable D8.12) is submitted in M6. It summarizes the scientific, technological and personal data expected to be collected or generated during the FrailSafe lifecycle but also the specific measures to be adopted for each distinguished dataset (standards and metadata, sharing, archiving and preservation, ethical issues etc.). Finally, the deliverable illustrates the envisaged strategy to achieve open access to FrailSafe research data and results.

The updated version of the FrailSafe DMP will be made available in M24. During the next period, relevant activities will focus, among others, on the following:

- Adopt the latest "Guidelines on FAIR Data Management in Horizon 2020" (v3), published on 26 July 2016, where an updated template for dataset reporting has been provided.
- Track the progress performed and the results generated throughout the project execution.
- Update descriptions of the datasets collected, also clearly depicting which of them will be made publicly available and under which management framework.
- Select appropriate research repositories to share data.

# 17 Deviations from the Annex

## *17.1 Deviations in Tasks of the Project*

As far as the WP2 is concerned, the main deviation of the programmed tasks was the time schedule of the study. Task 2.2 Clinical monitoring of older people was supposed to start in M4. The main reason for this delay in all three centers was the difficulty in creating a sufficient recruitment pool with eligible subjects and some technical challenges, which delayed the preparation and the integration of certain FrailSafe system devices. In the case of INSERM there was also the delay in obtaining of the approval of Ethical Committees, because of a lack of detail in the exact description of the material and operational procedures, mainly those which were going to be evolved during the development of the study. INSERM obtained approval from their local Ethics committee on Oct. 6$^{th}$ 2016. By M17, all three clinical centers have already managed to recruit all participants for group A and B. First clinical evaluations have been completed for all clinical centers and in Nancy and Patras the second round of clinical evaluations of group B has started. Participants who dropped off are being replaced. FrailSafe Sessions are also quite deviated in terms of time schedule. This is partly due to the non-availability on time of some devices and applications. Efforts are made to follow the mitigated plan proposed on M13.

Due to the delay in the beginning of the clinical part, the start of tasks 2.2, 2.3 and 2.4, to the extent of their dependence from clinical measurements, has been slightly shifted in time. A document outlining the background, issue on the recruitment rate delay, different alternatives and a proposal for a line to take (i.e., FrailSafe sessions' modified time schedule) has been communicated to the Project Officer on M13 and its proposed mitigation strategies are currently running. However, the possibility of the need of a short prolongation of the study cannot be eliminated.

Regarding WP3, all devices have been delivered as soon as they were ready and in due time, with two exceptions:

1. WWBS first version has been released in 8 units (according to Amendment to contract #1) with a slight delay, due to the fact that these devices are to be used with real users in their home environment, so a not-planned EC-certification was needed, testing their safety (both electric and electromagnetic), for their acceptance by Ethical Committees; and
2. beacons that will perform the monitoring of indoor movement of users will be delivered to clinical centers in July, 2017 (but they were due at M24).

## *17.2 Deviations in the Use of Resources*

The need for higher use of manpower from CERTH, strengthened by the economic crisis situation during the last years in Greece which has increased the brain-drain phenomenon that is affecting the recruitment of highly-qualified and experienced

personnel in Greece, led to the enrollment of an increased number of medium qualified personnel, in order to ensure that the expected efforts for supporting the WP1 activities (investigation and covering all current practices and technologies and analyzing concretely the different components of the Frailsafe architecture in order to support more complex scenarios and more layered adaptations) would be met. Therefore, it should be outlined that the changes in Person Months do not affect the overall budget / EC contribution for the CERTH beneficiary, since more people with lower rate than the original planned were finally recruited.

Smartex was deeply involved in the activity related to the amendment to the contract as responsible of WP3 generally and as purchaser of the ErgoGlove/dynamometers more specifically. The iterative process of amendment preparation was quite intense, causing the large use of resources in WP9; in any case, we did not exceed available resources and we do not expect to play such a central role in future project management activities, so no corrective actions in use of resources are foreseen.

AGE input to WP1 mainly consisted in providing input on the deliverable 1.2 developed by MATERIA. The deliverable is highly technical and will require some extra work to present the findings on users' requirements in plain language to be understandable by a wider audience of older people and their families. AGE Platform would like therefore to transfer the remaining 1,72 PM from WP1 to WP8 to develop easy-to-understand dissemination/exploitation material that will be targeting the wider non-expert audience of end users.

# 18 List of Project Meetings (held and foreseen)

The following table provides an overview of the FrailSafe project meetings.

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| Kickoff meeting | 19-20/01/2016, Patras Greece | - Introduction of consortium members<br>- Main concepts related to FrailSafe<br>- Expected contributions<br>- First timeline and deadlines set<br>- Administrative matters | **UoP**: Vasilis Megalooikonomou (FrailSafe coordinator), John Ellul, Kyriakos Sgarbas, Christos Makris, Andreas Kanavos, Georgios Drakopoulos, Evangelia Pippa, Pantelis Vikatos<br>**CERTH**: Nikos Fakotakis, Konstantinos Moustakas, Konstantinos Votis, Aris Lalos<br>**Hypertech**: Kosmas Petridis<br>**Gruppo SIGLA**: Luca Bianconi<br>**Inserm**: Athanasios Benetos (FrailSafe scientific coordinator)<br>**Materia-AgeCare**: Marina Polukarpou, Kimon Volikas, Ioanna Petridou<br>**SMARTEX**: Roberto Orselli, Carlo Mancuso<br>**BrainStorm**: Javier Montesa<br>**AgePlatform**: Maude Luherne |
| 2nd Plenary meeting | 01-02/06/2016, Thessaloniki Greece | - FrailSafe project progress<br>- Project report on all working packages<br>- Medical partners meeting<br>- ICT partners meeting<br>- i-PROGNOSIS Project presentation<br>- Next steps | **UoP**: Vasilis Megalooikonomou (FrailSafe coordinator), John Ellul, Andreas Kanavos, Konstantinos Deltouzos, Georgios Drakopoulos, Eirini Tsiamaki, Maria Dimopoulou, Rafaela Sibola<br>**CERTH:** Konstantinos Moustakas, Andreas Vasilakis, Dimitrios Tzovaras, Konstantinos Votis, Elias Kalamaras, Konstantia Kotta, Fotini Trikka, Anastasia Chatzidimitriou, Christina Karamanidou, Smerla Stavroula, Hatziioannou Diane<br>**Hypertech**: Kosmas Petridis |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| | | | **Gruppo SIGLA**: Cristiana Degano, Luca Bianconi, Fabio Podda<br>**Inserm**: Jirar Topouchian<br>**Materia-AgeCare**: Kimon Volikas, Ioanna Petridou<br>**SMARTEX**: Roberto Orselli, Carlo Mancuso<br>**AgePlatform**: Nathalie de Craecker, Nhu Tram |
| 3rd Plenary meeting | 12-13/12/2016, Genova, Italy | - FrailSafe project progress<br>- Project report on all working packages<br>- Evaluation of the first year<br>- Next steps | **UoP**: Vasileios Megalooikonomou, John Ellul, Eirini Tsiamaki, Dimitrios Vlachakis<br>**CERTH**: Andreas Vasilakis, Elias Kalamaras<br>**Hypertech**: Kosmas Petridis<br>**Gruppo SIGLA**: Cristiana Degano, Luca Bianconi, Fabio Podda, Matteo Toma<br>**Inserm**: -<br>**Materia-AgeCare**: Marina Polycarpou, Ioanna Petridou, Dr Volikas Kimonas<br>**SMARTEX**: Roberto Orselli, Carlo Mancuso, Rita Paradiso<br>**BrainStorm**: Luisa Perez, Javier Montesa<br>**AgePlatform**: Nhu Tram |
| 4th Plenary meeting | 30-31/05/2017, Nicosia, Cyprus | -FRAILSAFE Project Progress and upcoming deliverables/milest ones/review<br>- Work Packages status and open issues<br>- Discussion with Advisory Board Member Mr. Filios Savvides<br>- Break out sessions: Medical / ICT<br>- Discussion regarding the upcoming review | **UoP**: Vasileios Megalooikonomou, John Ellul, Eirini Tsiamaki, Dimitrios Vlachakis, Konstantinos Deltouzos, Rafaela Tsela<br>**CERTH:** Andreas Vasilakis, Ilias Kalamaras<br>**INSERM:** Athanase Benetos<br>**SMARTEX:** Roberto Orselli, Gianluca De Toma<br>**AGE:** Nhu Tram<br>**MATERIA:** Marina Polycarpou, Ioanna Petridou, Sotia Nicolaou, Dr Volikas Kimonas<br>**Gruppo Sigla:** Cristiana Degano, Luca Bianconi, Fabio Podda |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| | | and proposed demos | **Hypertech:** Kosmas Petridis<br>**Brainstorm:** Javier Montesa |

The following table provides an overview of the FrailSafe project teleconference meetings (through skype).

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| WP Leaders meeting | 03/02/2016 | - Cost of devices and budget allocation<br>- Technical issues (data transmission, battery consumption, architecture)<br>- Prepare website and logo<br>- Discussion about falls (detection vs prevention) | Vasilis Megalooikonomou, John Ellul, Andreas Kanavos (**UoP**), Ilias Kalamaras, Kostas Moustakas, Kostas Votis (**CERTH**), Luca Bianconi (**SIGLA**), Roberto Orselli, (**SMARTEX**) Kosmas Petridis (**HYPERTECH**), Javi Montesa (**BRAINSTORM**), Maude Luherne, Nathalie De Craecker (**AGE**), Ioanna Petridou (**MATERIA**) |
| ICT Partners meeting | 23/02/2016 | - Table of parameters to be measured and means of measurement<br>- Devices to be used (beacons, dynamometers, smartphones, tablets) | Vasilis Megalooikonomou (FrailSafe coordinator), Georgios Drakopoulos (**UoP**), Konstantinos Moustakas, Konstantinos Votis (**CERTH**), Luca Bianconi (**SIGLA**), Roberto Orselli, Carlo Mancuso (**SMARTEX**), Javier Montesa (**BrainStorm**) |
| ICT and medical Partners meeting | 10/03/2016 | - Discussion on the cost of the devices and their usage (beacons, blood pressure monitor, mobilograph, impedance scale) | Vasilis Megalooikonomou, John Ellul, Andreas Kanavos (**UoP**), Konstantinos Moustakas, Konstantinos Votis, Ilias Kalamaras (**CERTH**), Luca Bianconi (**SIGLA**), Roberto Orselli, Carlo Mancuso (**SMARTEX**), Javier Montesa (**BrainStorm**), Kosmas Petridis (**Hypertech**), Thanos Benetos, Jirar Topouchian (**INSERM**), Kimon |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| | | | Volikas, Ioanna Petridou (**MATERIA**) |
| ICT Partners meeting | 11/03/2016 | - Discussion on the architecture of the FrailSafe project<br>- Discussion on the use cases | Vasilis Megalooikonomou, John Ellul, Andreas Kanavos (**UoP**), Ilias Kalamaras, Kostas Moustakas, Kostas Votis(**CERTH**), Luca Bianconi (**SIGLA**), Roberto Orselli, Carlo Mancuso (**SMARTEX**), Javier Montesa (**BrainStorm**), Kosmas Petridis (**Hypertech**) |
| WP Leaders meeting | 17/03/2016 | - Update about the PO's comments on the amendment and discussions | Vasilis Megalooikonomou, John Ellul, Andreas Kanavos (**UoP**), Ilias Kalamaras, Kostas Moustakas, Kostas Votis (**CERTH**), Luca Bianconi (**SIGLA**), Roberto Orselli, (**SMARTEX**) Kosmas Petridis (**HYPERTECH**), Javi Montesa (**BRAINSTORM**), Maude Luherne, Nathalie De Craecker (**AGE**), Ioanna Petridou (**MATERIA**) |
| Clinical meeting | 13/04/16 | - - Practical issues and technical characteristics of BP monitors, bio-impendence scales and Mobil-o-graph were discussed | V. Megalooikonomou, J. Ellul, Eir. Tsiamaki, M. Dimopoulou (**UoP**), Ath. Benetos, J. Topouchian, M. Kotsani (**INSERM**), I. Petridou (**MATERIA**) |
| WP Leaders meeting | 20/04/2016 | - Update on the progress of each WP<br>- Feedback from INSERM about the vests | Vasilis Megalooikonomou, John Ellul, Andreas Kanavos, Konstantinos Deltouzos (**UoP**), Ilias Kalamaras, Kostas Moustakas, Andreas Vasilakis (**CERTH**), Luca Bianconi (**SIGLA**), Roberto Orselli (**SMARTEX**), Kosmas Petridis (**HYPERTECH**), Javi Montesa (**BRAINSTORM**), Nhu Tram (**AGE**), Marina Polykarpou (**MATERIA**), Athanase Benetos, Marina Kotsani (**INSERM**) |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| WP Leaders meeting | 04/05/2016 | - Additional discussion on the budget to acquire the devices | Vasilis Megalooikonomou, John Ellul, Andreas Kanavos, Konstantinos Deltouzos (**UoP**), Ilias Kalamaras, Konstantinos Moustakas (**CERTH**), Roberto Orselli (**SMARTEX**), Luca Bianconi (**SIGLA**), Kosmas Petridis (**HYPERTECH**), Javi Montesa (**BRAINSTORM**), Nhu Tram (**AGE**), Ioanna Petridou (**MATERIA**), Athanase Benetos (**INSERM**) |
| Clinical meeting | 06/05/2016 | - TC was entirely dedicated on the clinical assessment | V.Megalooikonomou, J. Ellul, Eir. Tsiamaki, M. Dimopoulou (**UoP**), Ath. Benetos, J. Topouchian, M. Kotsani (**INSERM**), I.Petridou (**MATERIA**) |
| WP Leaders meeting | 11/05/2016 | - Update from the Working Package leaders | Vasilis Megalooikonomou, Andreas Kanavos, Konstantinos Deltouzos (**UoP**), Andreas Vasilakis, Ilias Kalamaras, Konstantinos Moustakas (**CERTH**), Luca Bianconi (**SIGLA**), Roberto Orselli (**SMARTEX**), Luca Bianconi (**SILGA**), Kosmas Petridis (**HYPERTECH**), Javi Montesa (**BRAINSTORM**), Nhu Tram (**AGE**), Marina Kotsani (**INSERM**) |
| Clinical meeting | 13/05/2016 | - Discussion on clinical assessment completed<br>- Definition of MCI | J. Ellul, Eir. Tsiamaki, M. Dimopoulou (**UoP**), M. Kotsani (**INSERM**), I. Petridou (**MATERIA**) |
| Clinical meeting | 19/05/2016 | - Text acquisition, social media quest., and big five were discussed<br>- | J. Ellul, A. Kanavos, Eir.Tsiamaki, M. Dimopoulou, R. Tsela (**UoP**), M. Kotsani (**INSERM**), I. Petridou (**MATERIA**) |
| Clinical meeting | 10/06/2016 | - Final version of clinical assessment discussed | V. Megalooikonomou, Eir.Tsiamaki, M. Dimopoulou, R. Tsela (**UoP**), Ath. Benetos, J. Ellul, M. Kotsani (**INSERM**), I. Petridou (**MATERIA**) |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| Clinical meeting | 15/06/2016 | - Requirements of eCRF were analysed | J.Ellul, Eir.Tsiamaki (**UoP**), Luca Bianconi (**SIGLA**), M. Kotsani (**INSERM**) |
| Clinical meeting | 17/06/2016 | - Queries on clinical assessment resolved | M. Kotsani (**INSERM**), J. Ellul, Eir. Tsiamaki (**UoP**) |
| ICT and medical Partners meeting | 17/06/2016 | - Generation of the eCFR platform | Luca Bianconi (**SIGLA**), Matteo Toma (**SIGLA**), Marina Kotsani **(INSERM)** |
| ICT and medical Partners meeting | 2/06/2016 | - Generation of the eCFR platform | Luca Bianconi (**SIGLA**), Matteo Toma (**SIGLA**), Fabio Podda (**SIGLA**), Marina Kotsani **(INSERM)** |
| ICT and medical Partners meeting | 2/06/2016 | - Discussion on FrailSafe system installation: check list of nurse's home visit as well as potential difficulties regarding prevention strategies | Andreas Kanavos **(UoP),** Konstantinos Deltouzos **(UoP),** Marina Kotsani **(INSERM)** |
| ICT and medical Partners meeting | 23/06/2016 | - Discussion on methodology of data collection regarding social interaction and natural language analysis tool | Kuriakos Sgarbas **(UoP)**, Christos Makris **(UoP)**, Andreas Kanavos **(UoP)**, Pantelis Vikatos **(UoP)**, Charalampos Tsimpouris **(UoP)**, Nikos Fazakis **(UoP)**, Marina Kotsani **(INSERM)** |
| Medical Partners meeting | 27/06/2016 | - Update of the tasks of WP2 | Eirini Tsiamaki **(UoP),** Marina Kotsani **(INSERM)** |
| Medical Partners meeting | 27/06/2016 | - Update of the tasks of WP2 | Ioanna Petridou **(MATERIA),** Marina Kotsani **(INSERM)** |
| WP leaders meeting | 06/07/2016 | - Amendment<br>- Purchase of devices | Vasilis Megalooikonomou, John Ellul, Andreas Kanavos, Konstantinos Deltouzos **(UoP)**, Andreas Vasilakis, Ilias Kalamaras, Konstantinos |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| | | - Project name conflict<br>- Update from the Work Package leaders | Moustakas **(CERTH)**, Roberto Orselli **(SMARTEX)**, Luca Bianconi, Cristiana Degano **(SIGLA)**, Kosmas Petridis **(HYPERTECH)**, Javi Montesa **(BRAINSTORM)**, Nhu Tram **(AGE)**, Marina Kotsani **(INSERM)**, Ioanna Petridou **(MATERIA)** |
| WP leaders meeting | 29/07/2016 | - General update by the Coordinator concerning the amendment, the purchase of the devices and the name conflict<br>67. Update from the Work Package leaders | Vasilis Megalooikonomou, John Ellul, Christos Makris, Andreas Kanavos, Konstantinos Deltouzos **(UoP)**, Ilias Kalamaras, Konstantinos Moustakas **(CERTH)**, Roberto Orselli **(SMARTEX)**, Cristiana Degano **(SIGLA)**, Kosmas Petridis **(HYPERTECH)**, Nhu Tram **(AGE)**, Thanos Benetos, Jirar Topouchian, Marina Kotsani **(INSERM)** |
| WP leaders meeting | 07/09/2016 | - Review meeting preparation<br>- Amendment<br>- Project name conflict<br>68. Update from the Work Package leaders | Vasilis Megalooikonomou, John Ellul, Christos Makris, Dimitris Vlachakis, Konstantinos Deltouzos **(UoP)**, Ilias Kalamaras, Andreas Vasilakis **(CERTH)**, Javi Montesa **(BRAINSTORM)**, Roberto Orselli **(SMARTEX)**, Cristiana Degano, Luca Bianconi **(SIGLA)**, Kosmas Petridis **(HYPERTECH)**, Nhu Tram **(AGE)**, Thanos Benetos, Marina Kotsani **(INSERM)** |
| Clinical – Technical meeting | 28/09/2016 INSERM (Nancy, France) | - eCRF consolidation | Luca Bianconi, Fabio Podda **(SIGLA)**<br>Marina Kotsani, Thanos Benetos, Sylvie Gautier, Jirar Topouchian **(INSERM)** |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| WP leaders meeting | 11/10/2016 | - General update by the Coordinator concerning the amendment request, the workshop he attended<br>- Next plenary meeting<br>- Review meeting<br>- Device loan document<br>69. Update from the Work Package leaders | Vasilis Megalooikonomou, Christos Makris, Eirini Tsiamaki, Dimitris Vlachakis, Konstantinos Deltouzos **(UoP)**, Konstantinos Moustakas, Kostas Votis, Ilias Kalamaras, Andreas Vasilakis **(CERTH)**, Javi Montesa **(BRAINSTORM)**, Roberto Orselli **(SMARTEX)**, Luca Bianconi **(SIGLA)**, Kosmas Petridis **(HYPERTECH)**, Nhu Tram **(AGE)**, Thanos Benetos, Marina Kotsani **(INSERM)**, Ioanna Petridou **(MATERIA)** |
| WP leaders meeting | 09/11/2016 | -Discussion regarding the review meeting and the points that reviewers made<br>-plans for the near future<br>40. Update from the Work Package leaders | Vasilis Megalooikonomou, Ellul John, Eirini Tsiamaki, Dimitris Vlachakis, Kostas Votis, Andreas Vasilakis **(CERTH)**, Javi Montesa, Luisa Perez Devesa**(BRAINSTORM)**, Roberto Orselli **(SMARTEX)**, Luca Bianconi **(SIGLA)**, Kosmas Petridis **(HYPERTECH)**, Nhu Tram **(AGE)**, Thanos Benetos, Marina Kotsani **(INSERM)**, Ioanna Petridou **(MATERIA)** |
| WP8: bilateral meeting | 22/11/2016 | Agreement on content of the article "Virtual Patient Model" for the newsletter | - **CERTH: Andreas Vasilakis**<br>- **AGE Platform Europe : Nhu Tram** |
| Game design meeting | 24/11/2016 | Discussions among clinical and ICT partners about the games design | Vasilis Megalooikonomou (UoP), John Ellul (UoP), Andreas Vasilakis, Ilias Kalamaras (CERTH), Konstantinos Moustakas (CERTH), Konstantinos Votis (CERTH), Ioanna Petridou (MATERIA), Javi Montesa (BRAINSTORM), Luisa Perez (BRAINSTORM) |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| WP leaders meeting | 09/12/2016 | -Discuss the comments and recommendations that received fron the review panel<br>-The leaders that asre responsible for the Deliverables, informed about the status of the deliverable.<br>41. Update from the Work Package leaders | Vasilis Megalooikonomou, Ellul John, Eirini Tsiamaki, Dimitris Vlachakis **(UoP)**, Kostas Votis, Andreas Vasilakis **(CERTH)**, Luisa Perez Devesa **(BRAINSTORM)**, Roberto Orselli **(SMARTEX)**, Luca Bianconi **(SIGLA)**, Kosmas Petridis **(HYPERTECH)**, Nhu Tram **(AGE)**, Thanos Benetos, Marina Kotsani**(INSERM)**, Ioanna Petridou **(MATERIA** |
| WP leaders meeting | 11/01/2017 | - Status of M12 deliverables<br>- Changes in the DoA<br>- Cloud computing service<br>- Advisory board<br>- Report on progress of WPs | Vasilis Megalooikonomou, Eirini Tsiamaki, Dimitris Vlachakis, Konstantinos Deltouzos (UoP), Ilias Kalamaras, Andreas Vasilakis (CERTH), Luisa Perez (BRAINSTORM), Carlo Mancuso (SMARTEX), Matteo toma (SILGA), Kosmas Petridis (HYPERTECH), Nhu Tram (AGE), Marina Kotsani (INSERM), Ioanna Petridou (MATERIA) |
| WP8: bilateral meeting | 17/01/2017 | Agreement on content of the press release “official release of the frailsafe high-level system architecture” | **Smartex: Roberto Orselli**<br>**AGE Platform Europe: Nhu Tram** |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| WP leaders meeting | 02/02/2017 | - Work Package progress report<br>- Updates on advisory board | Vasilis Megalooikonomou, John Ellul, Eirini Tsiamaki, Dimitris Vlachakis, Konstantinos Deltouzos (UoP), Ilias Kalamaras, Andreas Vasilakis, Thomas Tegou (CERTH), Javi Montesa, Luisa Perez (BRAINSTORM), Roberto Orselli (SMARTEX), Luca Bianconi (SILGA), Kosmas Petridis (HYPERTECH), Nhu Tram (AGE), Marina Kotsani, Thanos Benetos (INSERM), Ioanna Petridou (MATERIA) |
| WP6-WP3 technical meeting | 06/02/2017 | - discuss about possible usages of a Docking Station<br>- verifying the advancement stage of the WWBS implementatio ntest WWBS software | Rita Paradiso, Roberto Orselli, Carlo Mancuso, Gianluca De Toma, Tommaso Faetti **(SMARTEX)**, Luca Bianconi, Fabio Podda, Matteo Toma **(SIGLA)** |
| WP leaders meeting | 01/03/2017 | - Updates on amendment and advisory board<br>- Work Package progress report | Vasilis Megalooikonomou, Eirini Tsiamaki, Dimitris Vlachakis, Konstantinos Deltouzos, Evangelia Pippa, Aimilia Papagiannaki (UoP), Ilias Kalamaras, Andreas Vasilakis, Thomas Tegou, Eftychia Lakka (CERTH), Javi Montesa, Luisa Perez (BRAINSTORM), Roberto Orselli, Carlo Mancuso (SMARTEX), Luca Bianconi (SILGA), Kosmas Petridis (HYPERTECH), Nhu Tram (AGE), Marina Kotsani (INSERM) |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| Concertation meeting with MyAHA project (Prof. Alessandro Vercelli) | 10/03/2017 Ospedale San Luigi (Orbassano – Torino) | - Presentation of FrailSafe project and MyAHA project.<br>- | Cristiana Degano, Luca Bianconi (SIGLA) |
| WP leaders meeting | 05/04/2017 | - Work Package progress report<br>- Updates on advisory board | Vasilis Megalooikonomou, John Ellul, Eirini Tsiamaki, Dimitris Vlachakis, Konstantinos Deltouzos (UoP), Kostas Votis, Ilias Kalamaras, Thomas Tegou (CERTH), Luisa Perez (BRAINSTORM), Roberto Orselli (SMARTEX), Luca Bianconi (SILGA), Kosmas Petridis (HYPERTECH), Marina Kotsani (INSERM), Ioanna Petridou (MATERIA) |
| Game design meeting | 27/04/2017 | - Presentation of available AR games<br>- Discuss the requirements of the games<br>- Propose ideas to improve the games | Eirini Tsiamaki (UoP), Victor Kyriazakos (CERTH), Luisa Pérez, Enric Montesa (BRAINSTORM), Ioanna Petridou (MATERIA) |
| WP8 bilateral meeting on MS7 | 04/05/2017 | Discussion and agreement on content for the article on "FrailSafe augmented reality games" | CERTH: Andreas Vasilakis, Ilias Kalamaras<br>Brainstorm: Enric Montesa<br>AGE Platform EU: Nhu Tram |
| Advisory board member meeting | 8/5/2017 | Discussion of business plan and exploitation issues focusing on health care professionals in Cyprus. | MATERIA: Marina Polycarpou, Kimon Volikas<br>Filios Savvides, advisory board member of Frailsafe |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| WP leaders meeting | 10/05/2017 | - General discussion concerning the next plenary and review meetings<br>- WP progress | Vasilis Megalooikonomou, Eirini Tsiamaki, Dimitris Vlachakis, Konstantinos Deltouzos (UoP), Andreas Kalamaras, Ilias Kalamaras (CERTH), Javi Montesa (BRAINSTORM), Roberto Orselli, Carlo Mancuso (SMARTEX), Luca Bianconi (SILGA), Kosmas Petridis (HYPERTECH), Thanos Benetos (INSERM), Ioanna Petridou (MATERIA) |
| WP8 bilateral meeting MS6 | 11/05/2017 | - Discussion and agreement on content of article "Frailsafe integration and data analysis" (newsletter #3) | UoP: Dimitris Vlachakis<br>AGE Platform EU: Nhu Tram |
| WP8 bilateral meeting – dissemination | 14/06/2017; 21/06/2017; 29/06/2017 | - Discussion on what should be addressed at the CHAFEA meeting in Valencia<br>- Updating coordinator on the strategy<br>- Follow-up of the meeting and next steps | Brainstrorm: Enric Montesa<br>UoP: Vasilis Megalooikonomou<br>AGE Platform EU: Nhu Tram |
| Concertation call with MyAHA project (Prof. Alessandro Vercelli) | 21/06/2017 Call meeting | - Identification of the main issues that could be of interests for both projects. | Prof. Vasilis Megalooikonomou (UoP), Cristiana Degano (SIGLA). |

| Title | Date and Place | Main conclusions | Participants |
|---|---|---|---|
| Meeting with the Ethical Advisory board member | 05/07/2017 | - Explain the security measures and policies adopted for keeping the project's data safe and secure while using the selected cloud provider's services<br>- Prof. Maggi produced a letter giving her opinion on the adopted approach | Prof. Stefania Maggi (CNR, Ethical Advisor of FrailSafe), Luca Bianconi, Fabio Podda (SIGLA) |

# 19 Concertation Activities and Synergies

## *19.1 Cooperation with other Projects*

### 19.1.1 i-Prognosis

The FrailSafe partners agreed to follow the work of I-Prognosis, a 4-year research project funded by the Horizon 2020 Framework Programme of the European Union. It aims to provide technology-based solutions against Parkinson's, as well as raise awareness on the disease and self-health management. i-PROGNOSIS will employ latest technology (smartphones, fitness bands, smart connected everyday objects and serious games) and the vast experience of i-PROGNOSIS medical partners to build its Parkinson's disease early detection tests and supportive interventions. As the two projects share similar motivation, synergies between i-PROGNOSIS and FrailSafe are possible. These could be applied both to medical and technological developmental phases, as both projects successfully combine the medical with the technological knowledge domains. Behavioral models that come from both projects could be tested and validated in the corresponding participants, showing the modelling potentiality for generalization under the cases of the older adults with co-morbidities (such as Parkinson's disease). Moreover, both projects target the same population and tackle issues that relate to the older population (Frailty focusing on the 70+ and i-Prognosis on the 50+). Overall, various levels of communication between the two projects could definitely contribute to the active and healthy ageing endeavor.

A presentation was organized at the first FrailSafe consortium meeting on 2 June 2016 in Thessaloniki, by I-Prognosis project coordinator, Prof. Leontios Hadjileontiadis. Some views on the use of noSQL databases for data management were exchanged among the technical groups of the two projects in Dec. 2016.

### 19.1.2 EIP AHA A3

The FrailSafe partners also decided to follow the activities of the EIP AHA A3 group on prevention of functional decline and frailty. Given the nature of their work on frailty and the extensive network of relevant stakeholders, it would be useful for the dissemination of FrailSafe among European stakeholders to be in contact with that group of the EIP AHA. Moreover, the newsletter of July has been spread among the EIP AHA A3 stakeholders, offering a good opportunity to increase the visibility of FrailSafe work.

### 19.1.3 PreventIT

Given the common objective of enabling the older population to live longer in an active and healthy way through the help of technology and personalized intervention, FrailSafe partners are in touch with the PreventIT project. The idea is to organize a meeting with the two projects to discuss both clinical and technical approaches.

### 19.1.4 City4age

Together with City4age consortium we are investigating ways for collaboration especially on geriatric modeling and data sharing. For the geriatric modeling we are exploring the possibility of using as much as possible compatible geriatric profiles and avoid differences that can be avoided. There is also discussion on the particular data being collected by the two projects and how they are processed. Certain, relevant to these topics deliverables of Frailsafe, have been shared with City4age.

Prof. Paolo Paolini, attended the FrailSafe Plenary meeting that was held in Genova on the 12th and 13th of December 2016 in order to start an operative collaboration that will start on January 2017 with the design of a protocol of cooperation among the two projects and the identification of a set of commons objective and the related activities.

Documentation exchange among the two consortiums has been already started in order to start to compare the key factors that City4Age and FrailSafe have considered to analyse and understand the behavior of ageing people.

### 19.1.5 MyAHA

The FrailSafe consortium has decided to start concertation activities with MyAHA project which main aim is to reduce frailty risk by improving physical activity, cognitive function, psychological state, etc.

SIGLA already started the concertation activities trhough a face to face meeting and a call meeting during which Prof. Alessandro Vercelli (MyAHA coordinator), Prof. Vasilis Megalooikonomou, and SIGLA, identified the main issues that are of interest of both consortiums:

- standardization of devices in use;
- data accuracy needs to focus from the clinical and technological point of view;
- clinical issues.

In particular, concertation could aim to a more precise definition of “frailty” and how it can be measured. Discussion should be also about the Inclusion criteria: >60 y My-AHA, >70 Frailsafe. How these inclusion and exclusion criteria could be combined? Which is the ratio of pre-frail and frail?

### 19.1.6 ICT4Life

The ICT4Life project objectives are the following:

- ICT4Life aims at increasing the quality of life and the autonomy of individuals with early or intermediate stage cognitive impairment at their own homes, nursing homes, day care centres and hospitals by providing proactive and patient centred care from caregivers and health professionals thanks to the help of user-friendly IT solutions.

- ICT4Life Platform is being developed to deliver a series of innovative services which will connect patients, caregivers and health professionals supporting them.
- ICT4Life radical innovations for integrated care is being implemented by means of an efficient and cost-effective ICT-based Health Service Platform which exploits the latest technological advances.

Some similarities are noticeable between the two projects: target to older people (though ICt4Life is specifically for people with cognitive declines); will use a platform to provide recommendations or services to prevent frailty/cognitive decline; and they both use technology to determine patterns that might explain or predict the medical state of frailty/cognitive decline.
Both projects have been in contact and share when possible the information of the othe project.

FrailSafe also had the opportunity to attend one of CHAFEA's meeting in Valencia on 28 June 2017. It gathered 10 EU projects funded by CHAFEA around Frailty. Hopefully, it will enable FrailSafe partners to establish a sustanaible working relationship with the other EU project partners to create synergies.

### 19.1.7 Local European Networks

FrailSafe also had the opportunity to attend one of CHAFEA's meeting in Valencia on 28 June 2017. It gathered 10 EU projects funded by CHAFEA around Frailty. Hopefully, it will enable FrailSafe partners to establish a sustanaible working relationship with the other EU project partners to create synergies and convince local stakeholders to use FrailSafe platform in the future when it will be finalized.

# Periodic Financial Report

Part C

# 20 Periodic Financial Report

## *20.1 Financial Statement for Beneficiaries for the Current Reporting Period*

N/A: This is not reported in this 1st periodic report.

| Eligible costs (per budget category)[1] | | | | | | | | | | | Receipts | EU contribution | | | Additional Information |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | | | |
| | A. Direct personnel costs | | | | b. Direct costs of subcontracting | [C Direct costs of fin. support] | D. Other direct costs | | E. Indirect costs[2] | Total Costs | Receipts | Reimbursement rate % | Maximum EU contribution[3] | Request EU contribution | Information for indirect costs: |
| | A.1 Employees (or equivalent)<br>A.2 Natural Persons under direct contract<br>A.3 Seconded persons<br>(A.6 Personnel for providing access to research infrastructure) | | A.4 SME owners without salary<br>A.5 Beneficiaries that are natural persons without salary | | | | D.1 Travel<br>D.2 Equipment<br>D.3 Other goods and services | [D.4 Costs of large research infrastructure] | | | Receipts of the action to be reported in the last reporting period according to Article 5.3.3 | | | | Costs of in-kind contributions not used on premises |
| Form of Costs[4] | Actual | Unit | Unit:<br>XX Euro/Hour | | Actual | Actual | Actual | Actual | FlatRate[5]<br>25% | | | | | | |
| | a | Total b | No hours | Total c | d | [e] | f | [g] | H= 0.25 x(a+b+c+f+[g])-o) | J = a+b+c+d+[e]+f+[g]+h | k | l | m | n | o |
| UoP | 267.809,00 € | | | | | | 27.197,17 € | | 73.751,54 € | 368.757,71 € | | 100 | 368.757,71 € | 368.757,71 € | |
| BRA | 112.139,00 € | | | | | | 3.172,00 € | | 28.827,75 € | 144.138,75 € | | 100 | 144.138,75 € | 144.138,75 € | |
| SMARTEX | 216.081,13 € | | | | 2.100,00 € | | 33.981,05 € | | 62.515,55 € | 314.677,73 € | | 100 | 314.677,73 € | 314.677,73 € | |
| AGE | 36.660,55 € | | | | | | 4.786,77 € | | 10.361,83 € | 51.809,15 € | | 100 | 51.809,15 € | 51.809,15 € | |
| CERTH | 238.145,56 € | | | | | | 14.781,97 € | | 63.231,88 € | 316.159,41 € | | 100 | 316.159,41 € | 316.159,41 € | |
| MATERIA | 81.970,26 € | | | | | | 11.905,00 € | | 23.468,82 € | 117.344,08 € | | 100 | 117.344,08 € | 117.344,08 € | |
| SIGLA | 176.774,08 € | | | | | | 15.320,42 € | | 48.023,63 € | 240.118,13 € | | 100 | 240.118,13 € | 240.118,13 € | |
| HYPERTECH | 86.030,97 € | | | | | | 4.871,26 € | | 22.725,56 € | 113.627,79 € | | 100 | 113.627,79 € | 113.627,79 € | |
| INSERM | 79.924,95 € | | | | | | 5.161,48 € | | 21.271,61 € | 106.358,04 € | | 100 | 106.358,04 € | 106.358,04 € | |

1. See article 6 for eligibility conditions
2. The indirect costs claimed must be free of any amounts covered by and operating grant (received under any EU or Euratom funding programme; see Article 6.2.E). If you have received an operating grant during this reporting period, you cannot claim indirect costs
3. This is the theoretical amount of EU contribution that the system calculates automatically (by multiplying the reimbursement rate by the total costs declared). The amount you request (in the column 'requested EU contribution') may have to be less (e.g. if you and the other beneficiaries are above budget, if the 90% limit (see Article 21) is reached, etc)
4. See Article 5 for the form of costs
5. Flat rate: 25% of eligible costs from which are excluded: direct costs of subcontracting, costs of in-kind contributions not use on premises, direct costs of financial support, and unit costs declared under budget category F if they include indirect costs (see Article 6.2.E)
6. Only specific unit costs that do not include indirect costs

# 21 Report on Explanations on the use of resources

## *21.1 Direct personnel costs declared as unit costs*

| | Person Months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Partner short name** | **WP1** | **WP2** | **WP3** | **WP4** | **WP5** | **WP6** | **WP7** | **WP8** | **WP9** | **Total** |
| **UoP** | | | | | | | | | | |
| **BRA** | | | | | | | | | | |
| **SMARTEX** | | | | | | | | | | |
| **AGE** | | | | | | | | | | |
| **CERTH** | | | | | | | | | | |
| **MATERIA** | | | | | | | | | | |
| **SIGLA** | | | | | | | | | | |
| **HYPERTECH** | | | | | | | | | | |
| **INSERM** | | | | | | | | | | |
| **Total** | | | | | | | | | | |

## *21.2 Total Person Months Allocated to Each WP*

| | Person Months | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Partner short name** | **WP1** | **WP2** | **WP3** | **WP4** | **WP5** | **WP6** | **WP7** | **WP8** | **WP9** | **Total** |
| **UoP** | 8 | 11 | 5 | 42 | 8 | 7 | 14 | 7 | 18 | 120 |
| **BRA** | 1 | 6 | - | - | 25 | 8 | 8 | 5 | - | 53 |
| **SMARTEX** | 4 | 1 | 42 | - | - | 3 | - | 3 | 1 | 54 |
| **AGE** | 3 | - | - | - | - | - | - | 15 | 1.5 | 19.5 |
| **CERTH** | 6 | - | 20 | 18 | 20 | 4 | - | 2 | 3 | 73 |
| **MATERIA** | 11 | 13 | - | - | 3 | - | 20 | 7 | - | 54 |
| **SIGLA** | 12 | - | 6 | - | - | 44 | 3 | 5 | 3 | 73 |
| **HYPERTECH** | 3 | - | - | 3 | 3 | 5 | - | 14 | - | 28 |
| **INSERM** | 8 | 20 | - | - | 3 | - | 14 | 5 | 1 | 51 |
| **Total** | 56 | 51 | 73 | 63 | 62 | 71 | 59 | 63 | 27.5 | 525.5 |

## *21.3 Use of in kind contribution from third party*

No contribution from third parties in the current reporting period

## *21.4 Direct cost of subcontracting*

| Responsible partner | Description | Foreseen in Annex 1 [Yes]/[No] | Explanation (if not foreseen in Annex 1) | Costs |
|---|---|---|---|---|
| SMARTEX | EC certificatin of first version of WWBS | No | According to Amendment to contract # 8 units of the first version of WWBS have been released to be used with real users in their home environment, instead of on unit for laboratory testing. To be used on real-users, according to Ethical Committees' needs, a not-planned beforehand EC certification was due, certifying their safety (both electric and electromagnetic). | € 2.100.00 |
| | | | | |

No costs of subcontracting in the current reporting period.

## *21.5 Direct costs of providing financial support to third parties*

No contribution from third parties in the current reporting period.

## *21.6 Other direct costs: Explanation of major cost items if the amount exceeds 15% of personnel costs*

| Responsible partner | Short Description | Category [Travel]/ [Equipment]/ [Other goods and services] | Associated WP | Foreseen in Annex 1 [Yes]/[No] | Explanation (if not foreseen in Annex 1) | Costs |
|---|---|---|---|---|---|---|
| MATERIA CYPRUS For the purposes of the periodic management report, other direct costs for Materia are below 15% of personnel costs | Kick off meeting Patras | TRAVEL | | | | TICKETS = 287.55 euro ACCOMMODATION = 245 euro TAXI SERVICES = 44.72 euro |
| MATERIA CYPRUS | 2nd meeting Thessaloniki | TRAVEL | | | | TICKETS= 164.12 euro ACCOMMODATION = 607 euro TAXI SERVICES = 23.38 euro |
| MATERIA CYPRUS | Frailsafe flyers banner | Other goods | | | | 169 euro |
| MATERIA CYPRUS | Computers (3) printer (1) | Equipment | | | | 3.465.54 euro |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Server (1) | | | | | |
| MATERIA CYPRUS | Review meeting Brussels | travel | | | | Tickets= 486.07 euro<br>Accommodation: 374 euro<br>Food: 127.48 euro<br>Taxi&bus 75 euro |
| MATERIA CYPRUS | Plenary meeting Genova | travel | | | | Tickets= euro<br>Accommodation:<br>1.244.9<br>Food: 219.50 euro<br>Trains: 179.66 euro |
| SMARTEX | Kickoff meeting in Patras<br>(19-20/01/2016) | Travel costs for 2 resources (C. Mancuso, R. Orselli) | WPs 1,3,9 | YES | | Flights and transportation: € 715,57,<br>Hotel: 208,00<br>Food: € 89,63<br>TOTAL: € 1.013,20 |

| | | | | | | |
|---|---|---|---|---|---|---|
| SMARTEX | Dissemination activity in Genoa (06/04/16) | Travel costs for 1 resource (R.Orselli) | WP8 | YES | | Car rental + Gasoline + Motorway fee: € 160,70 |
| SMARTEX | Plenary meeting in Thessaloniki (01-02/06/2016) | Travel costs for 2 resources (C. Mancuso, R. Orselli) | WPs 1, 3 | YES | | Flights and transportation: € 969,72,<br>Hotel: 296,08<br>Food: € 170,97<br>TOTAL: € 1.436,77 |
| SMARTEX | Review meeting in Brussels (24-26/10/2016) | Travel costs for 2 resources (C. Mancuso, R. Orselli) | WPs 1, 3 | YES | | Flights and transportation: € 626,85,<br>Hotel: 236,74<br>Food: € 183,54<br>TOTAL: € 1.047,13 |
| SMARTEX | Plenary meeting in Genoa (12-13/12/2016) | Travel costs for 5 resources (C. Mancuso, R. Orselli, G. De Toma, T. Faetti, R.Paradiso) | WPs 1, 3 | YES | | Flights and transportation: € 296,94,<br>Hotel: 225,36<br>Food: € 72,20<br>TOTAL: € 594,50 |

| | | | | | | |
|---|---|---|---|---|---|---|
| SMARTEX | Technical meeting in Navacchio with Sigla (06/02/17) | Hosting a meeting (8 people) | WPs 1, 3 | YES | | Food: € 69,91 |
| SMARTEX | Plenary meeting in Lefkosia (29/05-01/06/2017) | Travel costs for 2 resources (R. Orselli, G. De Toma) | WPs 1, 3 | YES | | Flights and transportation: € 1.372,23,<br>Hotel: 376,13<br>Food: € 147,95<br>TOTAL: € 1.896,31 |
| SMARTEX | Electronic components | Other goods and services | WP3 | YES | | € 4.981,10 |
| SMARTEX | Board assebly | Other goods and services | WP3 | YES | | € 2.727,21 |
| SMARTEX | Garment material and manufacturing | Other goods and services | WP3 | YES | | € 1.489,65 |
| SMARTEX | Dynamometers and commercial IMUs | Other goods and services | WP3 | YES | | € 13.616,25 |
| SMARTEX | Tablets | Other goods and services | WP3 | YES | | € 2.762,39 |
| SMARTEX | EC Certification | Subcontracting | WP3 | NO | SMARTEX will request for a budget allocation for | € 2.100.00 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | Subcontracting (*2) | |
| AGE | Kick Off meeting | Travel | | YES | | 586,88 EUR |
| AGE | Consortium meeting – Thessaloniki (2 PAX) | Travel | | YES | | 693,94 EUR |
| AGE | Design of logo | Other goods and services | WP 8 | No | In order to create the visual identity of FrailSafe, AGE outsourced the creation of the logo to Association Bug | 403,20 EUR |
| AGE | Purchase of 2 Google C Tablets | Equipment | WP3 | No | | €1205.31 |
| AGE | 2nd Plenary meeting in Genoa (2 PAX) | Travel | WP8 | | Flight, hotel, per diem | Flight: 654 EUR<br>Hotel: 762 EUR<br>Per Diem: 446.50<br>TOTAL: 1862,50 EUR |
| AGE | 3rd plenary meeting in Nicosia | Travel | WP8 | | Flight, hotel, per diem | Flight: 104.02 EUR<br>Hotel: 280 EUR |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | Per Diem: 251.10 EUR<br>TOTAL: 635.12 EUR |
| INSERM | Kick off meeting Patras | Travel | WP2 | | | 542,11 Euros |
| INSERM | Plenary meeting in Thessaloniki | Travel | WP2 | | | 664,41 Euros |
| INSERM | 24 Blood Pressure devices &<br>8 Weight scales | Equipment | WP2 | | | 445 Euros |
| INSERM | Purchase of covers for tablets, smartphones and material | Equipment | WP2 | | | 236,95 Euros |
| INSERM | Review meeting Bruxelles | Travel | WP2 | | | 531,6 Euros |
| INSERM | Plenary Meeting Genova | Travel | WP2 | | | 909,17 euros |
| INSERM | Mobile Telephone subscription | Equipment | WP2 | | | 135,6x2= 271,2 euros |
| BRAINSTORM | Kick off meeting Patras | TRAVEL | WP6 | YES | | 581Eur |
| BRAINSTORM | Consortium meeting Genova | TRAVEL | WP6 | YES | | 1389,71 Eur |

| | | | | | | |
|---|---|---|---|---|---|---|
| BRAINSTORM | Consortium meeting Cyprus | TRAVEL | WP6 | YES | | 866,53 Eur |
| BRAINSTORM | Purchase of 3 Google Pixel C tablets and 2 covers for trials sites (Total amount 1237,19) | Equipment (depreciation) | WP2 | NO | Brainstorm requests for a budget allocation for equipment. (*1) | 335,07 Eur |

**BRAINSTORM:**
(*1) As smart devices are needed for development, validation and usage by the older adults but not foreseen for all partners, the overall consortium decided to split the global purchase proportionally among different partners. Brainstorm does not have a specific budget for equipment so they will request for a budget allocation for this category.
(*2) According to Amendment to contract # 8 units of the first version of WWBS have been released to be used with real users in their home environment, instead of on unit for laboratory testing. To be used on real-users, according to Ethical Committees' needs, a not-planned beforehand EC certification was due, certifying their safety (both electric and electromagnetic). A second certification step (and cost) will be needed at the moment of the release of WWBS 2.0 (at M24).

**SIGLA:**
Personnel cost for the reporting period is 176.774,08 Euros. Other costs are 15.320that is less than 15% (8.68%)of personnel cost.

**UoP:**
Personnel cost for the reporting period is 267.809 Euros. Other costs are 27.197,17 Euros which is less than 15% of personnel costs.

## *21.7 Other directs costs reported as use of in kind contribution from third party*

No contribution from third parties in the current reporting period.

# APPENDIX:

## *A. Copies of Ethical approvals of the three Centers and related documentations (consent forms and information forms)*

**From Nancy – Inserm**

ansm
Agence nationale de sécurité du médicament et des produits de santé

RÉPUBLIQUE FRANÇAISE

**Télécopie / Fax**

Saint-Denis, le 22 NOV. 2016

**Direction de la Maîtrise des flux et des référentiels / INOTIF**
**Pôle Instruction et Notification des dossiers dispositifs médicaux et autres flux**
**Dossier suivi par :** Nadia BENSAHA
**Tel.** +33(0)1 55 87 40 25
**Fax :** +33 (0)1 55 87 37 99
**E-mail :** nadia.bensaha@ansm.sante.fr
**Réf. Sortant :** 2016112100009

***TOPOUCHIAN JIRAR***
JTCRC SAS
**Fax :** ***03.83.15.76.68***

**nombre de pages incluant celle-ci :** 1

**Objet :** AUTORISATION D'UN ESSAI CLINIQUE NE PORTANT PAS SUR UN PRODUIT DE SANTE

Madame, Monsieur,

Par courrier électronique daté du 18/11/2016, reçu le 18/11/2016, vous avez adressé, conformément aux dispositions des articles L.1123-8 et R.1123-30 du code de la santé publique (CSP), une demande d'autorisation d'essai clinique ne portant pas sur un produit mentionné à l'article L. 5311-1 du CSP (Essai-HPS) :

| **Identification de l'essai clinique** | | **IDRCB : 2016-A01286-45** | |
|---|---|---|---|
| **Titre** | ***ETUDE FRAILSAFE : DETECTION ET TRAITEMENT PREVENTIF DE LA FRAGILITE ET DES COMORBIDITES ASSOCIEES A L'AIDE DE MODELES PERSONALISES ET D'INTERVENTIONS CIBLEES*** | | |
| **Promoteur** | **JTCRC SAS** | **Réf. Promoteur** | **FRAILSAFE** |
| **CPP** | EST-III | **Réf. CPP** | 16.09.05 |

Vu le code de la santé publique et notamment ses articles L. 1123-8, R. 1123-32 ;
L'autorisation mentionnée à l'article L. 1123-8 du code de la santé publique est accordée pour l'essai clinique cité en objet.
Cette autorisation est valable pour toute la durée de l'essai à compter de la date de la présente. Toutefois, conformément à l'article R. 1123-33 du code de la santé publique, la présente autorisation devient caduque si la recherche n'a pas débuté dans un délai d'un an.

Je vous prie d'agréer, Madame, Monsieur, l'assurance de ma considération distinguée.

Le Directeur adjoint de la maîtrise des flux et des référentiels
David MORELLE




143/147 boulevard Anatole France - F-93285 Saint-Denis Cedex - Tél.: +33 (0)1 55 87 30 00 - **www.ansm.sante.fr**

COMITÉ de PROTECTION des PERSONNES EST-III

Hôpital de Brabois. Rue du Morvan - 54511 VANDŒUVRE-LES-NANCY Cedex

**Téléphone** : 03 83 15 43 24 - **Télécopie** : 03.59.62.06.02 - **Courriel** : cppest.3@chru-nancy.fr

Nancy, le jeudi 6 octobre 2016

Mr le Pr Athanase BENETOS
Service de Gériatrie
CHRU Nancy
Rue du Morvan

54511 Vandoeuvre Lès Nancy

Projet de recherche enregistré
Sous les références
N° ID RCB: 2016-A01286-45
N° CPP: 16.09.05

Monsieur et Cher Confrère,

Je vous prie de bien vouloir trouver ci-joint l'avis du Comité concernant les modifications apportées au protocole intitulé :

**Détection et traitement préventif de la fragilité et des comorbidités associées à l'aide de modèles personnalisés et d'interventions ciblées.**

Veuillez agréer, Monsieur et Cher Confrère, l'assurance de ma sincère considération.

Le Président

Docteur P. PETON

# COMITÉ de PROTECTION des PERSONNES EST-III

Hôpital de Brabois. Rue du Morvan - 54511 VANDŒUVRE-LES-NANCY Cedex

**Téléphone** : 03 83 15 43 24 - **Télécopie** : 03.59.62.06.02 - **Courriel** : cppest.3@chru-nancy.fr

Projet de recherche enregistré
Sous les références
N° ID RCB: 2016-A01286-45
N° CPP: 16.09.05

Le Comité a été saisi le 22 septembre 2016 par Mr le Pr Athanase BENETOS, Service de Gériatrie du CHRU de Nancy, en qualité d'investigateur principal, représentant et mandaté par JTCRC sas, promoteur, pour l'examen des modifications apportées du protocole intitulé :

**Détection et traitement préventif de la fragilité et des comorbidités associées à l'aide de modèles personnalisés et d'interventions ciblées.**

Le Comité a examiné ces modifications lors de sa séance du **4 octobre 2016**. Ont participé aux délibérations :

- les membres du Collège n° 1 :
Catégorie 1 : Mr Peton (Titulaire), Mme Le Dr Luporsi (Titulaire), Mr Perrin (Titulaire), Mr Beau (Titulaire),
Catégorie 2 : Mr Grang (Titulaire),
Catégorie 3 : Mr Bureau (Titulaire),
Catégorie 4 : Mr Pfeiffer (Titulaire),
- les membres du Collège n° 2 :
Catégorie 7 : Mme Batt (Titulaire),
Catégorie 9 : Mr Vidal (Titulaire), Mme Boutet (Suppléante).

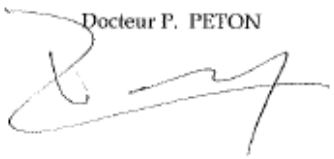
Le Comité a adopté la délibération suivante : **AVIS FAVORABLE** pour :

- Le courrier de demande d'avis daté du 02.08.2016
- Le formulaire de demande d'avis daté du 19.09.2016
- Le bordereau d'enregistrement ANSM daté du 28.07.2016
- Le document additionnel daté du 19.09.2016
- L'attestation d'assurance datée du 11.08.2016
- Le protocole : version 1 du 19.09 2016
- Le synopsis de l'étude : version 1 du 19.09 2016
- Le formulaire d'information et de consentement groupe A : version 1 du 19.09 2016
- Le formulaire d'information et de consentement groupe B : version 1 du 19.09 2016
- La lettre destinée au médecin traitant
- L'avis d'un comité scientifique consulté par le promoteur.
- Les CV investigateurs
- Les annexes : marquage CE pour la ceinture thoracique, l'appareil à tension, le mobilographe, le dynamomètre.

jeudi 6 octobre 2016

Le Président

Docteur P. PETON



COMITÉ de PROTECTION des PERSONNES EST-III

Hôpital de Brabois. Rue du Morvan - 54511 VANDŒUVRE-LES-NANCY Cedex

**Téléphone** : 03 83 15 43 24 - **Télécopie** : 03.59.62.06.02 - **Courriel** : cppest.3@chru-nancy.fr

Nancy, le mercredi 5 avril 2017

Mr le Pr Athanase BENETOS
Service de Gériatrie
CHRU Nancy
Rue du Morvan

54511 Vandoeuvre Lès Nancy

Projet de recherche enregistré
Sous les références
N° ID RCB: 2016-A01286-45
N° CPP: 16.09.05

Monsieur et Cher Confrère,

Je vous prie de bien vouloir trouver ci-joint l'avis du Comité concernant la modification substantielle n°1 apportée au protocole intitulé :

**Détection et traitement préventif de la fragilité et des comorbidités associées à l'aide de modèles personnalisés et d'interventions ciblées.**

Veuillez agréer, Monsieur et Cher Confrère, l'assurance de ma sincère considération.

Le Président

Docteur P. PETON

# COMITÉ de PROTECTION des PERSONNES EST-III

Hôpital de Brabois. Rue du Morvan - 54511 VANDŒUVRE-LES-NANCY Cedex

**Téléphone** : 03 83 15 43 24 - **Télécopie** : 03.59.62.06.02 - **Courriel** : cppest.3@chru-nancy.fr

Projet de recherche enregistré
Sous les références
N° ID RCB: 2016-A01286-45
N° CPP: 16.09.05

Le Comité a été saisi le 14 mars 2017 par Mr le Pr Athanase BENETOS, Service de Gériatrie du CHRU de Nancy, en qualité d'investigateur principal, représentant et mandaté par JTCRC sas, promoteur, pour l'examen d'une modification substantielle n°1 apportée au protocole intitulé :

**Détection et traitement préventif de la fragilité et des comorbidités associées à l'aide de modèles personnalisés et d'interventions ciblées.**

Le Comité a examiné cette modification substantielle n°1 lors de sa séance du **4 avril 2017**. Ont participé aux délibérations :

- les membres du Collège n° 1 :
Catégorie 1 : Mr Peton (Titulaire), Mme Ayav (Suppléante), Mr Pfeiffer (Titulaire), Mr Beau (Titulaire),
Catégorie 3 : Mr Bureau (Titulaire),
Catégorie 4 : Mme Hertz (Suppléante),
- les membres du Collège n° 2 :
Catégorie 7 : Mme Batt (Titulaire), Mme Dumas Lavenac (Titulaire)
Catégorie 8 : Mme Toussaint (Titulaire), Mme Dumas Lavenac (Titulaire),
Catégorie 9 : Mr Vidal (Titulaire), Mr Lesur (Suppléant).

Le Comité a adopté la délibération suivante : **AVIS FAVORABLE** pour la modification substantielle n°1 à savoir:

- Le courrier de demande d'avis daté du 13.03.2017
- La traçabilité des changements concernant la modification substantielle n°1
- Le document additionnel daté du 13.03.2017
- Le protocole : version 3 du 13.03.2017
- Le synopsis de l'étude : version 3 du 13.03.2017
- Le formulaire d'information et de consentement groupe A : version 3 du 13.03.2017
- Le formulaire d'information et de consentement groupe B : version 3 du 13.03.2017
- Formulaire de déclaration des évènements indésirables
- Formulaire de traçabilité des prélèvements sanguins
- Notices du dispositif WWBS (2 docs)
- Notices du dispositif IMUs (2 docs)
- Notices du dispositif Coin-beacons (2 docs).

mercredi 5 avril 2017

Le Président

Docteur P. PETON

v/réf : version 3 /13.03.2017

N° enregistrement : ID RCB : 2016-A01286-45

# ETUDE « FrailSafe »

**Détection et traitement préventif de la fragilité et des comorbidités associées à l'aide de modèles personnalisés et d'interventions ciblées**

**FORMULAIRE D'INFORMATION ET DE CONSENTEMENT**

**Groupe A**

Chère Madame, Cher Monsieur,

Vous avez été sollicité(e) pour prendre part à une étude de recherche médicale. Il est par conséquent important que vous soyez informé(e) et compreniez la façon dont est menée cette étude. Nous vous remercions de prendre le temps de lire attentivement ce document et d'en parler éventuellement à votre médecin traitant. Pour toute question relative à l'étude et sa mise en place, n'hésitez pas à vous rapprocher du médecin référent de l'étude. Vous êtes entièrement libre de décider de prendre part à cette étude, ainsi que d'arrêter à tout moment. Si vous acceptez, nous vous demanderons de bien vouloir signer et dater ce formulaire de consentement, et d'en conserver une copie.

Cette étude est financée par la Commission Européenne ; elle est mise en place et gérée en France par l'INSERM.

Nous vous proposons de prendre part à cette étude parce que vous avez plus de 70 ans et êtes apte à participer à un projet sur l'identification des facteurs responsables de la fragilité des personnes âgées ; ceci à terme pourra contribuer à mieux cibler la prévention de la fragilité.

La fragilité est un état compris entre la robustesse (sujets complètement autonomes et actifs) et la dépendance (sujets ayant besoin d'aides quotidiennes pour accomplir les actes de la vie courante). Cela correspond à une diminution des réserves fonctionnelles, qui entraîne une moins bonne adaptation aux différents types de stress. La fragilité, qui se manifeste le plus souvent par de la fatigue, une faiblesse musculaire, une baisse des activités et une perte d'appétit et de poids, peut conduire à un risque plus élevé de chutes, maladies aigües, incapacités, perte d'autonomie, institutionnalisation et décès.

L'objectif de l'étude FrailSafe est de créer des recommandations de « prévention de fragilité » à partir des données des examens et tests cliniques, mais aussi à partir des informations obtenues par les moyens technologiques utilisés dans le cadre de cette étude. FrailSafe peut aider dans la recherche de nouveaux programmes de prise en charge et de maintien à domicile de personnes vieillissantes.

L'équipe du CHRU-INSERM de Nancy, dirigée par le Pr Bénétos, va recruter et suivre 120 hommes et femmes de plus de 70 ans. Ils seront répartis en deux groupes, qui vont tester le système FrailSafe. Le groupe A (80 participants) le teste 2 fois, alors que le groupe B (40 participants) le teste 9 fois. La durée de l'étude clinique sera de 31 mois pour le groupe A et 26 mois pour le groupe B.

A la suite de cette étude, les informations seront réunies, analysées, puis utilisées pour la conception d'un système innovant visant à mieux détecter et prévenir la fragilité chez les personnes âgées.

**Vous êtes inclus dans le Groupe A**, par conséquent votre durée de participation sera de 31 mois. Si vous acceptez de participer à cette étude, une consultation gérontologique et une visite à domicile seront organisées à votre inclusion.

Au début de l'étude le médecin qui en est responsable vous verra en consultation pour une **évaluation clinique**, afin de définir votre statut de fragilité. Cette consultation gérontologique sera répétée 21 et 27 mois plus tard, afin de surveiller l'évolution de votre état de santé.

Chacune de ces 3 **consultations** durera environ 2 heures. Le médecin recueillera les données démographiques (poids, taille, contacts sociaux, activité physique, antécédents médicaux), effectuera une évaluation gériatrique (mémoire, dépression, douleur, équilibre/démarche, autonomie, continence, vision, audition, nutrition, analyse de texte écrit). Il prendra votre pression artérielle et mesurera la rigidité de vos artères et votre force musculaire. Ces mesures sont non-invasives, non douloureuses, et ne présentent aucun risque pour votre santé. Il vous donnera également des questionnaires à remplir vous-même.

A la suite de votre inclusion dans l'étude, une **infirmière** diplômée d'état (IDE) vous rendra **visite à domicile** et mettra à votre disposition les outils du système FrailSafe afin de recueillir des données physiques, cognitives et environnementales. Elle vous donnera toutes les explications et vous formera à l'utilisation du matériel dont vous vous servirez pendant une période de 3 à 5 jours consécutifs (cette période est appelée par la suite « Séance »). Vous aurez au total 2 Séances : la première à la suite de votre inclusion, et la dernière 21 mois plus tard.

L'infirmière recueillera des informations sur votre logement et vos conditions de vie, et vous aidera à remplir les questionnaires qui vous ont été donnés préalablement par le médecin.

**L'équipement du système FrailSafe** se composait déjà de :

- une ceinture thoracique avec capteurs sensoriels que vous porterez de façon continue pendant la Séance afin de mesurer vos fréquences cardiaque et respiratoire. Bien entendu, vous pourrez retirer puis remettre cette ceinture quand cela vous paraitra nécessaire ;
- un téléphone mobile avec application GPS afin de mesurer vos déplacements et éventuellement communiquer avec l'infirmière ;
- une tablette numérique pour faire des jeux stimulant votre mémoire ;
- un tensiomètre électronique semi-automatique, afin de prendre 3 mesures de votre pression artérielle le matin et 3 le soir pendant la Séance.

Le concept original de l'étude FrailSafe à laquelle vous participez permet une interaction constante entre le système FrailSafe et les usagers afin de proposer des dispositifs mieux acceptés et adaptés à vos besoins. Afin de pouvoir les intégrer à l'étude, nous avons besoin de votre accord complémentaire.

Dans le but de toujours faire évoluer les outils, nous vous proposons trois nouveaux dispositifs disponibles lors des séances à votre domicile (3 à 5 jours) :

- Une veste avec des capteurs sensoriels que vous porterez pendant la séance FrailSafe afin de mesurer vos paramètres cardiaques, respiratoires ainsi que vos mouvements. Bien entendu, vous pourrez retirer puis remettre cette veste quand cela vous paraitra nécessaire ;
- Un dynamomètre électronique connecté avec une tablette numérique pour un entraînement à la fois cognitif et musculaire (jeux) ;
- Des capteurs de positionnement et de déplacement à l'intérieur du domicile.

Il vous sera demandé d'utiliser l'ensemble de ces appareils le plus souvent possible au cours d'une Séance ; cependant, seul l'usage du téléphone mobile est indispensable pour la participation dans l'étude. Toutes les méthodes utilisées sont non-invasives, non douloureuses, et ne présentent aucun risque pour votre santé.

De plus, pour certains d'entre vous, des capteurs de mouvements (IMUs) vous seront proposés lors de votre évaluation clinique. Cet enregistrement ne dure que quelques minutes.

Enfin, une analyse linguistique vous est proposée à partir d'échantillons de votre écriture ancienne et actuelle.

Les données enregistrées par ces nouveaux outils, ainsi que toutes les données recueillies dans le contexte de l'étude, seront traités à postériori et ne font pas l'objet d'une surveillance médicale immédiate. Par conséquent, elles ne contribuent pas à la détection ni à la prise en charge d'une situation d'urgence, pour laquelle si elle se présente vous continuerez à agir comme vous le feriez en dehors de l'étude (appel de votre médecin traitant, ou du 15 téléphonique etc).

Une **prise de sang unique** de 10 ml sera effectuée à la première visite de l'IDE afin de mesurer un indice de vieillissement biologique (longueur des télomères). Les prélèvements sanguins ne comportent aucun risque particulier, seule une légère douleur et éventuellement un hématome (bleu) au point de ponction peuvent apparaître. Ce prélèvement sera détruit après son analyse, et ne sera pas conservé pour constituer une biobanque.

A la fin de la période d'expérimentation, l'IDE viendra chez vous pour récupérer le matériel. En cas de besoin et si vous êtes d'accord, elle passera à votre domicile entre les visites d'installation et de récupération du matériel.

Bien entendu les consultations, visites et prêt de matériel sont tout à fait gratuits pendant la période de l'expérimentation. Les bilans gérontologiques se faisant dans les lieux où vous allez habituellement faire des activités ou à votre domicile, les frais de déplacement ne sont pas pris en charge.

L'IDE vous contactera par téléphone tous les jours pendant la Séance afin de s'assurer du bon déroulement de l'étude, ainsi qu'entre les visites pour s'informer de votre état général.

Aussi longtemps que vous participerez à l'étude, il est essentiel que vous respectiez les visites prévues et coopériez avec le médecin et l'IDE de l'étude. Cependant, ce programme sera flexible afin de ne pas trop interférer avec vos activités quotidiennes.

La décision de prendre part à cette étude est entièrement vôtre. Si vous acceptez, vous restez néanmoins libre de vous en retirer à tout moment. Votre décision n'affectera en aucun cas les soins que vous recevez.

L'accès à votre dossier médical sera strictement confidentiel. Tout transfert de données médicales sera fait en conformité avec les lois en vigueur (loi « Informatique et Libertés » du 6 janvier 1978 modifiée par la loi du 6 août 2004) ; vous bénéficierez d'un droit d'accès et de rectification aux informations qui vous concernent. Si vous souhaitez exercer ce droit et obtenir communication des informations vous concernant, vous pourrez vous adresser aux médecins chargés de l'étude. Vous pourrez également, pour des motifs légitimes, vous opposer au traitement des données vous concernant.

Toutes les données personnelles collectées durant l'étude seront strictement confidentielles et utilisées de manière anonyme (vous serez identifié par un nombre) et uniquement dans un but de recherche. Votre dossier médical et autres données personnelles générées durant l'étude pourront être examinés par le gestionnaire (INSERM), par des personnes travaillant pour le compte du gestionnaire et par des membres des Autorités de Santé.

Les résultats cliniquement significatifs vous concernant pourront être communiqués à votre médecin traitant, ceci uniquement avec votre accord.

Les données et résultats de cette étude pourront faire l'objet de publications dans des journaux médicaux ou utilisés dans des rapports scientifiques, étant entendu que ni votre nom ni vos données personnelles n'apparaîtront. Le Comité de Protection des Personnes (CPP EST III) dont votre centre dépend, et l'Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) ont approuvé cette étude. Si vous aviez la moindre question concernant cette étude, vous pouvez contacter le Dr Kotsani, le Dr Gautier, ou le Pr Bénétos (Téléphone : 03.83.15.33.22).

Je soussigné (nom et prénom)....., habitant (adresse complète)..... accepte de mon plein gré de participer à l'étude « FrailSafe ». Toutes les informations et explications sur l'étude « FrailSafe » m'ont été données par le Dr ....., qui a dirigé l'entretien de consentement sur la nature, l'objectif et la durée de l'étude. J'ai été en mesure de lui poser toutes les questions sur l'ensemble des aspects de cette étude. Le nom d'un contact m'a été donné si j'ai des questions au cours du déroulement de l'étude.

Après réflexion, j'accepte de collaborer avec le Docteur /Professeur..... et les personnes de son équipe. J'ai bien noté que j'étais libre de quitter cette étude à tout moment et que

cette décision n'affecterait pas les soins que je suis en droit d'attendre. J'ai bien noté que ce médecin garantira mes droits d'accès ou si nécessaire de modification de mes données personnelles.

Mon identité ne sera jamais révélée et toutes les données collectées seront confidentielles. J'accepte que mon dossier médical et les données générées durant l'étude soient examinés par le gestionnaire (INSERM), par des personnes travaillant pour le gestionnaire ou par les représentants des Autorités de Santé.

J'accepte / Je n'accepte pas (barrer la mention inutile) que mon praticien ou d'autres praticiens soient informés de ma participation à cette étude et éventuellement des résultats de celle-ci.

| | |
|---|---|
| Date et signature du participant | Date et signature de la personne ayant dirigé l'entretien de consentement |

v/réf : version 3 /13.03.2017

N° enregistrement : ID RCB : 2016-A01286-45

# ETUDE « FrailSafe »

**Détection et traitement préventif de la fragilité et des comorbidités associées à l'aide de modèles personnalisés et d'interventions ciblées**

**FORMULAIRE D'INFORMATION ET DE CONSENTEMENT**

**Groupe B**

Chère Madame, Cher Monsieur,

Vous avez été sollicité(e) pour prendre part à une étude de recherche médicale. Il est par conséquent important que vous soyez informé(e) et compreniez la façon dont est menée cette étude. Nous vous remercions de prendre le temps de lire attentivement ce document et d'en parler éventuellement à votre médecin traitant. Pour toute question relative à l'étude et sa mise en place, n'hésitez pas à vous rapprocher du médecin référent de l'étude. Vous êtes entièrement libre de décider de prendre part à cette étude, ainsi que d'arrêter à tout moment. Si vous acceptez, nous vous demanderons de bien vouloir signer et dater ce formulaire de consentement, et d'en conserver une copie.

Cette étude est financée par la Commission Européenne ; elle est mise en place et gérée en France par l'INSERM.

Nous vous proposons de prendre part à cette étude parce que vous avez plus de 70 ans et êtes apte à participer à un projet sur l'identification des facteurs responsables de la fragilité des personnes âgées ; ceci à terme pourra contribuer à mieux cibler la prévention de la fragilité.

La fragilité est un état compris entre la robustesse (sujets complètement autonomes et actifs) et la dépendance (sujets ayant besoin d'aides quotidiennes pour accomplir les actes de la vie courante). Cela correspond à une diminution des réserves fonctionnelles, qui entraîne une moins bonne adaptation aux différents types de stress. La fragilité, qui se manifeste le plus souvent par de la fatigue, une faiblesse musculaire, une baisse des activités et une perte d'appétit et de poids, peut conduire à un risque plus élevé de chutes, maladies aigües, incapacités, perte d'autonomie, institutionnalisation et décès.

L'objectif de cette étude est de créer des recommandations de « prévention de fragilité » à partir des données des examens et tests cliniques, mais aussi à partir des informations obtenues par les moyens technologiques utilisés dans le cadre de cette étude. FrailSafe peut aider dans la recherche de nouveaux programmes de prise en charge et de maintien à domicile de personnes vieillissantes.

L'équipe du CHRU-INSERM de Nancy, dirigée par le Pr Bénétos, va recruter et suivre 120 hommes et femmes de plus de 70 ans. Ils seront répartis en deux groupes, qui vont tester le système FrailSafe. Le groupe A (80 participants) le teste 2 fois, alors que le groupe B (40 participants) le teste 9 fois. La durée de l'étude clinique sera de 31 mois pour le groupe A et 26 mois pour le groupe B.

A la suite de cette étude, les informations seront réunies, analysées, puis utilisées pour la conception d'un système innovant visant à mieux détecter et prévenir la fragilité chez les personnes âgées.

**Vous êtes inclus dans le Groupe B**, par conséquent votre durée de participation sera de 26 mois. Si vous acceptez de participer à cette étude, une consultation gérontologique et une visite à domicile seront organisées à votre inclusion.

Au début de l'étude le médecin qui en est responsable vous verra en consultation pour une **évaluation clinique**, afin de définir votre statut de fragilité. Cette consultation gérontologique sera répétée 6 et 12 mois plus tard, ainsi qu'à la fin de l'étude (4 fois au total), afin de surveiller l'évolution de votre état de santé.

Chacune de ces **4 consultations** durera environ 2 heures. Le médecin recueillera les données démographiques (poids, taille, contacts sociaux, activité physique, antécédents médicaux), effectuera une évaluation gériatrique (mémoire, dépression, douleur, équilibre/démarche, autonomie, continence, vision, audition, nutrition, analyse de texte écrit). Il prendra votre pression et mesurera la rigidité de vos artères et votre force musculaire. Ces mesures sont non-invasives, non douloureuses, et ne présentent aucun risque pour votre santé. Il vous donnera également des questionnaires à remplir par vous-même.

A la suite de votre inclusion dans l'étude, une **infirmière** diplômée d'état (IDE) vous rendra **visite à domicile** et mettra à votre disposition les outils du système FrailSafe afin de recueillir des données physiques, cognitives et environnementales. Elle vous donnera toutes les explications et vous formera à l'utilisation du matériel dont vous vous servirez pendant une période de 3 à 5 jours consécutifs (cette période est appelée par la suite « Séance »). Vous aurez au total 9 Séances : la première à la suite de votre inclusion, puis les suivantes tous les deux mois.

L'infirmière recueillera des informations sur votre logement et vos conditions de vie, et vous aidera à remplir les questionnaires qui vous ont été donnés préalablement par le médecin.

**L'équipement du système FrailSafe** se composait déjà de :

- une ceinture thoracique avec capteurs sensoriels que vous porterez de façon continue pendant la Séance afin de mesurer vos fréquences cardiaque et respiratoire. Bien entendu, vous pourrez retirer puis remettre cette ceinture quand cela vous paraitra nécessaire ;
- un téléphone mobile avec application GPS afin de mesurer vos déplacements et éventuellement communiquer avec l'infirmière ;
- une tablette numérique pour faire des jeux stimulant votre mémoire ;
- un tensiomètre électronique semi-automatique, afin de prendre 3 mesures de votre pression artérielle le matin et 3 le soir pendant la Séance.

Le concept original de l'étude FrailSafe à laquelle vous participez permet une interaction constante entre le système FrailSafe et les usagers afin de proposer des dispositifs mieux acceptés et adaptés à vos besoins. Afin de pouvoir les intégrer à l'étude, nous avons besoin de votre accord complémentaire.

Dans le but de toujours faire évoluer les outils, nous vous proposons trois nouveaux dispositifs disponibles lors des séances à votre domicile (3 à 5 jours) :

- Une veste avec des capteurs sensoriels que vous porterez pendant la séance FrailSafe afin de mesurer vos paramètres cardiaques, respiratoires ainsi que vos mouvements. Bien entendu, vous pourrez retirer puis remettre cette veste quand cela vous paraitra nécessaire ;
- Un dynamomètre électronique connecté avec une tablette numérique pour un entraînement à la fois cognitif et musculaire (jeux) ;
- Des capteurs de positionnement et de déplacement à l'intérieur du domicile.

Il vous sera demandé d'utiliser l'ensemble de ces appareils le plus souvent possible au cours d'une Séance ; cependant, seul l'usage du téléphone mobile est indispensable pour la participation dans l'étude. Toutes les méthodes utilisées sont non-invasives, non douloureuses, et ne présentent aucun risque pour votre santé.

De plus, pour certains d'entre vous, des capteurs de mouvements (IMUs) vous seront proposés lors de votre évaluation clinique. Cet enregistrement ne dure que quelques minutes.

Enfin, une analyse linguistique vous est proposée à partir d'échantillons de votre écriture ancienne et actuelle.

Les données enregistrées par ces nouveaux outils, ainsi que toutes les données recueillies dans le contexte de l'étude, seront traités à postériori et ne font pas l'objet d'une surveillance médicale immédiate. Par conséquent, elles ne contribuent pas à la détection ni à la prise en charge d'une situation d'urgence, pour laquelle si elle se présente vous continuerez à agir comme vous le feriez en dehors de l'étude (appel de votre médecin traitant, ou du 15 téléphonique etc).

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Bien entendu les consultations, visites et prêt de matériel sont tout à fait gratuits pendant la période de l'expérimentation. Les bilans gérontologiques se faisant dans les lieux où vous allez habituellement faire des activités ou à votre domicile, les frais de déplacement ne sont pas pris en charge.

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Aussi longtemps que vous participerez à l'étude, il est essentiel que vous respectiez les visites prévues et coopériez avec le médecin et l'IDE de l'étude. Cependant, ce programme sera flexible afin de ne pas trop interférer avec vos activités quotidiennes.

La décision de prendre part à cette étude est entièrement vôtre. Si vous acceptez, vous restez néanmoins libre de vous en retirer à tout moment. Votre décision n'affectera en aucun cas les soins que vous recevez.

L'accès à votre dossier médical sera strictement confidentiel. Tout transfert de données médicales sera fait en conformité avec les lois en vigueur (loi « Informatique et Libertés » du 6 janvier 1978 modifiée par la loi du 6 août 2004) ; vous bénéficierez d'un droit d'accès et de rectification aux informations qui vous concernent. Si vous souhaitez exercer ce droit et obtenir communication des informations vous concernant, vous pourrez vous adresser aux médecins chargés de l'étude.

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Les résultats cliniquement significatifs vous concernant pourront être communiqués à votre médecin traitant, ceci uniquement avec votre accord.

Les données et résultats de cette étude pourront faire l'objet de publications dans des journaux médicaux ou utilisés dans des rapports scientifiques, étant entendu que ni votre nom ni vos données personnelles n'apparaîtront. Le Comité de Protection des Personnes (CPP EST III) dont votre centre dépend, et l'Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) ont approuvé cette étude. Si vous aviez la moindre question concernant cette étude, vous pouvez contacter le Dr Kotsani, le Dr Gautier, ou le Pr Bénétos (Téléphone : 03.83.15.33.22).

Je soussigné (nom et prénom)....., habitant (adresse complète)..... accepte de mon plein gré de participer à l'étude « FrailSafe ». Toutes les informations et explications sur l'étude « FrailSafe » m'ont été données par le Dr....., qui a dirigé l'entretien de consentement sur la nature, l'objectif et la durée de l'étude. J'ai été en mesure de lui poser toutes les questions sur l'ensemble des aspects de cette étude. Le nom d'un contact m'a été donné si j'ai des questions au cours du déroulement de l'étude.

Après réflexion, j'accepte de collaborer avec le Docteur /Professeur..... et les personnes de son équipe. J'ai bien noté que j'étais libre de quitter cette étude à tout moment et que cette décision n'affecterait pas les soins que je suis en droit d'attendre. J'ai bien noté que ce médecin garantira mes droits d'accès ou si nécessaire de modification de mes données personnelles.

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J'accepte / Je n'accepte pas (barrer la mention inutile) que mon praticien ou d'autres praticiens soient informés de ma participation à cette étude et éventuellement des résultats de celle-ci.

| | |
|---|---|
| Date et signature du participant | Date et signature de la personne ayant dirigé l'entretien de consentement |

**From Patras – University of Patras**

ΑΝΑΡΤΗΤΕΑ ΣΤΟ ΔΙΑΔΙΚΤΥΟ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
ΠΑΝΕΠΙΣΤΗΜΙΑΚΟ ΓΕΝΙΚΟ ΝΟΣΟΚΟΜΕΙΟ ΠΑΤΡΩΝ
"ΠΑΝΑΓΙΑ Η ΒΟΗΘΕΙΑ"
26504 ΡΙΟ ΠΑΤΡΩΝ

ΑΠΟΣΠΑΣΜΑ ΠΡΑΚΤΙΚΟΥ
ΤΗΣ ΑΡ.15/20-04-2016 ΤΑΚΤΙΚΗΣ ΣΥΝΕΔΡΙΑΣΗΣ
ΤΟΥ ΔΙΟΙΚΗΤΙΚΟΥ ΣΥΜΒΟΥΛΙΟΥ ΤΟΥ Π.Γ.Ν.Π.

Στην Πάτρα σήμερα 20.04.2016, ημέρα Τετάρτη και ώρα 12:45 στην αίθουσα συνεδριάσεων του Δ.Σ. του Π.Γ.Ν. Πατρών συνήλθε σε τακτική συνεδρίαση το Δ.Σ. το οποίο συγκροτήθηκε και λειτουργεί, σύμφωνα με τις αριθμ. ΔΥ1δ/Γ.Π.31408/22.4.2014 (Φ.Ε.Κ 243/ΥΟΔΔ/5.5.2014), όπως τροποποιήθηκε με την αριθμ. Αλβ/Γ.Π.: 100428/15 (ΦΕΚ 40/ΥΟΔΔ/27.1.2016), και ΔΥ16/Γ.Π.40759/19.5.2014 (Φ.Ε.Κ. 285/ΥΟΔΔ/23.5.2014) αποφάσεις του Υπουργού Υγείας .

Κατόπιν της αριθ. πρωτ. 7797/18.4.2016 πρόσκλησης της Αντιπροέδρου του Δ.Σ. ήρθαν τα τακτικά, αναπληρωματικά μέλη και εισηγητές, παρέστησαν οι :

| | |
|---|---|
| 1.ΚΩΝΣΤΑΝΤΟΠΟΥΛΟΥ ΕΙΡΗΝΗ | ΑΝΑΠΛ. ΔΙΟΙΚΗΤΡΙΑ, ΑΝΤΙΠΡΟΕΔΡΟΣ Δ.Σ |
| 2.ΤΖΟΥΤΗ ΑΘΗΝΑ | ΤΑΚΤΙΚΟ ΜΕΛΟΣ Δ.Σ |
| 3.ΜΑΛΛΙΩΡΗ-ΣΤΑΘΑΚΗ ΑΙΚΑΤΕΡΙΝΗ | ΤΑΚΤΙΚΟ ΜΕΛΟΣ Δ.Σ |
| 4.ΑΝΘΡΑΚΟΠΟΥΛΟΣ ΜΙΧΑΛΗΣ | ΤΑΚΤΙΚΟ ΜΕΛΟΣ Δ.Σ |
| 5.ΛΑΖΑΡΟΥ ΝΙΚΟΛΑΟΣ | ΤΑΚΤΙΚΟ ΜΕΛΟΣ Δ.Σ |

Ως Γραμματέας του Δ.Σ. παρέστη η υπάλληλος Καλλιόπη Μακρή.
Επίσης παρέστη ο δικηγόρος του Νοσοκομείου κος Ανδρέας Νικολετάτος.
Παρευρέθησαν, ο κος Σοφοκλής Γεωργακόπουλος Διοικητικός Διευθυντής και η κα Όλγα Οικονόμου Αν. Υποδιευθύντρια Οικονομικού, για διευκρινήσεις επί θεμάτων της αρμοδιότητάς τους, μετά τη λήξη των οποίων αποχώρησαν, ενώ το Συμβούλιο συνέχισε με τα υπόλοιπα θέματά του.

Αφού διαπιστώθηκε απαρτία το Διοικητικό Συμβούλιο προχώρησε στη συζήτηση των θεμάτων της Ημερήσιας Διάταξης τα οποία καθορίστηκαν από την αριθμ. 15/20.04.2016 πρόσκληση της Αντιπροέδρου.

**ΘΕΜΑΤΑ ΔΙΟΙΚΗΤΙΚΑ** ΑΔΑ: ΘΥΠΝ7Θ9ΟΘΓ-ΘΩΨ
**Θέμα 5ο**

Η Αντιπρόεδρος θέτει υπόψη των μελών του Δ.Σ το αριθ. πρωτ. 5954/11-4-16 διαβιβαστικό έγγραφο του Γρ. Προσωπικού το οποίο έχει ως εξής:

ΘΕΜΑ: «Έγκριση για την διεξαγωγή Μελέτης»
Σχετ:α) Η αριθ.145/06.04.2016 έγκριση του Επιστημονικού Συμβουλίου
β) Η υπ'αριθ.37/02.03.2016 απόφαση της Επιτροπής Έρευνας Ηθικής και Δεοντολογίας.

Σας υποβάλλουμε την πιο πάνω (α) σχετική έγκριση του Επιστημονικού Συμβουλίου σχετικά με την διεξαγωγή μελέτης παρακολούθησης-αξιολόγησης για την ευθραυστότητα στα πλαίσια του προγράμματος ''FRAILSAFE;; με θέμα **«sensing and predictive treatment of frailty and associated co-morbiditics using advanced personalized models and advanced interventions»**, με επιστημονικά υπεύθυνο τον Αναπληρωτή Καθηγητή Νευρολογίας κ.Ιωάννη Ελλούλ

Η παρούσα μελέτη δεν θα επιβαρύνει οικονομικά το Νοσοκομείο.

Παρακαλούμε για τη σύμφωνη γνώμη του Διοικητικού Συμβουλίου του Νοσοκομείου προκειμένου να εγκριθεί η διεξαγωγή της παραπάνω μελέτης.

Ο ΔΙΟΙΚΗΤΙΚΟΣ ΔΙΕΥΘΥΝΤΗΣ
ΣΟΦΟΚΛΗΣ ΓΕΩΡΓΑΚΟΠΟΥΛΟΣ

Το Δ.Σ αφού έλαβε υπόψη το ανωτέρω έγγραφο και μετά από διαλογική συζήτηση,

**ΟΜΟΦΩΝΑ ΑΠΟΦΑΣΙΖΕΙ**

Εγκρίνει τη διεξαγωγή μελέτης παρακολούθησης-αξιολόγησης για την ευθραυστότητα στα πλαίσια του προγράμματος ''FRAILSAFE'' με θέμα **«sensing and predictive treatment of frailty and associated co-morbiditics using advanced personalized models and advanced interventions»** και επιστημονικά υπεύθυνο τον Αναπληρωτή Καθηγητή Νευρολογίας κ.Ιωάννη Ελλούλ.

**Η ΑΝΤΙΠΡΟΕΔΡΟΣ ΤΟΥ Δ.Σ** **ΤΑ ΜΕΛΗ**

ΚΩΝΣΤΑΝΤΟΠΟΥΛΟΥ ΕΙΡΗΝΗ

ΤΖΟΥΤΗ ΑΘΗΝΑ
ΜΑΛΛΙΩΡΗ ΣΙΑΘΑΚΗ ΑΙΚ.
ΑΝΘΡΑΚΟΠΟΥΛΟΣ ΜΙΧΑΛΗΣ
ΛΑΖΑΡΟΥ ΝΙΚΟΛΑΟΣ

ΑΚΡΙΒΕΣ ΑΠΟΣΠΑΣΜΑ
Η ΑΝΤΙΓΡΑΜΜΑΤΕΑΣ ΤΟΥ Δ.Σ

ΜΑΚΡΗ ΚΑΛΛΙΟΠΗ

Committee on Research and Ethics of Univ. Hospital of Patras ,Scientific Council of Univ. Hospital of Patras ,Administrative Council of Univ. Hospital of Patras

**ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ**
**6η ΥΓΕΙΟΝΟΜΙΚΗ ΠΕΡΙΦΕΡΕΙΑ**
**ΠΑΝΕΠΙΣΤΗΜΙΑΚΟ ΓΕΝΙΚΟ ΝΟΣΟΚΟΜΕΙΟ ΠΑΤΡΩΝ**
**"ΠΑΝΑΓΙΑ Η ΒΟΗΘΕΙΑ"**
**26504 ΡΙΟ ΠΑΤΡΩΝ**

ΑΠΟΣΠΑΣΜΑ ΠΡΑΚΤΙΚΟΥ
ΤΗΣ ΑΡ.17/26.4.2017 ΤΑΚΤΙΚΗΣ ΣΥΝΕΔΡΙΑΣΗΣ
ΤΟΥ ΔΙΟΙΚΗΤΙΚΟΥ ΣΥΜΒΟΥΛΙΟΥ ΤΟΥ Π.Γ.Ν.Π.

Στην Πάτρα σήμερα **26.4.2017 ημέρα ΤΕΤΑΡΤΗ και ώρα 12.30** στην αίθουσα συνεδριάσεων του Δ.Σ. του Π.Γ.Ν. Πατρών, συνήλθε σε τακτική συνεδρίαση το Δ.Σ. το οποίο συγκροτήθηκε και λειτουργεί, σύμφωνα με την αριθμ. Α2β/Γ.Π.:38773/30.5.16 (ΦΕΚ 304/Υ.Ο.Δ.Δ/13.06.16) απόφαση του Υπουργού Υγείας, όπως τροποποιήθηκε από την αριθμ. Α2β/Γ.Π.:82556/21-11-2016 Κοινή Απόφαση του Υπουργού και Αναπλ. Υπουργού Υγείας.

Κατόπιν της αριθ. πρωτ. 9798/24.4.2017 πρόσκλησης του Προέδρου του Δ.Σ. προς τα τακτικά, αναπληρωματικά μέλη και εισηγητές, παρέστησαν στην συνεδρίαση οι :

| | |
|---|---|
| 1.ΠΙΣΙΜΙΣΗΣ ΘΕΟΔΩΡΟΣ | ΔΙΟΙΚΗΤΗΣ, ΠΡΟΕΔΡΟΣ Δ.Σ |
| 2.ΚΩΝΣΤΑΝΤΟΠΟΥΛΟΥ ΕΙΡΗΝΗ | ΑΝΑΠΛ. ΔΙΟΙΚΗΤΡΙΑ, ΑΝΤΙΠΡΟΕΔΡΟΣ Δ.Σ. |
| 3.ΤΖΟΥΤΗ ΑΘΗΝΑ | ΤΑΚΤΙΚΟ ΜΕΛΟΣ |
| 4.ΑΝΘΡΑΚΟΠΟΥΛΟΣ ΜΙΧΑΛΗΣ | ΤΑΚΤΙΚΟ ΜΕΛΟΣ Δ.Σ |
| 5.ΚΑΤΣΑΚΟΥΛΗΣ ΕΥΑΓΓΕΛΟΣ | ΤΑΚΤΙΚΟ ΜΕΛΟΣ Δ.Σ |

Ως Γραμματέας του Δ.Σ. παρέστη η υπάλληλος Αντωνία Γιαννίκα.
Επίσης παρέστη ο Δικηγόρος του Νοσοκομείου κ. Νικολετάτος
Παρευρέθησαν, ο κ. Διονύσιος Παπαδιονυσίου, Δ/κός Δ/ντής, η κα Αναστασία Κυριαζή, Αναπλ. Υποδ/ντρια Διοικητικού και η κα Όλγα Οικονόμου, Αν. Υποδιευθύντρια Οικονομικού, για διευκρινίσεις επί θεμάτων της αρμοδιότητάς τους, μετά τη λήξη των οποίων αποχώρησαν, ενώ το Συμβούλιο συνέχισε με τα υπόλοιπα θέματά του.

Αφού διαπιστώθηκε απαρτία το Διοικητικό Συμβούλιο προχώρησε στη συζήτηση των θεμάτων της Ημερήσιας Διάταξης τα οποία καθορίστηκαν από την αριθμ. 17/26.4.2017 πρόσκληση του Προέδρου.

**ΘΕΜΑΤΑ ΔΙΑΦΟΡΑ**
**ΘΕΜΑ 19ο**

Ο Πρόεδρος θέτει υπόψη των μελών του Δ.Σ την αριθ. πρωτ. 9475/19.4.17 Απόφαση του Επιστ. Συμβουλίου, το οποίο έχει ως εξής:

Το Επιστημονικό Συμβούλιο στην συνεδρίαση **12.04.2017** λαμβάνοντας υπ' όψιν την υπ. αρ. **178/04.04.2017** απόφαση της Επιτροπής Έρευνας Ηθικής και Δεοντολογίας, εγκρίνει την τροποποίηση της κάτωθι μελέτης :

**ΤΙΤΛΟΣ ΜΕΛΕΤΗΣ: " Frailsafe": sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions**

1. **Νεότερη έκδοση του AMENDMENT Reference No AMD-690140-13, του προγράμματος " Frailsafe"**

Πραγματοποιήθηκε τροποποίηση της προηγούμενης έκδοσης του **AMENDMENT** της μελέτης " Frailsafe", με σκοπό την αποσαφήνιση του τρόπου διαχείρισης και επεξεργασίας των δεδομένων που συλλέγονται από τους συμμετέχοντες κατά τη διάρκεια της μελέτης αυτής. Συγκεκριμένα, καθώς η επεξεργασία των δεδομένων που συλλέγονται από τους συμμετέχοντες πραγματοποιείται σε δεύτερο χρόνο και εκτός σύνδεσης (off line), δεν είναι δυνατή η άμεση ενημέρωση, άρα και παρέμβαση της ιατρικής ομάδας της μελέτης για τυχόν ανεπιθύμητα συμβάντα ή επείγουσες καταστάσεις π.χ. πτώσεις, αρρυθμίες κ.τ.λ., που μπορεί να προκύψουν κατά τη διάρκειά της. Σε κάθε περίπτωση, όταν διαπιστωθεί κάποιο ανεπιθύμητο συμβάν θα ενημερώνεται τόσο ο συμμετέχων όσο και ο θεράπων ιατρός του, εφ όσον το επιθυμεί ο συμμετέχων.
Οι αλλαγές πραγματοποιήθηκαν στις σελίδες: 7, 14,15,16, 55,56,65,70, 120,121,122 (επισυνάπτονται οι αναφερόμενες σελίδες, με τις αλλαγές που πραγματοποιήθηκαν υπογραμμισμένες, καθώς και μία λίστα των αλλαγών αυτών). Επίσης, παρατίθεται το έγγραφο αποδοχής των αλλαγών από την Ευρωπαϊκή Ένωση.

2. **Τροποποίηση εντύπου συγκατάθεσης και ενημέρωσης των συμμετεχόντων στη μελέτη**

Προσθήκη κειμένου σχετικά με τις αιμοληψίες που θα πραγματοποιηθούν κατά τη διάρκεια της μελέτης και προσθήκη κειμένου ενημέρωσης των συμμετεχόντων σχετικά με τη διαχείριση ανεπιθύμητων συμβάντων ή επειγουσών καταστάσεων που μπορεί να προκύψουν κατά τη διάρκεια της μελέτης.

3. **Παράθεση εντύπων ανεπιθύμητων συμβάντων ( Undesirable events/Adverse events/Serious Adverse events).**

Κατατέθηκαν και εγκρίθηκαν τα παρακάτω έγγραφα:

- Τροποποιήσεις στη νεότερη έκδοση του AMENDMENT Reference No AMD-690140-13, έγγραφο αποδοχής των τροποποιήσεων από την Ευρωπαϊκή Ένωση.
- Τροποποιημένο έντυπο συγκατάθεσης και ενημέρωσης συμμετεχόντων
- Έντυπα συμπλήρωσης ανεπιθύμητων συμβάντων

**Επιστημονικός υπεύθυνος: Ιωάννης Ελλούλ Αναπλ. Καθηγητής Νευρολογίας**
**Ερευνητές: Ιωάννης Ελλούλ**
**Ειρήνη Τσιαμάκη**

Ο ΠΡΟΕΔΡΟΣ ΤΟΥ ΕΠΙΣΤ. ΣΥΜΒΟΥΛΙΟΥ
ΚΑΘΗΓΗΤΗΣ ΜΑΡΚΟΣ ΜΑΡΑΓΚΟΣ

Το Δ.Σ αφού έλαβε υπόψη τα ανωτέρω και μετά από διαλογική συζήτηση,

**ΟΜΟΦΩΝΑ ΑΠΟΦΑΣΙΖΕΙ**

Αποδέχεται την Απόφαση του Επιστ. Συμβουλίου για έγκριση τροποποίησης της κάτωθι μελέτης με: **ΤΙΤΛΟ : " Frailsafe": sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions.**
**Επιστημονικός υπεύθυνος: Ιωάννης Ελλούλ Αναπλ. Καθηγητής Νευρολογίας**
**Ερευνητές: Ιωάννης Ελλούλ**
**Ειρήνη Τσιαμάκη**

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**Ο ΠΡΟΕΔΡΟΣ ΤΟΥ Δ.Σ**

ΠΙΣΙΜΙΣΗΣ ΘΕΟΔΩΡΟΣ

**ΑΚΡΙΒΕΣ ΑΠΟΣΠΑΣΜΑ**
Η ΓΡΑΜΜΑΤΕΑΣ ΤΟΥ Δ.Σ

ΑΝΤΩΝΙΑ ΓΙΑΝΝΙΚΑ

# Consent forms and information forms

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**

**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΑΡΧΙΚΉ ΟΜΑΔΑ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια δύο πενταήμερα (σε διάστημα περίπου 2 ετών). Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 3 φορές) και συνολικά δύο αιμοληψίες. Στα πενταήμερα της συμμετοχής σας κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς. Θα έχετε την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**

**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΚΥΡΙΑ ΟΜΑΔΑ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και

στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά 7 πενταήμερα (πέντε συνεχόμενες μέρες κάθε δύο μήνες). Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 4 φορές) και συνολικά δύο αιμοληψίες. Στα πενταήμερα της συμμετοχής σας κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**

**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΜΕΓΑΛΗ ΤΕΛΙΚΗ ΟΜΑΔΑ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 2 φορές στο διάστημα ων έξι μηνών) και συνολικά δύο αιμοληψίες. Για τρία πενταήμερα (πέντε συνεχόμενες μέρες κάθε δύο μήνες) κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας δοθούν συμβουλές καλύτερης διατροφής, καθώς και μια σειρά (ή οδηγίες) ασκήσεων ενδυνάμωσης. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**

**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΜΙΚΡΗ ΤΕΛΙΚΗ ΟΜΑΔΑ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 2 φορές στο διάστημα των έξι μηνών) και συνολικά δύο αιμοληψίες. Για δύο μήνες, από Δευτέρα έως Παρασκευή, κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που ελέγχει τη λειτουργία της καρδιάς και της αναπνοής. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας

ηλεκτρονικώς. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας δοθούν συμβουλές καλύτερης διατροφής, καθώς και μια σειρά (ή οδηγίες) ασκήσεων ενδυνάμωσης. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**

**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΟΜΑΔΑ ΕΛΕΓΧΟΥ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό πουσήμερα λέγεται ευθραυστότητα στουςηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 2 φορές). Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Στο τέλος θα συμπληρώσετε προφορικά ένα ερωτηματολόγιο. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ**

Ενημερώθηκα από τους συνεργάτες του προγράμματος για την Μελέτη της Ευθραυστότητας των ηλικιωμένων. Μου δόθηκε επίσης κείμενο που περιγράφει τις συνθήκες της συμμετοχής μου στην μελέτη. Διάβασα το κείμενο και μου απαντήθηκαν όλες μου οι απορίες. Μου δόθηκε ο απαραίτητος χρόνος να το σκεφτώ και τελικά αποφασίζω να συμμετέχω. Γνωρίζω ότι οποτεδήποτε το αποφασίσω μπορώ, χωρίς να δώσω καμία εξήγηση, να διακόψω την συμμετοχή μου στην μελέτη.

Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**

**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΑΡΧΙΚΉ ΟΜΑΔΑ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια δύο πενταήμερα (σε διάστημα περίπου 2 ετών). Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 3 φορές) και συνολικά δύο αιμοληψίες που θα αφορούν στη μελέτη παραγόντων όπως πχ δεικτών φλεγμονής, βιταμίνης D κ.α. που πιθανόν σχετίζονται με την παρουσία του συνδρόμου ευθραυστότητας ( μελέτη που θα πραγματοποιηθεί στο Πανεπιστήμιο μας) καθώς και την εκτίμηση του μεγέθους των τελομερών, που έχει βρεθεί ότι σχετίζεται με αυξημένη προδιάθεση για την παρουσία του συνδρόμου ( μελέτη η οποία θα πραγματοποιηθεί σε εργαστήριο στη Γαλλία) . Στα πενταήμερα της συμμετοχής σας κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής.. Θα έχετε την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς, οι οποίοι θα τα επεξεργάζονται εκτός σύνδεσης (off line) και σε δεύτερο χρόνο. Για το λόγο αυτό, το σύστημα δεν παρέχει τη δυνατότητα άμεσης αντιμετώπισης επειγουσών καταστάσεων που μπορεί να προκύψουν . Οτιδήποτε προκύψει από την κλινική εξέταση για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός σας, θα σας γνωστοποιηθεί. Όπως επίσης, ο,τιδήποτε παθολογικό γίνει αντιληπτό κατά την μετέπειτα επεξεργασία των δεδομένων σας.

Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράψετε κάποιες προτάσεις.. Κάθε 3 μήνες ένας από τους

συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**

**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΚΥΡΙΑ ΟΜΑΔΑ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά 7 πενταήμερα (πέντε συνεχόμενες μέρες κάθε δύο μήνες). Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 4 φορές) και συνολικά δύο αιμοληψίες που θα αφορούν στη μελέτη παραγόντων όπως πχ δεικτών φλεγμονής, βιταμίνης D κ.α. που πιθανόν σχετίζονται με την παρουσία του συνδρόμου ευθραυστότητας ( μελέτη που θα πραγματοποιηθεί στο Πανεπιστήμιο μας) καθώς και την εκτίμηση του μεγέθους των τελομερών, που έχει βρεθεί ότι σχετίζεται με αυξημένη προδιάθεση για την παρουσία του συνδρόμου ( μελέτη η οποία θα πραγματοποιηθεί σε εργαστήριο στη Γαλλία) . Στα πενταήμερα της συμμετοχής σας κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής.. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς, οι οποίοι θα τα επεξεργάζονται εκτός σύνδεσης (off line) και σε δεύτερο χρόνο. Για το λόγο αυτό, το σύστημα δεν παρέχει τη δυνατότητα άμεσης αντιμετώπισης επειγουσών καταστάσεων που μπορεί να προκύψουν . Οτιδήποτε προκύψει από την κλινική εξέταση για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός σας, θα σας γνωστοποιηθεί. Όπως

επίσης, ο,τιδήποτε παθολογικό γίνει αντιληπτό κατά την μετέπειτα επεξεργασία των δεδομένων σας.

Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις.. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

frail safe

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**

**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΜΕΓΑΛΗ ΤΕΛΙΚΗ ΟΜΑΔΑ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που

καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 2 φορές στο διάστημα ων έξι μηνών) και συνολικά δύο αιμοληψίες που θα αφορούν στη μελέτη παραγόντων όπως πχ δεικτών φλεγμονής, βιταμίνης D κ.α. που πιθανόν σχετίζονται με την παρουσία του συνδρόμου ευθραυστότητας ( μελέτη που θα πραγματοποιηθεί στο Πανεπιστήμιο μας) καθώς και την εκτίμηση του μεγέθους των τελομερών, που έχει βρεθεί ότι σχετίζεται με αυξημένη προδιάθεση για την παρουσία του συνδρόμου ( μελέτη η οποία θα πραγματοποιηθεί σε εργαστήριο στη Γαλλία) . Για τρία πενταήμερα (πέντε συνεχόμενες μέρες κάθε δύο μήνες) κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής.. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας δοθούν συμβουλές καλύτερης διατροφής, καθώς και μια σειρά (ή οδηγίες) ασκήσεων ενδυνάμωσης. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις..

Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς, οι οποίοι θα τα επεξεργάζονται εκτός σύνδεσης (off line) και σε δεύτερο χρόνο. Για το λόγο αυτό, το σύστημα δεν παρέχει τη δυνατότητα άμεσης αντιμετώπισης επειγουσών καταστάσεων που μπορεί να προκύψουν . Οτιδήποτε προκύψει από την κλινική εξέταση για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός σας, θα σας γνωστοποιηθεί. Όπως επίσης, ο,τιδήποτε παθολογικό γίνει αντιληπτό κατά την μετέπειτα επεξεργασία των δεδομένων σας.

Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**
**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΜΙΚΡΗ ΤΕΛΙΚΗ ΟΜΑΔΑ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 2 φορές στο διάστημα των έξι μηνών) και συνολικά δύο αιμοληψίες που θα αφορούν στη μελέτη παραγόντων όπως πχ δεικτών φλεγμονής, βιταμίνης D κ.α. που πιθανόν σχετίζονται με την παρουσία του συνδρόμου ευθραυστότητας ( μελέτη που θα πραγματοποιηθεί στο Πανεπιστήμιο μας) καθώς και την εκτίμηση του μεγέθους των τελομερών, που έχει βρεθεί ότι σχετίζεται με αυξημένη προδιάθεση για την παρουσία του συνδρόμου ( μελέτη η οποία θα πραγματοποιηθεί σε εργαστήριο στη Γαλλία) . Για δύο μήνες, από Δευτέρα έως Παρασκευή, κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που ελέγχει τη λειτουργία της καρδιάς και της αναπνοής.. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας δοθούν συμβουλές καλύτερης διατροφής, καθώς και μια σειρά (ή οδηγίες) ασκήσεων ενδυνάμωσης.

Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς, οι οποίοι θα τα επεξεργάζονται εκτός σύνδεσης (off line) και σε δεύτερο χρόνο. Για το λόγο αυτό, το σύστημα δεν παρέχει τη δυνατότητα άμεσης αντιμετώπισης επειγουσών καταστάσεων που μπορεί να προκύψουν . Οτιδήποτε προκύψει από την κλινική εξέταση για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός σας, θα σας γνωστοποιηθεί. Όπως επίσης, ο,τιδήποτε παθολογικό γίνει αντιληπτό κατά την μετέπειτα επεξεργασία των δεδομένων σας.

Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις.. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ**
**ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΟΜΑΔΑ ΕΛΕΓΧΟΥ**

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια στις μελλοντικές σας ιατρικές υπηρεσίες.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (γιατρό, νοσηλευτή και ψυχολόγο) θα έχετε μια πλήρη ιατρική κλινική εξέταση (συνολικά 2 φορές). Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις.Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Στο τέλος θα συμπληρώσετε προφορικά ένα ερωτηματολόγιο. Η ανωνυμία σας θα είναι εξασφαλισμένη.

**ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ**

Ενημερώθηκα από τους συνεργάτες του προγράμματος για την Μελέτη της Ευθραυστότητας των ηλικιωμένων. Μου δόθηκε επίσης κείμενο που περιγράφει τις συνθήκες της συμμετοχής μου στην μελέτη. Διάβασα το κείμενο και μου απαντήθηκαν όλες μου οι απορίες. Μου δόθηκε ο απαραίτητος χρόνος να το σκεφτώ και τελικά αποφασίζω να συμμετέχω. Γνωρίζω ότι οποτεδήποτε το αποφασίσω μπορώ, χωρίς να δώσω καμία εξήγηση, να διακόψω την συμμετοχή μου στην μελέτη.

Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

## From Cyprus – Materia Group

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ

**ΕΘΝΙΚΗ ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΥΠΡΟΥ**

**Αρ. Φακ.:**ΕΕΒΚ ΕΠ 2016.01.109
**Αρ. Τηλ.:**22809038/039
**Αρ. Φαξ:** 22353878

15 Σεπτεμβρίου 2016

Κυρία Μαρίνα Πολυκάρπου
Αθαλάσσης 41
2221 Λατσιά

**Θέμα: «Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions»**

Αναφέρομαι στην αίτηση σας ημερομηνίας 14 Σεπτεμβρίου 2016 για το πιο πάνω θέμα, και επιθυμώ να σας πληροφορήσω ότι από τη μελέτη του περιεχομένου των εγγράφων που έχετε καταθέσει (καλυπτική επιστολή, πρωτόκολλο, έντυπα συγκατάθεσης και ερευνητικά εργαλεία), που αφορούν την πιο πάνω έρευνα, έχω την κατ' αρχήν γνώμη ότι η εν λόγω έρευνα σας **δεν χρήζει** περαιτέρω βιοηθικής αξιολόγησης από την Εθνική Επιτροπή Βιοηθικής Κύπρου (ΕΕΒΚ). Παρακαλούμε σημειώστε ότι το έντυπο ΕΕΒΚ02 δεν λήφθηκε υπόψη, καθότι η αίτηση σας είναι αίτηση για γνωμοδότηση.

2. Τελική γνώμη θα εκφέρουμε όταν κατατεθούν τα μεταφρασμένα και σταθμισμένα στην ελληνική γλώσσα ερευνητικά εργαλεία.

3. Σας ενημερώνουμε ότι για σκοπούς καλύτερου συντονισμού και αποφυγής επανάληψης ερευνών με το ίδιο θέμα ή/και υπό εξέταση πληθυσμό μέσα σε σύντομο σχετικά χρονικό διάστημα, η ΕΕΒΚ δημοσιεύει στην ιστοσελίδα της το θέμα της έρευνας, τον φορέα και τον υπό εξέταση πληθυσμό.

Με εκτίμηση,

Δρ. Κωνσταντίνος Ν. Φελλάς
Πρόεδρος
Εθνικής Επιτροπής Βιοηθικής Κύπρου

Κέντρο Υγείας Έγκωμης, Νίκου Κρανιδιώτη, 2411 Λευκωσία,
*Ηλεκτρονικό Ταχυδρομείο:* cnbc@bioethics.gov.cy *Ιστοσελίδα:* www.bioethics.gov.cy

ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
**ΕΘΝΙΚΗ ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΥΠΡΟΥ**

**Αρ. Φακ.:** ΕΕΒΚ ΕΠ 2016.01.109
**Αρ. Τηλ.:**22809038/039
**Αρ. Φαξ:** 22353878

14 Ιουλίου 2017

Κα Μαρίνα Πολυκάρπου
Αθαλάσσης 41
2221 Λατσιά
Λευκωσία

**Αίτηση γνωμοδότησης για την πρόταση με τίτλο:**
**«Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions»**

Σε συνέχεια προηγούμενης μας αλληλογραφίας ημερομηνίας 10 Ιανουαρίου 2017 για το πιο πάνω θέμα, θα θέλαμε να σας ευχαριστήσουμε για το αναθεωρημένο έντυπο πληροφόρησης συμμετεχόντων που καταθέσατε στις 09 Ιουνίου 2017.

Με εκτίμηση,

Καθ. Κωνσταντίνος Ν. Φελλάς
Πρόεδρος
Εθνικής Επιτροπής Βιοηθικής Κύπρου

ΕΘΝΙΚΗ ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΥΠΡΟΥ

Κέντρο Υγείας Έγκωμης, Νίκου Κρανιδιώτη, 2411 Λευκωσία,

# C2. Consent forms and information forms

**ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ**

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από 2 σελίδες)

Καλείστε να συμμετάσχετε σε ένα ερευνητικό πρόγραμμα. Πιο κάτω (βλ. **«Πληροφορίες για Ασθενείς ή/και Εθελοντές»**) θα σας δοθούν εξηγήσεις σε απλή γλώσσα σχετικά με το τι θα ζητηθεί από εσάς ή/και τι θα σας συμβεί σε εσάς, εάν συμφωνήσετε να συμμετάσχετε στο πρόγραμμα. Θα σας περιγραφούν οποιοιδήποτε κίνδυνοι μπορεί να υπάρξουν ή ταλαιπωρία που τυχόν θα υποστείτε από την συμμετοχή σας στο πρόγραμμα. Θα σας επεξηγηθεί με κάθε λεπτομέρεια τι θα ζητηθεί από εσάς και ποιος ή ποιοι θα έχουν πρόσβαση στις πληροφορίες ή/και άλλο υλικό που εθελοντικά θα δώσετε για το πρόγραμμα. Θα σας δοθεί η χρονική περίοδος για την οποία οι υπεύθυνοι του προγράμματος θα έχουν πρόσβαση στις πληροφορίες ή/και υλικό που θα δώσετε. Θα σας επεξηγηθεί τι ελπίζουμε να μάθουμε από το πρόγραμμα σαν αποτέλεσμα και της δικής σας συμμετοχής. Επίσης, θα σας δοθεί μία εκτίμηση για το όφελος που μπορεί να υπάρξει για τους ερευνητές ή/και χρηματοδότες αυτού του προγράμματος. **Δεν πρέπει να συμμετάσχετε, εάν δεν επιθυμείτε ή εάν έχετε οποιουσδήποτε ενδοιασμούς που αφορούν την συμμετοχή σας στο πρόγραμμα.** Εάν αποφασίσετε να συμμετάσχετε, πρέπει να αναφέρετε εάν είχατε συμμετάσχει σε οποιοδήποτε άλλο πρόγραμμα έρευνας μέσα στους τελευταίους 12 μήνες. Εάν αποφασίσετε να μην συμμετάσχετε και είστε ασθενής, η θεραπεία σας δεν θα επηρεαστεί από την απόφασή σας. **Είστε ελεύθεροι να αποσύρετε οποιαδήποτε στιγμή εσείς επιθυμείτε την συγκατάθεση για την συμμετοχή σας στο πρόγραμμα.** Εάν είστε ασθενής, η απόφασή σας να αποσύρετε την συγκατάθεση σας, δεν θα έχει οποιεσδήποτε επιπτώσεις στην θεραπεία σας. Έχετε το δικαίωμα να υποβάλετε τυχόν παράπονα ή καταγγελίες, που αφορούν το πρόγραμμα στο οποίο συμμετέχετε, προς την Επιτροπή Βιοηθικής που ενέκρινε το πρόγραμμα ή ακόμη και στην Εθνική Επιτροπή Βιοηθικής Κύπρου.

Πρέπει όλες οι σελίδες των εντύπων συγκατάθεσης να φέρουν το ονοματεπώνυμο και την υπογραφή σας.

| Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε |
|---|
| **Ευρωπαϊκό Πρόγραμμα Horizon 2020 – Ευθραυστότητα και Ενεργός Γήρανση** |
| Υπεύθυνος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε |
| MARINA POLYCARPOU |

| | | | |
|---|---|---|---|
| Επίθετο: | POLYCARPOU …… | Όνομα: | MARINA …… |
| Υπογραφή: | | Ημερομηνία: | 13/09/2016 |

| **ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ**<br>για συμμετοχή σε πρόγραμμα έρευνας<br>(Τα έντυπα αποτελούνται συνολικά από 2 σελίδες) |
|---|
| Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε |
| **Ευρωπαϊκό Πρόγραμμα Horizon 2020 – Ευθραυστότητα και Ενεργός Γήρανση** |

| | |
|---|---|
| Δίδετε συγκατάθεση για τον εαυτό σας ή για κάποιο άλλο άτομο; | |
| Εάν πιο πάνω απαντήσατε για κάποιον άλλο, τότε δώσετε λεπτομέρειες και το όνομα του. | |
| | |

| Ερώτηση | ΝΑΙ ή ΟΧΙ |
|---|---|
| Συμπληρώσατε τα έντυπα συγκατάθεσης εσείς προσωπικά; | |
| Τους τελευταίους 12 μήνες έχετε συμμετάσχει σε οποιοδήποτε άλλο ερευνητικό πρόγραμμα; | |
| Διαβάσατε και καταλάβατε τις πληροφορίες για ασθενείς ή/και εθελοντές; | |
| Είχατε την ευκαιρία να ρωτήσετε ερωτήσεις και να συζητήσετε το Πρόγραμμα; | |

| | |
|---|---|
| Δόθηκαν ικανοποιητικές απαντήσεις και εξηγήσεις στα τυχόν ερωτήματά σας; | |
| Καταλαβαίνετε ότι μπορείτε να αποσυρθείτε από το πρόγραμμα, όποτε θέλετε; | |
| Καταλαβαίνετε ότι, εάν αποσυρθείτε, δεν είναι αναγκαίο να δώσετε οποιεσδήποτε εξηγήσεις για την απόφαση που πήρατε; | |
| (Για ασθενείς) καταλαβαίνετε ότι, εάν αποσυρθείτε, δεν θα υπάρξουν επιπτώσεις στην τυχόν θεραπεία που παίρνετε ή που μπορεί να πάρετε μελλοντικά; | |
| **Συμφωνείτε να συμμετάσχετε στο πρόγραμμα;** | |
| Με ποιόν υπεύθυνο μιλήσατε; | |

| | | | |
|---|---|---|---|
| Επίθετο: | …… | Όνομα: | …… |
| Υπογραφή: | | Ημερομηνία: | |

**ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ**

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από 2 σελίδες)

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

**Ευρωπαϊκό Πρόγραμμα Horizon 2020 – Ευθραυστότητα και Ενεργός Γήρανση**

## ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ή/και ΕΘΕΛΟΝΤΕΣ

ΟΜΙΛΟΣ ΜΑΤΕΡΙΑ
ΦΡΟΝΤΙΔΑ - ΝΟΣΗΛΕΙΑ - ΑΠΟΚΑΤΑΣΤΑΣΗ

Horizon 2020
European Union funding
for Research & Innovation

frail safe

### ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ

### ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΑΡΧΙΚΉ ΟΜΑΔΑ

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια δύο πενταήμερα (σε διάστημα περίπου 2 ετών). Από συνεργάτες μας (νοσηλευτή και ψυχολόγο) θα έχετε μια κλινική αξιολόγηση (συνολικά 3 φορές). Στα πενταήμερα της συμμετοχής σας κατά την διάρκεια της

ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς. Θα έχετε την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

| **ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ**<br>για συμμετοχή σε πρόγραμμα έρευνας<br>(Τα έντυπα αποτελούνται συνολικά από 2 σελίδες) |
|---|
| Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε |
| **Ευρωπαϊκό Πρόγραμμα Horizon 2020 – Ευθραυστότητα και Ενεργός Γήρανση** |

## ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ή/και ΕΘΕΛΟΝΤΕΣ, συνέχεια:

**ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ**

Ενημερώθηκα από τους συνεργάτες του προγράμματος για την Μελέτη της Ευθραυστότητας των ηλικιωμένων. Μου δόθηκε επίσης κείμενο που περιγράφει τις συνθήκες της συμμετοχής μου στην μελέτη. Διάβασα το κείμενο και μου απαντήθηκαν όλες μου οι απορίες. Μου δόθηκε ο απαραίτητος χρόνος να το σκεφτώ και τελικά αποφασίζω να συμμετέχω. Γνωρίζω ότι οποτεδήποτε το αποφασίσω μπορώ, χωρίς να δώσω καμία εξήγηση, να διακόψω την συμμετοχή μου στην μελέτη.

Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

| | | | |
|---|---|---|---|
| Επίθετο: | …… | Όνομα: | …… |
| Υπογραφή: | | Ημερομηνία: | |

## ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ

## ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΚΥΡΙΑ ΟΜΑΔΑ

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά 7 πενταήμερα (πέντε συνεχόμενες μέρες κάθε δύο μήνες). Από συνεργάτες μας (νοσηλευτή και ψυχολόγο) θα έχετε μια κλινική αξιολόγηση (συνολικά 4 φορές). Στα πενταήμερα της συμμετοχής σας κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

# ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από 2 σελίδες)

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

**Ευρωπαϊκό Πρόγραμμα Horizon 2020 – Ευθραυστότητα και Ενεργός Γήρανση**

## ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ή/και ΕΘΕΛΟΝΤΕΣ, συνέχεια:

**ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ**

Ενημερώθηκα από τους συνεργάτες του προγράμματος για την Μελέτη της Ευθραυστότητας των ηλικιωμένων. Μου δόθηκε επίσης κείμενο που περιγράφει τις συνθήκες της συμμετοχής μου στην μελέτη. Διάβασα το κείμενο και μου απαντήθηκαν όλες μου οι απορίες. Μου δόθηκε ο απαραίτητος χρόνος να το σκεφτώ και τελικά αποφασίζω να συμμετέχω. Γνωρίζω ότι οποτεδήποτε το αποφασίσω μπορώ, χωρίς να δώσω καμία εξήγηση, να διακόψω την συμμετοχή μου στην μελέτη.

Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

| | | | |
|---|---|---|---|
| Επίθετο: | …… | Όνομα: | …… |
| Υπογραφή: | | Ημερομηνία: | |

## ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ

## ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΜΕΓΑΛΗ ΤΕΛΙΚΗ ΟΜΑΔΑ

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (νοσηλευτή και ψυχολόγο) θα έχετε μια κλινική αξιολόγηση (συνολικά 2 φορές στο διάστημα των έξι μηνών). Για τρία πενταήμερα (πέντε συνεχόμενες μέρες κάθε δύο μήνες) κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που θα ελέγχει τη λειτουργία της καρδιάς και της αναπνοής. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας δοθούν συμβουλές καλύτερης διατροφής, καθώς και μια σειρά (ή οδηγίες) ασκήσεων ενδυνάμωσης. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

# ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από 2 σελίδες)

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

**Ευρωπαϊκό Πρόγραμμα Horizon 2020 – Ευθραυστότητα και Ενεργός Γήρανση**

## ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ή/και ΕΘΕΛΟΝΤΕΣ, συνέχεια:

**ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ**

Ενημερώθηκα από τους συνεργάτες του προγράμματος για την Μελέτη της Ευθραυστότητας των ηλικιωμένων. Μου δόθηκε επίσης κείμενο που περιγράφει τις συνθήκες της συμμετοχής μου στην μελέτη. Διάβασα το κείμενο και μου απαντήθηκαν όλες μου οι απορίες. Μου δόθηκε ο απαραίτητος χρόνος να το σκεφτώ και τελικά αποφασίζω να συμμετέχω. Γνωρίζω ότι οποτεδήποτε το αποφασίσω μπορώ, χωρίς να δώσω καμία εξήγηση, να διακόψω την συμμετοχή μου στην μελέτη.

Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

| | | | |
|---|---|---|---|
| Επίθετο: | …… | Όνομα: | …… |
| Υπογραφή: | | Ημερομηνία: | |

## ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ

## ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΜΙΚΡΗ ΤΕΛΙΚΗ ΟΜΑΔΑ

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (νοσηλευτή και ψυχολόγο) θα έχετε μια κλινική αξιολόγηση (συνολικά 2 φορές στο διάστημα των έξι μηνών). Για δύο μήνες, από Δευτέρα έως Παρασκευή, κατά την διάρκεια της ημέρας και για όση ώρα το επιθυμείτε, θα φοράτε ένα μπλουζάκι που ελέγχει τη λειτουργία της καρδιάς και της αναπνοής. Τα δεδομένα σας θα μεταδίδονται αυτόματα στους συνεργάτες μας ηλεκτρονικώς. Θα έχετε επίσης την ευκαιρία να χρησιμοποιήσετε, με την βοήθεια του νοσηλευτή ή του ψυχολόγου μας, τάμπλετ με ειδικά σχεδιασμένα παιχνίδια και γυαλιά με τρισδιάστατα παιχνίδια. Θα έχετε μαζί σας ένα κινητό τηλέφωνο που θα μετράει πόσα βήματα κάνετε και πόση απόσταση διανύετε την ημέρα, μέσα και έξω από το σπίτι σας. Επίσης θα τοποθετήσουμε στο σπίτι σας μια μικρή συσκευή που θα μας πληροφορεί πόσο συχνά μετακινείστε ή αλλάζετε δωμάτιο κατά τη διάρκεια της ημέρας. Θα σας δοθούν συμβουλές καλύτερης διατροφής, καθώς και μια σειρά (ή οδηγίες) ασκήσεων ενδυνάμωσης. Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Κάθε 3 μήνες ένας από τους συνεργάτες μας θα επικοινωνεί μαζί σας τηλεφωνικά για να σας κάνει μερικές ερωτήσεις. Η ανωνυμία σας θα είναι εξασφαλισμένη.

# ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από 2 σελίδες)

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

**Ευρωπαϊκό Πρόγραμμα Horizon 2020 – Ευθραυστότητα και Ενεργός Γήρανση**

## ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ή/και ΕΘΕΛΟΝΤΕΣ, συνέχεια:

**ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ**

Ενημερώθηκα από τους συνεργάτες του προγράμματος για την Μελέτη της Ευθραυστότητας των ηλικιωμένων. Μου δόθηκε επίσης κείμενο που περιγράφει τις συνθήκες της συμμετοχής μου στην μελέτη. Διάβασα το κείμενο και μου απαντήθηκαν όλες μου οι απορίες. Μου δόθηκε ο απαραίτητος χρόνος να το σκεφτώ και τελικά αποφασίζω να συμμετέχω. Γνωρίζω ότι οποτεδήποτε το αποφασίσω μπορώ, χωρίς να δώσω καμία εξήγηση, να διακόψω την συμμετοχή μου στην μελέτη.

Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

| | | | |
|---|---|---|---|
| Επίθετο: | …… | Όνομα: | …… |
| Υπογραφή: | | Ημερομηνία: | |

## ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ

## ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΟΜΑΔΑ ΕΛΕΓΧΟΥ

Σας προσκαλούμε να πάρετε μέρος σε αυτή την Ευρωπαϊκή μελέτη που αφορά άτομα, άνδρες και γυναίκες, άνω των 70 ετών. Μελετάμε εκείνες τις καταστάσεις που καθιστούν τους μεγαλύτερους σε ηλικία ανθρώπους πιο ευάλωτους στις πτώσεις και στη νοσηλεία σε νοσοκομείο. Μελετάμε αυτό που σήμερα λέγεται ευθραυστότητα στους ηλικιωμένους.

Η συμμετοχή σας είναι εθελοντική και δεν θα σας επιβαρύνει με κανένα χρηματικό κόστος. Επιπλέον δεν θα γίνει καμία αλλαγή στη φαρμακευτική σας αγωγή. Εφόσον συμφωνήσετε να συμμετάσχετε, θα σας ζητηθεί να υπογράψετε ένα έγγραφο συγκατάθεσης. Οποτεδήποτε, όμως, αλλάξετε γνώμη και θελήσετε να διακόψετε την συμμετοχή σας, αυτό μπορεί να γίνει άμεσα, χωρίς να χρειασθεί να δώσετε καμία εξήγηση και φυσικά χωρίς καμία συνέπεια.

**Τι θα κάνω στη μελέτη;**

Η συμμετοχή σας θα έχει διάρκεια συνολικά έξι μήνες. Από συνεργάτες μας (νοσηλευτή και ψυχολόγο) θα έχετε μια κλινική αξιολόγηση (συνολικά 2 φορές). Θα σας ζητήσουμε να μας δώσετε, εφόσον το επιθυμείτε, γραπτά κείμενά σας, καθώς και να μας γράφετε κάποιες προτάσεις. Οτιδήποτε προκύψει από τις μετρήσεις σας για το οποίο χρειάζεται να ενημερωθεί ο θεράπων ιατρός θα σας γνωστοποιηθεί. Στο τέλος θα συμπληρώσετε προφορικά ένα ερωτηματολόγιο. Η ανωνυμία σας θα είναι εξασφαλισμένη.

# ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ

για συμμετοχή σε πρόγραμμα έρευνας

(Τα έντυπα αποτελούνται συνολικά από 2 σελίδες)

Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε

**Ευρωπαϊκό Πρόγραμμα Horizon 2020 – Ευθραυστότητα και Ενεργός Γήρανση**

## ΠΛΗΡΟΦΟΡΙΕΣ ΓΙΑ ΑΣΘΕΝΕΙΣ ή/και ΕΘΕΛΟΝΤΕΣ, συνέχεια:

**ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ**

Ενημερώθηκα από τους συνεργάτες του προγράμματος για την Μελέτη της Ευθραυστότητας των ηλικιωμένων. Μου δόθηκε επίσης κείμενο που περιγράφει τις συνθήκες της συμμετοχής μου στην μελέτη. Διάβασα το κείμενο και μου απαντήθηκαν όλες μου οι απορίες. Μου δόθηκε ο απαραίτητος χρόνος να το σκεφτώ και τελικά αποφασίζω να συμμετέχω. Γνωρίζω ότι οποτεδήποτε το αποφασίσω μπορώ, χωρίς να δώσω καμία εξήγηση, να διακόψω την συμμετοχή μου στην μελέτη.

Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

| | | | |
|---|---|---|---|
| Επίθετο: | …… | Όνομα: | …… |
| Υπογραφή: | | Ημερομηνία: | |

## *B. Prof Maggi letter*

National Research Council of Italy
INSTITUTE OF NEUROSCIENCE
Pisa Padova Milano Cagliari Firenze-Pisa

Padua, December 23, 2016

I have read with interest the manual of the Ethics, Safety, and mHealth Barriers for the FrailSafe project.

I believe that all issues are dealt appropriately and with a comprehensive approach.

Firstly, the privacy, safety, security and legal key issues that are related to the FrailSafe project and especially to the components associated to the innovative mHealth nature are identified.

Secondly, the manual provides the project's strategy to solve these issues and to minimize any related risk that may rise in the course of the project.

All appropriate European directives are reported in detail.

All these aspects considered, the current deliverable represents a document that will need to be continuously updated during the course of the project in order to address any emerging needs and requirements and to cover any additional risks identified.

Stefania Maggi

Stefania Maggi, MD, MPH, PhD
Ethics Supervisor
FrailSafe project

National Research Council of Italy
**INSTITUTE OF NEUROSCIENCE**
Pisa Padova Milano Cagliari Firenze-Pisa

Padua, July 5, 2017

With reference to my positive assessment of the FraiSafe project manual, sent on December 2016,

and the current request to express my opinion regarding the data protection issue in the cloud,

I hereby notify to have discussed in detail and to have revised the documentation prepared by SIGLA and by an external legal expert (Prof. Elena Bassoli, studiolegalebassoli@gmail.com).

All these aspects considered, the current protocol and activities ensure that the necessary steps have been taken in order to guarantee the data protection and the compliance to the new GDPR.

Stefania Maggi, MD, MPH, PhD
Ethics Supervisor
FrailSafe project

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