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Periodic Management Report (vers. b)

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Lead Author:	Megalooikonomou Vasileios (UoP)
Lead partners:	John Ellul, Dimitrios Vlachakis, Konstantinos Deltouzos, Georgios Drakopoulos, Andreas Kanavos, Vasileios Megaloikonomou, Evaggelia Pippa, Kyriakos Sgarbas (UoP), Roberto Orselli (SMARTEX), Ioanna Petridou (MATERIA), Cristiana Degano, Luca Bianconi (SIGLA), Javier Montesa (BRA), Athanase Benetos, Marina Kotsani (INSERM), Kosmas Petridis (HYPERTECH), Nhu Tram (AGE), Konstantinos Moustakas, Elias Kalamaras, Andreas Vasilakis, Konstantinos Votis, Dimitrios Tzovaras (CERTH)

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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, detect, predict, delay or even revert frailty. To achieve these aims plans are made to devise a comprehensive clinical assessment, to develop a 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 system and cost effective system.

Progress was made in all work packages. For this first annual report, an extensive list of the completed deliverables is provided together with the expected milestone achievements. A review of the state-of-the-art has been conducted in frailty models and metrics. Technical aspects related to software and hardware components, such as sensing systems, virtual patient modeling, data mining, information visualization, virtual and augmented reality games and personalized guidance systems were also reviewed, in order to provide sound study methodologies and a first proposal of system architecture. A comprehensive clinical protocol was agreed and reported including a face-to-face clinical assessment, self-administrated questionnaires, text sampling, and phone follow up assessment. The expected outcomes of the study have also been clarified. Physiological parameters to monitor have been listed and the specifications of the devices have been described. A data flow and in good detail high-level overall system architecture and specifications, detailing the distinct system components, their interconnections and security features were devised. After the analysis of user requirements and following a user-centered design methodology, a detailed set of use cases and a set of procedures to be applied with the users, has been put together. The dynamic user profiling models and patient modeling and representation framework has been designed and implemented. A first version of the linguistic analysis tool has been developed and preliminary test results have become available. In addition, some initial efforts have been focused on discovering a set of relevant and informative indicators for frailty, the state-of-the-art has been analyzed and some preliminary work has been done on signal processing algorithms (data fusion and association mining) for extracting frailty related indicators.

Ethical issues have been debated following all current European and National lows, directives and recommendations covering all possible steps, from ethical approval, written consent, safety, handling sensitive data, cloud and geolocation data, biological specimens, to safety and the person's right to be forgotten. The policy on incidental findings and emergency situations has been clarified. Improved risk analysis has been performed and mitigation procedures are in place and have been applied. Dissemination strategies are already in place with measurable results, which we are also reporting. Concertation activities are ongoing. Intellectual property rights are being discussed, whilst open research data are guaranteed. The first version of the IPR protection plan has been devised. Exploitation and plans for it are being considered more actively. All current progress from all work packages is fully explained below in this annual report.

DOCUMENT INFORMATION

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

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Nature	Report ☒	Demonstrator ☐	Other ☐	
Dissemination Level	Public☐	Consortium ☒		
Abstract (for dissemination)	This is a confidential report that summarizes organizational documentation and planning progress on a management level, which is notcovered by the documentation in the individual working groups.			
Keywords	Periodic progress report, periodic technical report, periodic financial report			

Contributing authors (beneficiaries)	Megalooikonomou Vasileios (UoP) John Ellul (UoP) Dimitrios Vlachakis (UoP)		
Responsible author(s)	Megalooikonomou Vasileios	**Email**	vasilis@ceid.upatras.gr
	Beneficiary UoP	**Phone**	+30 2610 996 993

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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 disability.

Frailty is a syndrome characterized by diminished strength, endurance, and reduced physiologic 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 is being 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 will be followed to ensure that the end-user needs remain at the center throughout the design and implementation phases of the project. Finally, preliminary versions of the FrailSafe architecture have been prepared, by first detailing the parameters that will be monitored from the user, along with the monitoring devices and their usage. Then, architectural diagrams of the flow of information within the system have been designed, showing the main components and their interconnections. A data aggregator is at the center of the design, gathering the data from the various sensors and software components and transmitting them to the FrailSafe servers where and analysis procedures for further storage and processing will be undertaken.

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 will provide additional information to continuous physiological parameters recorded via the FrailSafe platform. The natural language analysis has been introduced to detect subtle cognitive and language changes that might precede transition to frailty states. The adverse events of frailty are also recorded including, falls, fractures, hospitalization, and death.

The inflammation and endocrine system profile will be correlated with frailty in a smaller number of participants at UoP. Also at UoP, the autonomic nervous system (ANS) will be studied and correlated with frailty in another subgroup of participants. In addition to the conventional assessment of the ANS, an alternative technique will be used to measure heart rate variability (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. Furthermore, some participants in the Greek centre will undergo either DEXA or MRI scan to correlate sarcopenia indexes recorded by bio-impedance scales and dynamometers with the golden standard. The time schedule of the clinical assessment is placed to detect changes, as well as progression form one frailty state to other.

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.

After acquisition of the approval of the Committee of the Protection of the Person also in Nancy, the clinical study is now running in all 3 clinical centers. In Patras (Greece), the clinical evaluations of the participants allocated in group A and B have been completed, whereas in Nicosia (Cyprus) the recruitment of group A is completed and that of group B is currently running. In Nancy (France) group's A and B recruitment runs in parallel The application of the FrailSafe system devices has started in all clinical centers. Data from clinical assessments are entered into tailored made eCRF. A mitigation plan has been elaborated in order to compensate for delays in the study timetable observed up to M9.

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 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.

In the context of WP3 and as described in D3.1, 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 and dynamometers have been purchased and are in use. Mobil-O-Graphs will also be used. The iBeacon which will monitor participants' position at home, have also been purchased; however, they will not be used during the initial phase, because dedicated software is being developed. WWBS will be developed during the first one and a half to two years of the project and 15 systems

will be delivered at M24, plus 8 preliminary versions at M15 and on the base of the amendment request, 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- and long-term monitoring in not controlled conditions (if possible). The decision on which set will be purchased has been taken at the time of this report delivery. Regarding T3.3, several algorithms for activity classification and behavioral monitoring are first being separately 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. Additionally, a preliminary analysis and evaluation of the accelerometer and gyroscope signals has been performed regarding the problem of motion identification using multi-parametric data from the UCI HAR Dataset, as relevant FrailSafe data are still being collected.

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 frailty older adults as well as the generation of FrailSafe 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 UoP premises for the moment and it will be uploaded to the Amazon Web Services (AWS) cloud in the next period. 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. The goal of this type of analysis is to identify loss of balance, tendency to fall, and loss of orientation (indoors and outdoors) for older people. A preliminary work on real-time fall detection has been made. 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 groupswith 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. After further studying, state of the art methodology, a language model has started to be 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 which will be used. Task 4.6 - "Signal Processing for extraction of frailty-related indicators" aims at extracting frailty-related indicators from signal processing. During this period, 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. Also, fueled by our previous work on data fusion, three schemes were developed which will be tested on the collected FrailSafe data. 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. Additionally, the VPM, which will serve as a risk assessment panel for the clinicians, is being tested now.

WP5 has focused mainly on the analysis of smart devices, operative systems, end game engines to be used in FrailSafe. Because of this analysis, different important decisions have been taken, the tablet of reference in FrailSafe will be the Google Pixel C while the smart phone where the project developments will be tested has been decided to be a Nexus 5X. These devices will run Android 6.0 Marshmallow, and finally, over it, the games will be developed based on Unity. 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: (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.

Regarding WP8 "Dissemination and Exploitation" and to raise awareness of the project developments (T8.1) among key user groups, the scientific community and the 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 first version of the FrailSafe Dissemination Plan (D8.1) delivered in M3. Alongside the website, the project is present on the social media (Facebook and Twitter).

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 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 to verify their usefulness to start to design the business model and, consequently, the FrailSafe business plan.

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 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 is expected to focus exactly on these components.

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).

1.3 Progress beyond the state of the art

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

Some preliminary 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% achieved 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 preliminary 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 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.

Our preliminary work 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.

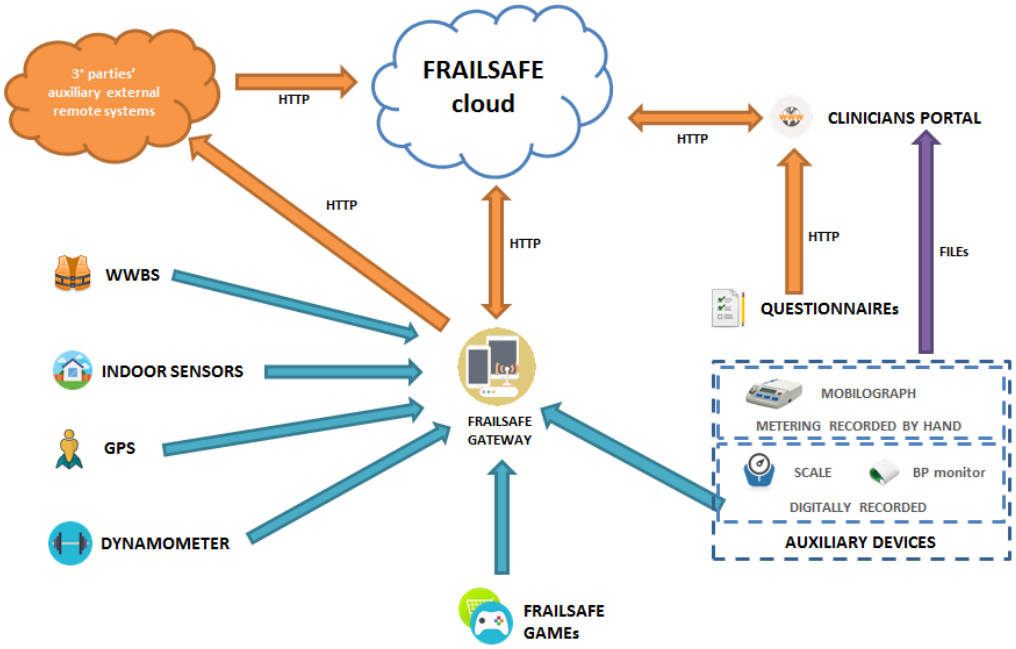


Figure 1: Data flows based architecture

A preliminary draft of a novel architecture has been developed. Particularly, the design of front-end architecture, based on data flow, has been faced in collaboration with WP1. Furthermore, the design of back-end architecture is currently in progress, always in collaboration with WP1. Regarding the preliminary draft of 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 together with WP1 to achieve a micro-service 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.

Publications produced:

[1] Pippa Evangelia, Iosif Mporas, and Vasileios 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] Drakopoulos Georgios and Vasileios 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] Drakopoulos Georgios and Vasileios 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] Drakopoulos Georgios and Vasileios Megalooikonomou, "A Higher Order Scheduling Policy with An Application To Biosignal Processing", IEEE Symposium Series on Computational Intelligence 2016, Athens, Greece

[5] Periklis Ntanasis, Evangelia Pippa, Ahmet Turanozdemur, Billur Barshan and Vasileios 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

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		Submitted	Detailed report of the communication policy of FrailSafe Preparation of the dissemination and communication tools (logo, website, press release, standard PPT presentation, leaflets, social media profiles)
D8.2	Dissemination plan and FrailSafe dissemination material	8	AGE	R	PU	M12	M12		Submitted	An updated version (ver. b) of deliverable D8.1
D8.5	Project Web	8	HYPERTECH	OTHER	PU	M3	M3		Submitted	Creation and launch of the FrailSafe

	presence									official website (http://frailsafe-project.eu/) Social media channels Wiki Repository (including meeting minutes)
D9.1	Project reference manual and quality plan	9	UoP	R	CO	M3	M3		Submitted	Presents the management structure, the quality procedures, and the various operational tools of the Project 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		Submitted	Quality control General (success criteria, corrective and preventative

										actions, contingency planning and risk management) Deliverables and documentation (document types, documents naming, and document templates) Whole project (peer-reviewing evaluation of project's deliverables)
D9.6	Ethics, Safety and mHealth Barriers (regulation, legislation, etc.) Manual	9	UoP	R	PU	M5, M36	M5		Submitted	Overview of Health, Safety and Wellbeing Legal Framework for Privacy Protection Legal and Ethical framework for Involvement of Human Subjects Cloud Computing on Privacy Issues FrailSafe Ethics Guidelines Data protection

										checklist
D9.3	Periodic Management Reports	9	UoP	R	CO	M6, M12, M24, M30	M6		Submitted	First 6 month progress report
D1.1	Analysis of current practices	1	CERTH	R	PU	M6	M6		Submitted	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
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.
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		Submitted	This is a public report describing the WWS manufacturing plan after ranking the different approaches that are essential for the whole concept like – low energy power supply system, system behavior in case of system failure, security aspects and performance issues, telecommunication aspects, ergonomics and usability.
D4.5	Dynamic User Profiling models and	4	CERTH	R	PU	M6	M6		Submitted	It reports on the user-profiling models

	Patient modeling and representation framework (vers. a)									developed based on data collected from participants belonging to different frailty stages plus healthy participants.
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 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.
D5.1	Analysis of hardware devices and software tools. Game hardware and software design.	5	BRA	R	PU	M6	M6		Submitted	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		Submitted	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.
D8.8	IPR Protection Plan		R	PU	M12	M12				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 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	This deliverable. First 12 month progress report

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	Comments

							date	
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		
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 sensing infrastructure	WP3	SMARTEX	M12	Internal report + s/w + h/w	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.
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		N/A	Policies are in place for encryption, sharing and transferring data
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 details 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) has accepted to serve 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 will be obtained in all cases. Agreement to participate will be voluntary and participants will be able to withdraw their consent at any point in the project. Data collected during the clinical assessment by members of the research team will be anonymized and encrypted. Data will contain no identifying information. These anonymized and encrypted data will then be 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 will be kept secure and unreachable by unauthorized persons. The data 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 will be ensured in all cases. Personal privacy of participants will also be respected. Research personnel will be flexible and clinical assessment sessions will be adapted to participants' everyday activities and needs, so that the monitoring period will have the least possible impact on personal life and day-schedule. Personal data 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.

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, questionnaires, social media posts & profiles and other sources of data will be collected and preprocessed to create a dataset. The collected data will be anonymized and then transferred using encryption technology in various forms of communication services. None third party will be able to alter information as access to collected information will be restricted only to the related tasks. The social media mining and monitoring tools to be deployed in the project will 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 specimen 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.

Telomeres measurements are performed by 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 will sign a specific informed consent indicating that this genetic analysis will be performed exclusively for scientific purposes of this study in an anonymous way. National and EU legislation will be respected. The specimen collection and analysis of TL will be 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 will 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 will enter force. The project will work closely with National and Local Ethics Committees and other regulatory authorities for the submission and the conduct of the planned clinical trials. FrailSafe members will 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, it 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 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 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 find 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 will 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. The protocol will state 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 will be set up 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. The protocol will state that in a such event 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.

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 will be informed about this right; the consortium will take all reasonable steps, including technical measures, to comply with the right to be forgotten.

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

N/A Auto-completed from the participant portal

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
2	Technical challenges regarding some FrailSafe system devices	1-6	Continuous interactions between all WPs, prevention of possible practical obstacles and adaptation of devices in the target population's specificities FrailSafe system devices already tested, fine-tuned and available for use (initial version for some of them). Process to be continued for next versions
3	Recruitment rate delay	1-6	Recruitment campaigns intensification and study's beginning shifting Parallel recruitment of groups A and B in Nancy 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.
4	Use of augmented reality glasses may be difficult for some of the subjects	WP5	Perform a technical hands-on evaluation of existing glasses in our labs before choosing the product to purchase

5	Delayed availability (M9) 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 the participants of group A already clinically evaluated (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
7	Possible liability risks in case of an "emergency" event for recruited persons	all	Clarifications in relevant deliverables and an amendment request to clarify these issues in the DoA
8	Role of clinicians in the final release of FrailSafe not clear	all	Clarifications in relevant deliverables and an amendment request to clarify these issues in the DoA
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
13	Safety issues of see-through AR glasses	3,5	Early decision for inclusion or not of these devices in the tests
14	AR games for acceptable by the older people	3,5	Design the games together with the participants and rely heavily on the user requirements analysis
15	Planned use of cloud services and referred lack of compliance with GDPR	6	Explore alternatives to the use of cloud services and potential impact

5.3 State of Risk Mitigation

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. 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. Clinical centers have either completed the recruitment for groups A and B (Patras) or have a sufficient number of eligible participants stand by and currently being recruited.
4	M6-M12	Yes	Not yet	Final outcome to be evaluated by end of January 2017.
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 group A 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	Partially	Not yet	We have provided clarifications in relevant deliverables (D2.1 (revised), D1.2 and D4.6). In addition, we plan to submit an amendment request by M13 to clarify these

				issues in the DoA
8	Since M10	Partially	Not yet	We have provided clarifications in relevant deliverables (D2.1 (revised), D1.2 and D4.6). In addition, we plan to submit an amendment request by M13 to clarify these issues in the DoA
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)
12	Since M8	Yes	Not yet	We are considering this important issue especially in the device choices and in the games design
13	Since M7	Yes	Not yet	We are experimenting with different alternatives that will reduce the possible risks.
14	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)
15	Since M7	Yes	Not yet	We are currently evaluating alternatives which we will communicate to the Project Officer as requested

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*	*N/A*	*N/A*	Georgios Drakopoulos, Vasileios Megalooikonomou	*The Eighth International Conference on eHealth, Telemedicine, and*	*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.

		Processing				*Social Medicine (eTELEMED), Venice, Italy,* *2016*							
2.	Conference proceedings paper	*Feature Selection Evaluation for Light Human Motion Identification in Frailty Monitoring System*	*10.5220/0005912200880095*	*N/A*	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*		*2016*	*85-95*	Both	YES	YES
3.	Conference proceedings paper	*Regularizing Large Biosignals with Finite Differences*	*10.1109/IISA.2016.7785346*	*N/A*	Vasileios Megalooikonomou; Georgios Drakopoulos	*7th International Conference on Information, Intelligence, Systems, and Applications (short name: IEEE IISA 2016), Chalkidiki, Greece, 2016*	*IEEE*		*2016*	*1-6*	*both*	*yes*	*no*
4.	Conference proceedings paper	*Investigation of sensor placement for accurate fall detection*	*N/A*	*N/A*	Periklis Ntanasis, Evangelia Pippa, Ahmet Turan Ozdemir, Billur Barshan and Vasileios Megalooikonomou	*6th EAI International Conference on Wireless Mobile Communication and HealthCare - "Transforming healthcare through innovations in mobile and wireless*	*Springer*		*2016*		*Both*	*Yes*	

						technologies"							
FORESEEN ACCEPTED PUBLICATIONS													
1.	Conference proceedings paper	*A Higher Order Scheduling Policy With An Application To Biosignal Processing*	*N/A*	*N/A*	Georgios Drakopoulosl; Vasileios Megalooikonomou;	*IEEE Symposium Series on Computational Intelligence 2016*	*IEEE*		*2016*		*both*	*yes*	
2.	Journal	*A comprehensive review on sensing and predictive treatment of frailty using advanced interventions & visualization interfaces*			*CERTH*	*Reviews in Biomedical Engineering*	*IEEE*		*2017*			*yes*	
3.	Journal	*Exploiting openEHR Archetypes for expressing frail older patient models*			*CERTH - UoP*	*International Journal of Medical Informatics*	*Elsevier*		*2017*			*Yes*	
4.	Journal	*Smart in-home monitoring system for older people via beacons technology*			*CERTH*	*Transactions on Information Technology in Biomedicine*			*2017*			*Yes*	
5.	Journal	*Usability study on physical & cognitive*			*CERTH*	*Serious Games and Applications for*			*2017*			*Yes*	

		training of older people via augmented reality glasses				*Health*							
6.													
7.													

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	0
Organization of a workshop	4
Press release	2
Non-scientific and non-peer reviewed publications (popularized publications)	5
Exhibition	0
Flyers training	0
Social media	2 (Twitter, Facebook)
Web-site	http://frailsafe-project.eu/
Communication campaign (e.g. radio, TV)	3

Participation to a conference	5
Participation to a workshop	2
Participation to an event other than a conference or workshop	13
Video/film	0
Brokerage event	0
Pitch event	0
Trade fair	0
Participation in activities organized jointly with other H2020 project(s)	0
Other	1
Total funding amount	

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*	*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*

[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.

2.	*Press Release*	*AGE*	*Launch of FrailSafe: A new EU project to delay frailty among older persons by bridging health data and new technologies*	*10 Feb 2016*		*Civil Society, Clinicians, ICT, policy-makers*	*N/A*	*Europe*
3.	*Organization of a workshop* *Article*	*Materia Group* *Materia Group*	*FrailSafe Presentation* *Article in newspaper for FrailSafe*	*6 Feb 2017* *8Feb 2017*	*nicosia, polidinamo lakatameias* *Filelefttheros newspaper*	*General public* *General public*	*20*	Cyprus Cyprus
4.	*Organization of a workshop*	*Materia Group*	*Frailsafe Presentation*	*24 March 2016*	*Polidinamo Lakatameias (day care center)*	*General public*	*25*	*Cyprus*
5.	*Organization of a workshop*	*Materia Group*	*Frailsafe workshop*	*30 March 2016*	*Polidinamo Lakatameias (day care center)*	*General public*	*15*	*Cyprus*
6.	*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*
7.	*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*
8.	*Participation to a Conference*	*Gruppo SIGLA*	*Life Tech Forum*	*6-7 April 2016*	*Genoa, Italy*	*Scientific community and stakeholders*	*80 key note speaker.* *500 participants.* *30 sponsor company.*	*Italy*
9.	*Article*	*AGE*	*Frailty, what is it?*	*11 April 2016*	*Brussels*	*Civil Society, Clinicians, ICT,*		*Europe*

						policy-makers		
10.	*Participation to an event other than a conference or workshop*	*INSERM*	*Informative meeting with ONPA*	*22 April 2016*	*Nancy, France*	*Older people*	*50*	France
11.	*Participation to a Conference*	*AGE*	*Societal Impact of Pain (SIP 2016)*	*24 April 2016*	*Brussels, Belgium*	*health care professionals, pain advocacy groups, politicians, insurances, representatives of health authorities, regulators and budget holders*		Europe
12.	*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*
13.	*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*
14.	*Participation to an event other than a conference or workshop*	*INSERM*	*Join the FrailSafe Study*	*25 May 2016*	*Nancy, France*	*Older people*	*25*	France
15.	*Communication Campaign*	*UoP*	*Σύνδρομο ευθραυστότητας των ηλικιωμένων (Syndrome Frailty of the older people)*	*26 May 2016*	*Greece*	*General Public*	*1000+*	Greece
16.	*Participation to an event other than a conference or workshop*	*INSERM*	*Join the FrailSafe Study*	*6 June 2016*	*Nancy, France*	*Older people*	*25*	France

17.	*Participation to an event other than a conference or workshop*	*INSERM*	*Join the FrailSafe Study*	*7 June 2016*	*Nancy, France*	*Older people*	*25*	France
18.	*Participation to an event other than a conference or workshop*	*INSERM*	*Join the FrailSafe Study*	*16 June 2016*	*Nancy, France*	*Older people*	*25*	France
19.	*Participation to an event other than a conference or workshop*	*INSERM*	*Join the FrailSafe Study*	*29 June 2016*	*Nancy, France*	*Older people*	*25*	France
20.	*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
21.	*Newsletter*	*AGE*	*Newsletter #1*	*30 June 2016*	*Brussels, Belgium*	*Civil society, Medical, technical, policy makers*		Europe
22.	*Article*	*AGE*	*FrailSafe publishes first newsletter*	*5 July 2016*	*Brussels, Belgium*	*Older people, European Stakeholders*	*N/A*	Europe
23.	*Article*	*UoP*	*Frailty indicators could help prevent problems with ageing*	*13 July 2016*	*Brussels, Belgium*	*Researchers, policy makers,*	*N/A*	Europe
24.	*Organization of a workshop*	*Materia Group*	*Frailsafe Workshop*	*5 sept 2016*	*Xalkanoras (day care center)*	*General Public*	*15*	Cyprus
25.	*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

26.	*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
27.	*Communication campaign (radio)*	*INSERM*	*France Bleu Lorraine Nord*	*30 Sept 2016*	*Lorraine, France*	*General Public*	*N/A*	France
28.	*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
29.	*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
30.	*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
31.	*Communication campaign (tv)*	*UoP*	*ΥγείαςΘέματα - Εκπομπή 53 - ΣύνδρομοΕυθαστότηταςΗλικιωμένων - Β' μέρος*	*15 Oct 2016*	*Ionian tv*	*General public*	*N/A*	Greece
32.	*Participation to an event other than a conference or workshop*	*INSERM*	*Join the Frailsafe Study*	*18 Oct 2016*	*Ludres, France*	*Older people*	*40*	France
33.	*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		
34.	*Participation to an event other than a conference or workshop*	*UoP*	*A public event was held regarding FrailSafe project. which was organized by "Panathinaiki Women's Association"*	*7 November 2016*	*Patras, Greece*	*Older people, practitioners, informal carers, general public*	*70*	Greece
35.	*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
FORESEEN ACTIVITIES								
1.	*Organization of a workshop*	*Materia Group*	*FrailSafe Presentation*	*9 Jan 2017*	*nicosia, polidinamo strovolou*	*General public*	*20*	Cyprus
2.	*Organization of a workshop*	*Materia Group*	*FrailSafe Presentation*	*23 Jan 2017*	*nicosia, polidinamo latsion*	*General public*	*20*	Cyprus
3.	*Organization of a workshop*	*Materia Group*	*FrailSafe Presentation*	*6 Feb 2017*	*nicosia, polidinamo lakatameias*	*General public*	*20*	Cyprus
4.	*Organization of a workshop*	*Gruppo Sigla*	*MATH 2017 - The International Symposium on Mobile and Assistive Technology for Healthcare*	*March 19 - 23, 2017*	*Nice, France*	*Scientific Community*		Europe, Asia, America
5.	*Participation to a conference*	*CERTH*	*Eurographics 2017*	*24-28 April*	*Lyon, France*	*Scientific Community*	*500+*	
6.	*Participation to an event other than a conference or workshop*	*Gruppo Sigla*	*LifeTech Forum*	*June 2017*	*Venice, Italy*	*Industry*		Italy

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 platform are currently underway and are expected to be finalized in M12 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.).

Discussions on IPR management focus 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 will be completed by month 12 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	
Testing activities (feasibility/demo)	
Clinical trials	

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

New product (good or service)	
New process	
New method	

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	2.154.605	34
Smartex s.r.l.	509.205	7.6	509.205	8.2
HYPERTECH	1.253.410,20 (2015)	25 (2016.01)	1.253.410,20 (2015)	25 (2016.01)
Gruppo SIGLA S.r.l.	5.002.500,00 Euro	At 01/01/2016: 68 employees	5.002.500,00 Euro	At 30/04/2016: 68 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:

i. Depositing the proposal publications in a repository selected from the recommended lists of online archives provided by OpenAIRE.
ii. Providing Open Access publishing ("Gold") to the proposal publications, implying that proposal publications not only will be accessible via the chosen repository, but also published in open access journals, subscription journals and hybrid journals.
iii. Ensuring open access to the bibliographic metadata through the identification of the deposited publication via the chosen repository.

Working on 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 section16of 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	4	11	15
BRA	2	4	6
SMARTEX	3.6	4.6	8.2
AGE	2	0	2
CERTH	4	11	15
MATERIA	7	3	10
SIGLA	3	7	10
HYPERTECH	1	3	4
INSERM	2	0	2
Total	28.6	43.6	72.2

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 has been finalized to a great extent
- Design of the database and the virtual patient model has progressed significantly and will be finalized within the first year of the project
- 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

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 individual patient's condition for purposes of detecting/alerting/averting of frailty events, merged to an integrated system, explicitly taking into account security and	Design of WWBS is being performed, and first prototypes have been realised for device testing, with positive results. Its finalisation is foreseen 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.	50% Design of hardware components: 80% development of hardware components: 40% merged to an integrated system: 25% taking into account security and privacy issues: 10 % WWBS: 60% in terms of hardware development, 30% in terms of ergonomics, user-friendliness compactness, unobtrusiveness and energy consumption Bluetooth beacons have been selected as an effective means of indoor location monitoring, due to their localization

	privacy issues **(*Measurable Result (MR)*: WP3 & WP6 - Ms5, Ms8, Ms9, Ms10)**.		capabilities, compatibility with existing technologies, economic advantage and ease of installation. Regarding the selection of the commercial IMUs to be purchased, a selection process has been performed leading at a purchase of X-IMU products from X-IO. Degree of completeness: 50%
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 existing datasets since FrailSafe data has just started to become available	50% Preliminary work has been done on applying time series analysis and peak detection in existing electrocardiogram (ECG) data from Internet databases. An application demonstrating the applicability of using beacons for indoor localization has been implemented. 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. Algorithms for instability & fall detection have been developed and are currently under testing. Degree of completion: 50% 10% 6 month report
TO3	Development of a self-adaptive virtual patient model offering optimal services for managing frailty ranging from critical situation management, facilitating social integration to day-to-day self-management and	The VPM has been designed, the parameters to be included have been defined and the implementation has started. The real-time update and communication with	70% The design of the Virtual Patient Model to be used in FrailSafe has been completed, although modifications are expected to happen after system validation and user feedback. Existing archetypes based on the openEHR model

	health preservation based on a personalized patient profile **(MR: WP4, WP6 & Ms6, Ms8 - Ms10).**	the FrailSafe system is to be implemented	have been adapted and modified, and new archetypes were built as needed. The implementation has started. Integration with the rest of the FrailSafe system is pending Degree of completion: 70%
TO4	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 - The games framework is under development taking into account the FrailSafe sensors. Some of their correspondent modules and plugins have been finalised. - Regarding data visualization and Decision Support System, visual analytics are being adapted from previous projects and are being applied based on existing health-related data.	15% Development of a generic monitoring and management infrastructure: 15%
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,	The data management infrastructure has been designed and started to be implemented. Part of the fusion and analysis methods for social and physical activities have been developed	25% 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 examined. Data fusion methods have been designed and started to be implemented.

	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 **(MR: WP4, WP6 & Ms6, Ms8-Ms10).**		Degree of completeness: 25%
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 utterances or suicidal manifestations in 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. Preliminary work on real-time fall detection has been performed. State of the art in streaming data management performed. Currently Investigating state-of-the-art for gait analysis and loss of balance as well as real-time analysis of written text.	20%
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 techniques for reducing raw streaming data to secondary or tertiary parameters. Effectively use virtual patient models and	Investigation of real-time trade-offs and data reduction techniques have started to be investigated.	20%

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

	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)**.		
TO8	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	15% Preliminary versions of 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. This game has also been improved in terms of graphics and usability. A first round of feedback acquisition from clinical partners has been conducted, regarding conceptual ideas about game designs, regarding their relevance to frailty. Degree of completeness: 15%.
TO9	Extensive testing of the FrailSafe integrated system in several validation scenarios while ensuring compliance with ethics standards **(MR: WP7 & Ms11 - Ms14).**	Not yet started	0%

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 their clinical evaluations are completed for the clinical centers of Patras and Nicosia and running for Nancy, whereas the recruitment of group B has been completed for Patras and running for Nicosia and Nancy.
- The eCRF features of the Clinical Web Portal were delivered by WP6 and already in use.

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	15%
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	15%

		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 via any kind of agreed sensors have also been defined. Clinical evaluations for group A and B completed in Patras (120/120 subjects) in 2 out of 3 clinical centers., almost completed in Nicosia (102/120 subjects) and intensively running in Nancy (65/120). In all 3 centers 287 subjects have been clinically assessed.	
MO3	Use the above measures to predict short and long-term outcome	Not yet started (outcome data are not available yet)	0%
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. Clinical evaluations completed for group A in 2 out of 3 clinical centers. Clinical evaluations for group A and B completed in Patras (120/120 subjects) in 2 out of 3 clinical centers., almost completed in Nicosia (102/120 subjects) and intensively running in Nancy (65/120). In all 3 centers 287 subjects have been clinically assessed.	15%
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	Not yet started	0%

	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, games, monitoring alerts, guidance and education and estimate the influence of these interventions	Not yet started	0%
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.	15%

11 Success Indicators as Related to the FrailSafe Main Objectives

WP No.	Indicator	Success Criteria
		1st year period
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. Web site of FrailSafe available (Month 3) 2. Project dissemination material available (posters, leaflets) as defined in WP8 3. At least 2 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
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	45%
	Standardization of the procedures and protocols for the clinical studies and objective measurements of performance collected through various means and analyzed	85%
WP3 (Smart Sensing, data	Integration of sensors and definition of the	20%

acquisition and signal processing)	communication framework	
	Sensing environment working properly and unobtrusively	20% of the supported sensing capabilities ready and functional
WP4 (Data Management and Analytics)	Completion of data analysis algorithms based on specific physiological input parameters	20%
	Measurable improvement of the developed approaches with respect to the SoA schemes in a simulated environment	10%
	Percentage of developed elderly models that capture clinical and physiological data	20%
	Number of physiological variables of the elderly models linked to frailty	15%
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	5%
	Graphical users interfaces customizable to the user requirements/needs	20%
	Information visualization framework fully parametric and customizable	5% of the functionality available in the first year for demonstration purposes
WP6 (Integration and FrailSafe Application and Services)	Completion of FrailSafe sensing and intelligent processing modules integration	5%
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 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 has 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.

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 milestoneMS2, “Design of use cases, user requirements, UCD methodology”.
- The selection of common UCD methodologies, to be used throughout the project design and implementations.
- A preliminary 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.

SIGLA Task 1.4 7.96 PMs

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 to be 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 all 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 has already started in all 3 clinical centers, though with a certain delay in Nancy (acquisition of the approval of the Committee of the Protection of the Person in 6th October 2016).

Clinical evaluation visits have taken place for all participants of group A in Patras and Nicosia and for a small number some of them in Nancy. The centers of Patras and Cyprus have also started recruiting participants for the group B, as predicted by the protocol for M10, recruitment of group B has started in all centers, and even finished for Patras. Subjects have been categorized according to conditions of interest for the study. All three centers have created a sufficient pool of eligible participants, which will be expanded and from which they will draw the rest of the participants required.

In parallel, the clinical data collected are being fed into the eCRF platform and, by these means, 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.

In the context of Task 2.3 a review of the literature is being conducted in order to investigate the current and most well-based recommendations referring to frailty related conditions.

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 FS 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)
c) WWS (T 3.2)
d) Smartphones and tablets to fit with the needs of older people

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.

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.

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 21/12/16 287 participants have been evaluated.

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: 30% for Nicosia, 93% for Patras, 90% for Nancy).

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.

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.

Table 4: Indices of study protocol completion (last updated on 21/12/16)

Indices of study protocol completion	Centre no 1: Patras	Centre no 2: Nicosia	Centre no 3: Nancy	Total in 3 centers
# of recruitments	120	102	65	287
# of clinical evaluation visits	120 (of which 39 with some missing data)	102 (102 of which missing data)	65	287
# of FS system sessions	45	32	1	80
Virtual games	7	21	1	31
Smartphones	44	17	1	64
BP monitoring	29	10	1	42
WWS	21	4	1	26
# of natural language analysis (written texts)	116	68	25	210
# blood drawings for telomeres	0	0	0	0
# of other investigations (only for Patras)		NA	NA	
Blood analysis	10	NA	NA	10
ANS evaluations	17	NA	NA	17
# phone call follow up questionnaires	41	0 (should start later)	0 (should start later)	41

Table 5: Frailty levels (according to Fried's criteria) analogy (last updated 21/12/16)

Frailty levels analogy	Centre no 1: Patras	Centre no 2: Nicosia	Centre no 3: Nancy	Total
Non frail:	42	11	29	82
Pre-frail:	42	56	24	122
Frail:	36	35	12	83

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. Analysis of data collected by clinical parameters' monitoring has started.

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: 82 (29%) non-frail, 122 (43%)pre-frail, 83 (29%) frail vs 50%, 25% and 25% desired respectively.

12.2.5 WP2 – Use of resources

As far as INSERM is concerned, the allocated resources have been used so far for hiring (full time) 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 or psychologist (, 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

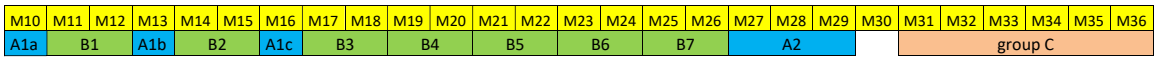
-dealing with technical issues regarding material

-carrying out selected administrative issues.

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.

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 trichotimization of group A's first cycle of FS session and its interference between the 1st-3rd sessions of group B (M11,M14, M17)
- The decrease of the duration of FS session for group A (3-5 days instead of 5)
- The publics for group B of the total number of FS sessions' cycles in 7 (instead of 9)
- A reflection period of 1 month (M30)
- No change in the conduction of the study for groups C and D (M31 and after).

A pool of eligible participants' is already available after intensified campaigns: enough participants for immediate recruiting are "stand by". A parallel recruitment of group A and B for Nancy will be attempted.

Data provision to other WPs will be accelerated, thanks to immediate feeding in eCRF of the data collected by clinical evaluations and by the FrailSafe system monitoring recently implemented. These first 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.

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 parameter of interest.

In the frame of Task 3.2 "Development of FrailSafe wearable sensing systems" (started at M4, running) wearable product (WWBS) have been partially 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)

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 so far in order to evaluate performances of WWBS preliminary versions.

T3.1

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 require 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.

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

On the base of an amendment request, 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. Within the activity of **Task 3.2**, a preliminary version of WWBS electronic device has been designed and developed. The device 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 an ARM 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).

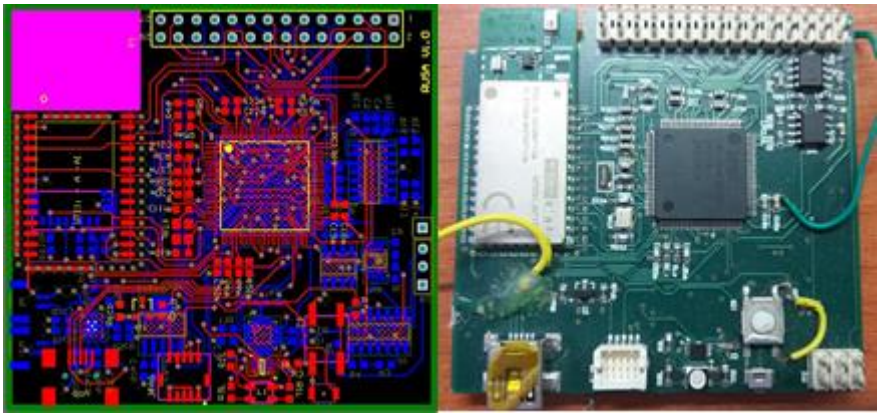


Figure 2: Evaluation board.

A second phase of testing has been conducted concerning the power consumption of the device. The final electronic should be able to record and send data wirelessly for several hours, so a careful management of power consumption of all components is necessary. This aspect involves 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 newest electronic device has been done. The major changes were done on ECG and breath analog front-ends. 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 a design that may improve comfort (e.g. a vest easy to don and doff), will require 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. A new phase of tests has just started, including tests with a second 9DoF module, external to the device described so far, but wired with it, devoted to monitor the limb movements. The chip of 9DoF IMU external module is the same of the one already integrated on the board: this solution should give 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).

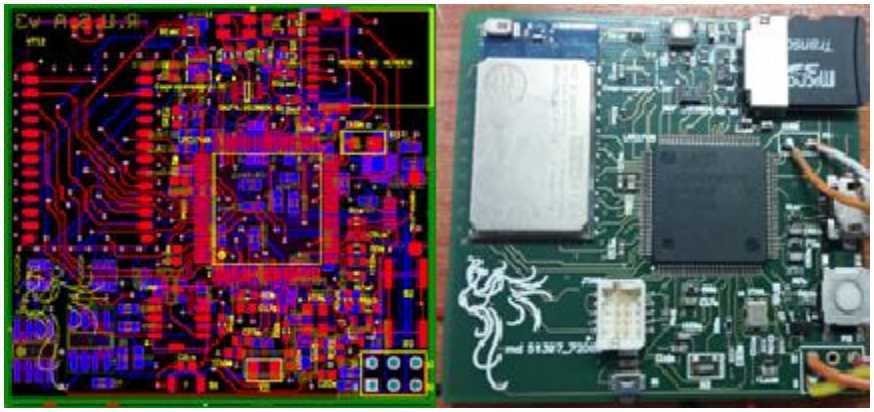
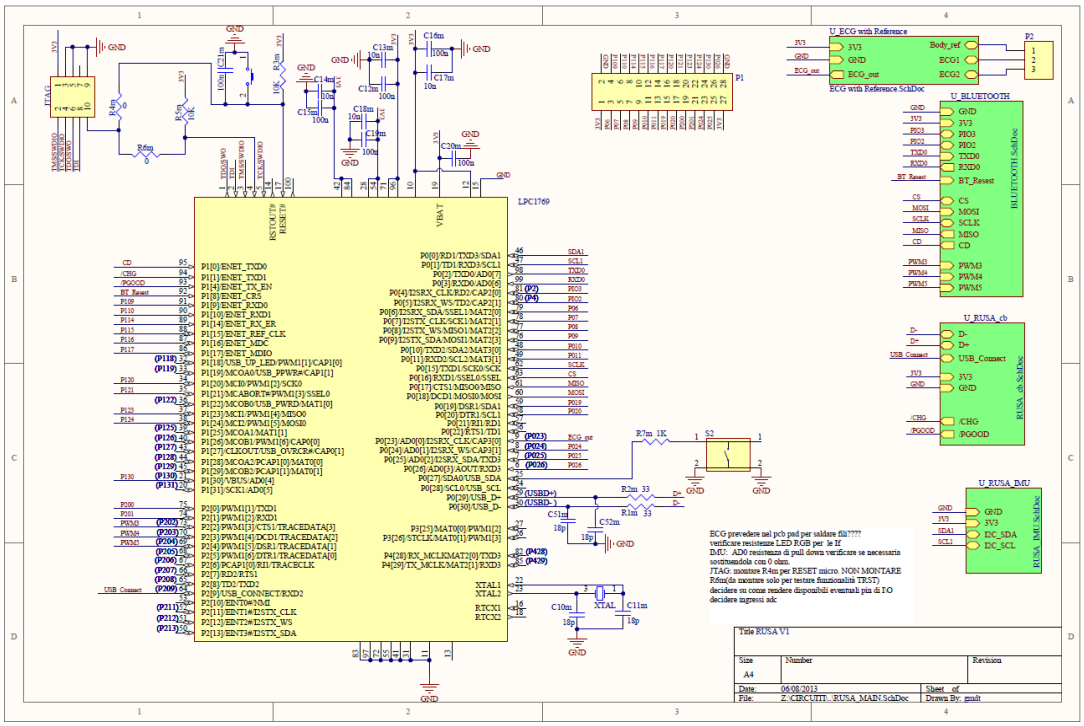
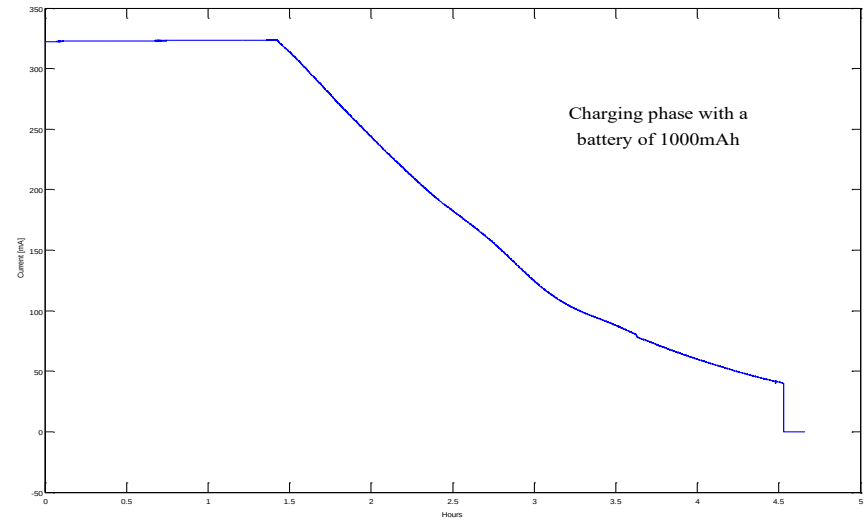


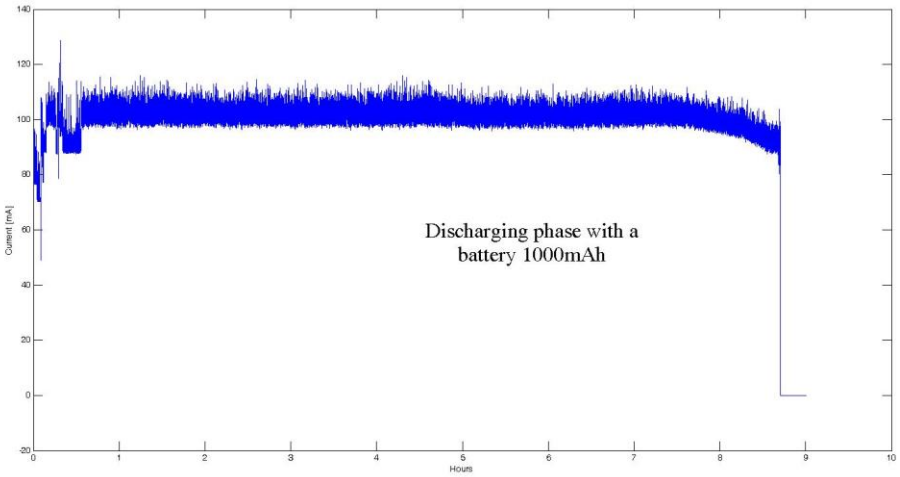
Figure 3: Latest device picture and PCB gerber.

Schematic of the latest device is shown below.



After the second phase of tests it was decided to make a further new breath front-end to increase the dynamic of the signal. This should allow a better amplification of the breath signal, also when the vest is not perfectly worn.
The results of the 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.



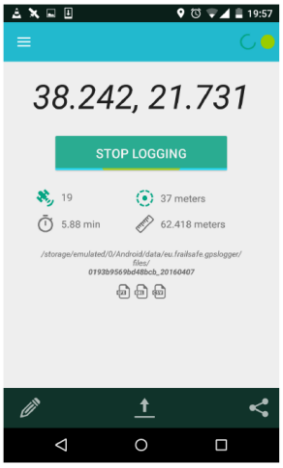


Furthermore, another power consumption optimization has been developed in order to improve the battery duration as much as possible. A repetition of the test above has shown an increase in battery duration equal to 25%.
Regarding the tests for the external IMU's (on the limbs), a higher attention has been given on wired connection design in order to guarantee the correct communication with central device.

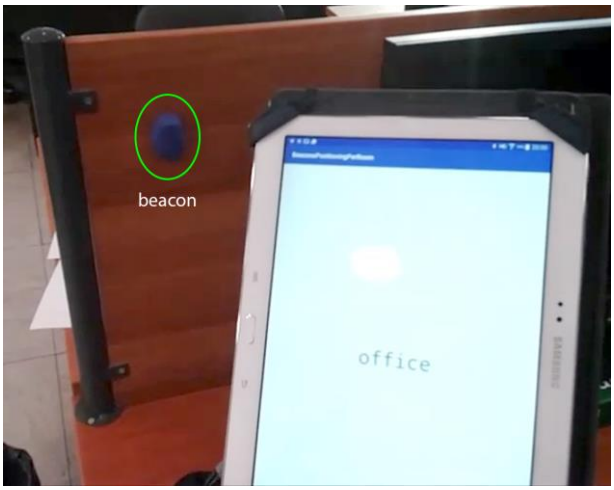
During the first months of activity of **Task 3.3**, several algorithms for location acquisition and activity classification are being developed and tested.

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.



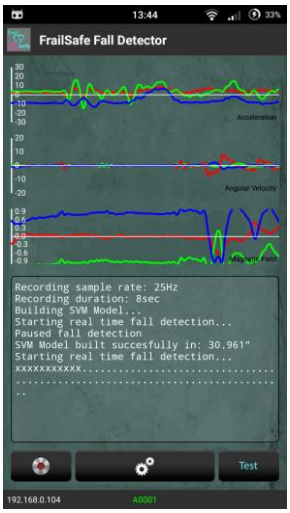
Regarding the indoor localization process of older people, we are currently working on a **beacons-based** configuration system. Bluetooth beacons represents small devices emitting a unique ID via a Bluetooth Low Energy (BLE) protocol. A smartphone can read the IDs of the nearby beacons and their approximate distances. Thus, beacons can be used to locate an older person carrying a smart device in his/her home. A preliminary application is already prepared for demonstration purposes (see Figure below) and is currently adjusted/updated in order to be more configurable and adaptable to different facilities and beacon numbers. 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.



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

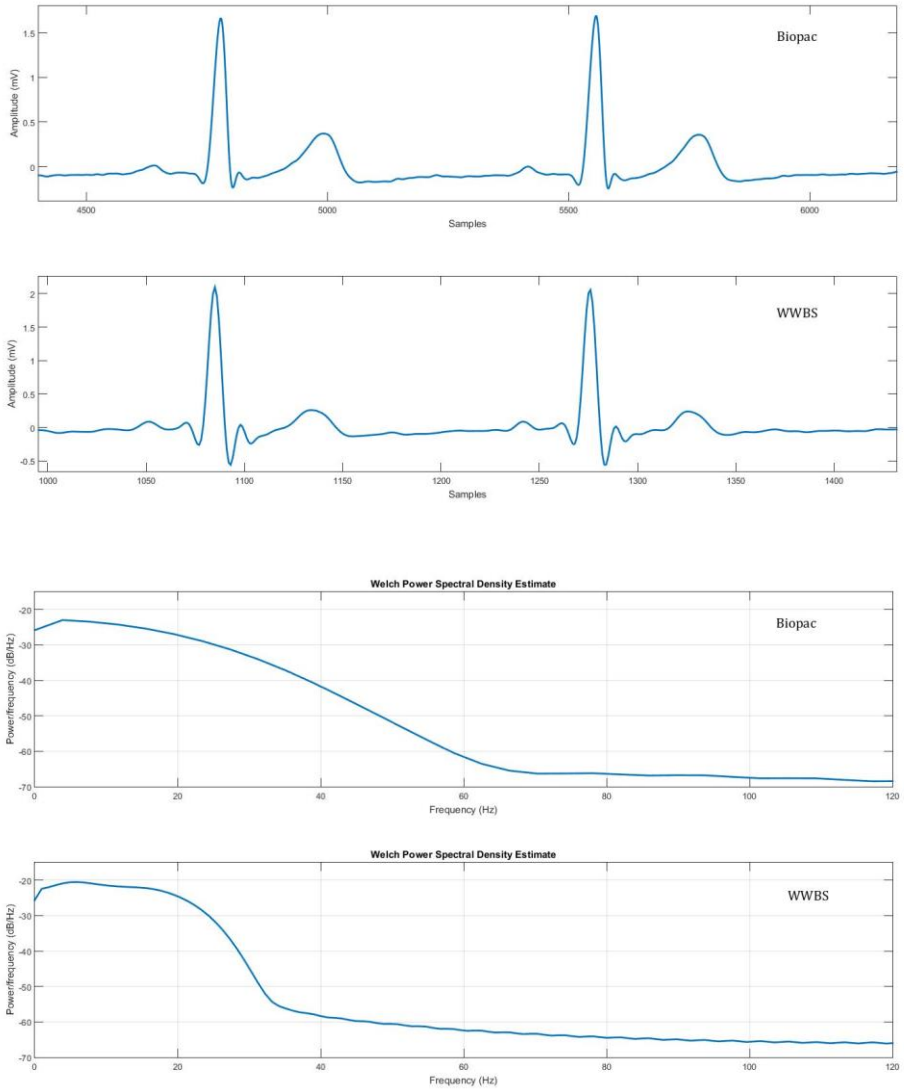
proposed for the dataset under consideration (multi-parametric sensor data acquired from accelerometers and gyroscopes using a large number of time-domain and frequency domain features). Note that the data extracted from the GPS Tracker App can further be exploited (task of offline analysis) for walking,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

Last but not least, concerning behavioral monitoring meaning risk events detection such as falls and loss of orientation, we have developed an Android application (see Figure below) that uses sophisticated machine learning algorithms for real-time **fall detection** purposes via exploiting the accelerometer, gyroscope and magnetometer of a smartphone device (tested on several ones including the Nexus 5X which is selected as the best candidate for the project, see D5.1). However, currently the results are not robust enough, so we are moving to a variation that explores training data from falls/non-falls collection examples to enhance the reliability of the final method. An extension of this algorithm is currently under investigation for inspecting instability during walking. Acceleration data have been recorded using the smartphone and in our future directions is to test it under IMUs hardware.



Regarding **Task 3.4**, a primary discussion on the lightweight protocol for in WWS communication and for WBAN to mobile device has been performed. An energy efficient vital signal telemonitoring scheme ensuring reliable data transmission by exploiting compressed sensing (CS) for low-complexity signal compression-reconstruction is an essential option.

In the frame of **Task 3.5** several tests have been 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.

12.3.3 WP3 – Significant results and achievements

Decision on and purchase of sensors composing the FrailSafe network

Design and purchase of motherboard of WWBS

Purchase of IMUs

Development of GPS Tracker /Pedometer Android Application.

Development of Fall Detector Android Application.

Development of a prototype indoor localization application using BLE beacons.

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. The consortium has finalized the process of selecting the products to be used instead of WWS during the first clinical study periods, i.e., before the WWBS becomes available to collect additional data. This is shown in the amendment request that has been submitted.

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

No corrective action foreseen so far.

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 on offline data analysis was performed using publicly available datasets.

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 goal of this type of analysis is to identify loss of balance, tendency to fall, and loss of orientation (indoors and outdoors) of older people. In cooperation with CERTH and Task 3.3, a preliminary work has been done in real-time activity classification and fall detection.

In Task 4.3, we employ 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 are developed to reflect concepts that are not encompassed by existing archetypes. Finally, a set of rules is 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 is currently 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 will be 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 that will be 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 will be aggregated in a gateway and then will be uploaded in the HBase database. The offline analysis will be performed using a cloud service by Amazon Web Services (AWS).

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. This architecture is intended to be the framework of the subsequent offline data analysis.

Additionally, a preliminary 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 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.

T4.2 Online Data Management and Analysis

After a careful consideration, it was decided that the device that will be used as a gateway to collect the sensor data, will be the one that will perform the online data analysis as well. This device will analyze the collected data and potentially identify emergency situations for the older people. A special effort will be made to assess the balance of the older person and identify loss of balance, tendency to fall, and loss of orientation (indoors and outdoors). Additionally, medical indicators will be examined

such as increased heart rate. In case of such an emergency situation, an alarm will be triggered notifying the older person, but also the clinicians through the VPM (Virtual Patient Model). Towards this direction, a preliminary work in real-time fall detection and activity classification has been done in cooperation with CERTH and Task 3.3.

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

In this task, we collect 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. For example, we can consider as aspects that differentiate user behavior, the number of followers of a user, the number of contributions to the corresponding social network as well as the frequency of contributions. However, given the difficulties in collecting data in this age range from their interaction with social media platforms, we have proposed a set of questions plus a big five questionnaires to correlate (with use of machine learning approaches) the word usage and the social media behavior of subjects to frailty symptoms thus providing an extra tool to the doctors to determine the clinical status of the subject. In addition, this questionnaire would provide more insight when building the profile of

the older people especially in the case of text analytics, where we are more than clear that this correlation actually exists.

The main idea is to connect frailty symptoms with the Big Five personality traits (i.e., Agreeableness, Conscientiousness, Extraversion, Neuroticism, and Openness) and combine them with techniques that emotionally characterize elderly scripts. The plan is to collect data and plan to investigate techniques that connect text features and multiple values of the Big Five personality traits with symptoms of frailty. The training classification phase aims at predicting/characterizing frailty based on the written scripts (T4.5).

The current progress in this task includes the design of a crawler that is capable of retrieving facebook and twitter posts and storing them in the FrailSafe database. Based on these posts and the answers from questionnaires, a corpus has been created for Greece and Cyprus participants. Also, the design of IMAP client for e-mail collection is being implemented at the moment.

Concerning T4.4 (Sensing Social media), the following work has been implemented and thus corresponding output will be provided to T4.5. Till now we have data from Greece (UoP) and Cyprus (MATERIA). We have conducted detailed experiments for the Big Five Personality Traits Extraction in 43 and 47 subjects respectively for Greek and Cyprus. Data from their social media interaction (twitter, facebook and e-mail) are being collected from Patras and Cyprus, while in France we have problem with their ethical committee that denied access to them. Concerning 4.5, we have been provided with written text describing an image and an important life event, from 80 (total is 85) subjects in Greece, and 52 subjects from Cyprus. Moreover, we implemented a methodology derived from study of F.Celli (Unsupervised personality recognition for social network sites) that use unsupervised learning techniques to recognize the Personality Traits for an individual using his/her texts. This implementation could be used in case of missing data from questionnaire.

Furthermore, we have contributed with:

- Twitter crawler in Python and alternative implementation in Java.
- Facebook crawler in Python (for Facebook pages).
- Design of IMAP client for e-mail collection. It will be deployed once privacy concerns are resolved.
- Design of Web interfaces for the execution of the social crawlers and the IMAP client.
- Implementation of Twitter web interface. It will be deployed once privacy concerns are resolved.
- Design of SQL database for storing texts collected by the above social crawlers.

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

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 Syntactic Parser, and a Semantic 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, some initial sample user writings are needed in order to build a user model for each individual. This user model will include 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 51 older persons showed low accuracy (~60%). A further investigation on the appropriate features is needed and to this direction more raw data are being collected.

Concerning T4.5 (Processing social media) work is proceeding as reported in "D4.10 LingTester (Prototype) (vers a)". The LingTester prototype is in early alpha stage, but still it is able to perform classification according to levels of frailty. The D4.10 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. 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 going to be explored, the detection of suicidal statements and the patient mental state transition over time.

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.

Flowingly, a preliminary work on signal processing and data mining techniques was performed in 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 as mentioned above in the feature extraction & classification example. 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). Performing a Tucker decomposition for the whole set of K tensors will conclude to having a set of features for each sample, living in the core tensor of each decomposition. The latter simplified representation is computationally expensive, and for that reason all sample tensors can be concatenated into a single tensor preferably vectorized, whose core tensor will include all features from all samples. The vectorized core tensor will include all possible features. Up until that point, it is hopefully clear that even though the size of the data volume is important, manipulating the data as vectors guarantees that the data analysis at least offline is viable. Moving further the analysis, after extracting the features from the tensor training set classification should be performed. The choice of the classificator must be done after experimenting with the input data and features extracted. Hopefully feature ranking and feature selection will conclude to a stable set of features, which will account for the frailty indicator. A tensor test set of will be given as input to the classifier in order for each sample to be assigned to a frailty-dependent class. As discussed above, the use of tensor representation and tensor decompositions for the data provided during the FrailSafe system development, is highly recommended for the purpose of frailty indicator extraction. The computational cost of the analysis is low, making it an attractive solution for a wide range of data analysis problems, including FrailSafe.

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 a 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. The estimated feature vectors from each sensor unit are concatenated into a single feature vector. This 'super' feature vector is used as a representative signature for the corresponding frame. Although such a scheme exploits the information from all dimensions of the data, it leads to a feature vector of high dimensionality imposing the need either for feature selection before classification, or the availability of a large number of training samples.

In the Late Integration fusion with local (sensor dependent) training models, a separate classification model is built for each sensor unit. Each one of the available sensor units is processed in parallel by the feature extraction algorithm and the estimated feature vectors are used to form N training sets, one for each sensor unit. For each epoch, N decisions are made by each one of the N local classifiers. A final decision is made by combining the N output class labels using a fusion rule, such as majority voting. In LI fusion schemes the dimensionality of the feature vector is smaller than in EI fusion schemes. However, this scheme uses training samples only of the corresponding sensor unit.

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. In this scheme the number of training samples is larger since each data frame appears in the training set N times, one time for each one of the available sensor units. During the test phase, for each frame, N decisions are made by feeding the signature from each sensor unit to the global classification model. A final decision is made at a score level by combining the N output class labels using the same fusion rule (majority voting) as before. Although this scheme is less specific, it handles better both the high dimensionality and the problem of small number of training instances.

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.

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. 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.
- First draft version of the VPM, which will serve as a 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.

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

The main objective in WP5 during this period has been to analyze the required hardware devices to run the games, their capabilities and sensors and their operative systems and libraries that will allow device programming, 3D rendering and sensor access. In second term and based on the decisions taken during this analysis, the next objective has been to analyze more in deep and learn the available

libraries and game engines to be used, and to start the development of modules, games and analysis tools.

This analysis has been completed and detailed in the deliverable D5.1 whose results are decisive for the further development of the game framework and the games themselves.

The development of the framework has progressed as planned. New modules have been included and a deeper knowledge about the Unity graphics engine has been achieved from the developers´ side. Finally, in collaboration with clinicians, some preliminary game proposals have been attained with a double purpose, on the one hand, to specify the type of capacities and sensors which the definitive games will need to communicate with, and on the other hand, to allow developers to base the games framework on the data obtained, enabling to carry out different tests over some use cases and realistic scenarios.

12.5.2 WP5 – Summary of progress

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.

With regards to task T5.2, some sample applications have been 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 has been extended to allow the user have better control on the bluetooth devices he wants to use in the game.

There are also developed new modules to keep records of the user performance and relevant data of any event happening for each game for the active session. These records will provide the clinician a full view of the user historic performance on the different games and the physiological and cognitive domains.

Regarding the game development, small examples have been 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 has been developed, and is in the testing phase to verify its usability. Additionally, the development of features (discussed and agreed with involved partners in further Skype meetings) and other improvements to provide a better gameplay for the different users, e.g. level selection or difficulty evolution in real time, are ongoing.

Furthermore, two augmented reality demo games are currently under development on both tablet and glasses testing the ergonomics, user-friendliness compactness and unobtrusiveness. Note that these games may not be part of the final game suite.

Last but not least, the virtual supermarket game (available from CERTH), a cognitive training game that help detect mild cognitive impairment, has been improved in terms of graphics quality, multi-lingual support and capability of communication with the mobile gateway of the FrailSafe architecture.

12.5.3 WP5 – Significant results and achievements

The main outcome during this period is the deliverable D5.1 which details the results of the hardware devices and software tools analysis. After this analysis, having purchased some Google Pixel C tablets, and having selected Unity as the game engine for FrailSafe, some developments have already been tested, smart device IMU sensor access and 3D rendering. There is still a battery of analysis and tests to be performed before the game framework will be designed (Internet access, Database access or Menu and GUI creation).

Two sample applications have been developed based on the connection module to the MicroFET handgrip device, making some improvements on this one after the firsts tests, one of which is a game based on its force interface, that is currently being improved for a better gameplay, and the other, graphically displays the received data through a dial and through a force vs. time chart.

Also new modules are in development, like one for login the users progression based on the different games.

Upgrade of virtual supermarket game and development of two augmented reality demo games.

12.5.4 WP5 – Deviations and critical issues

No deviations have been produced during this period in WP5.

12.5.5 WP5 – Use of resources

WP5 Resources have been used as expected in this first period of the project. They have been invested mostly in the analysis of hardware devices and software tools in T5.1.

The allocated resources have been divided among the different tasks of the work package, being initially more allocated to task 5.1 and once finished, focusing during

the last months on task 5.2, 5.3 and 5.4 which are devoted to the development of the games, the necessary libraries and the DSS.

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 6: 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 7: WP6 Deliverables and Milestones

Deliverables	D6.1 FrailSafe Virtual Community Platform	M28: preliminary version M32: final version
	D6.2 FrailSafe mHealth Integrated version	M18: first version M25: second version 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 (aka e-CRF), in collaboration with WP2 and WP4;
- Designed front-end architecture, based on Data Flow, in collaboration with WP1;
- Deeply investigating Data Security and Privacy EU Directives and Regulation and how they affect the Cloud Host choice (production of documentation for the Project Officer and the D1.3 deliverable supported by a legal consultant in matter of privacy matters);
- 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.
- Release of user-guide for the Clinical Web Portal for ECRF.

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

- Design of back-end (server-side) system architecture, in collaboration with WP1;
- Design mobile ecosystem, in collaboration with WP1;
- Implementing the Virtual Community Platform (T6.1)
- Understanding and Designing the Security and Privacy features of FRAILSAFE (T6.2).

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 showing frailty results from elderly to caregivers and their families. More specifically, with use of this platform, older people will exchange disease and health related information as well as the promotion of positive health-related activities (fitness, daily habits, environmental safety) and they can ask and answer questions about diagnoses, etiology and treatment.

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

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 25th of May 2016;
    - EU Directive 95/46/EC (1995), replaced by the EU General Data Protection Regulation.
- Design of a technical security checklist and of how to apply security measure to system's architecture;

Furthermore, analyzing activities dealing with Privacy by Design and by Default in order to understand how data protection must be designed into the development of FrailSafe integrated system and how privacy settings must be set at a high level by default.

T6.3 System 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.

- Concerning integration, complete 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 micro-services architecture;
- Defining a unified Data Model for the system to ease the data exchange;
- Finalize the discussion about "cloud" choice and, most of all, having the double-check of relying on a compliant public cloud provider's services.

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 front-end architecture, based on Data Flow, in collaboration with WP1;
- Deployment of first version of Clinical Web Portal for ECRF (Electronic Case Report Form) features first test run to be 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.

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

This WP starts on M18. However, 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 above 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

Task 2.3 (for deliverable 9.3) is in the stage of literature review in order to investigate the current and most well-based recommendations referring to frailty related conditions. Extended data gathering from the study's subjects has not yet started.

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 official starts on M18.

12.7.4 WP7 – Deviations and critical issues

No deviations or critical issues to report.

12.7.5 WP7 – Use of resources

Nothing to report.

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 eight months (May- December 2016), it attracted nearly 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 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 to announce the official launch of the website (check here).

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 centres that will help clinicians explain the project to older people and convince them to take part as volunteers in the FrailSafe study.

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.

Facebook: A Facebook account (@frailsafe) 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 is due in M12 (December 2016) and narrated the most recent outcomes and deliverables of the project during the last 6 months.

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 two (2) 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 not started yet, but due to its critical importance, preliminary research and discussions have already started related to the business potential of FrailSafe, its innovative aspects and the added value compared to the current market state (see Section 11 for more). The Advisory Stakeholder Board has been established with three initial members (reported in D9.1). However, considering the suggestion from the reviewers (from the 1st interim review) to start involvement of the Advisory Board in fostering exploitability of future project's results, we have started to take several actions including inviting more stakeholders to become part of the advisory group and have regular meetings with the board, so that they can monitor and control that the project outcomes maintain commercial exploitability and in general steering the project in commercial directions.

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. Compilation of the Data Transfer Agreement that shall be used for the transfer of data is also underway. A first version of the IPR protection plan will be 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

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 deliverable "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) Scientific dissemination activities took place both to scientific communities and to stakeholders through the participation at events listed in section6.2.3.
- 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 M12: 2nd periodic report M24: 3rd periodic report 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 M36: final version

12.9.1 WP9 – Objectives of WP9 during the period

The main objectives of WP9 during this first year 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' developmentd

- 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 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 issues
- 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. → YIANNI OK???

12.9.3 WP9 – Significant results and achievements

The most significant results and achievements with regard to 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)]

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 1st annual periodic report.

14 Summary of Actual PMs Allocation for the Reporting Period (cumulative M1-M12)

	Person Months									
Partner short name	**WP1**	**WP2**	**WP3**	**WP4**	**WP5**	**WP6**	**WP7**	**WP8**	**WP9**	**Total**
UoP	6.48	1.76	0.82	14.29	2.34	0.29	-	0.285	4.424	30.689
BRA	0.9	3.2	-	-	8.5	1.4	-	1.1	-	15.1
SMARTEX	3.48	0.05	20.13	-	-	-	-	0.05	0.78	24.49
AGE	1.28	-	-	-	-	-	-	3.43	0.86	5.58
CERTH	9.9	-	4.94	3.03	7.24	-	-	1.15	0.27	26.53
MATERIA	11	6	-	-	1.3	-	-	0.83	-	19.13
SIGLA	12	-	2.28	-	-	6.34	-	1.32	0.99	22.93
HYPERTECH	3	-	-	1.91	0.5	-	-	5.16	-	10.57
INSERM	1	8.2	-	-	0.8	2	-	0.5	-	12.5
Total	47.796	19.21	28.17	19.23	20.68	10.03	0	15.075	7.724	167.915

15 Updates of the exploitation and dissemination plan

The dissemination activities are going according to the envisaged plan (deliverable D8.1) submitted in M3. Certain communication materials still need to be approved by the consortium partners before being officially published on the website.

Important European conferences and events have been selected that were not mentioned on the first version of the dissemination plan. These events would be an opportunity to have a greater visibility about the project.

Officially, the exploitation and business models creation task (T8.2) has not started yet, but due to its critical importance, preliminary research and discussions have already started related to the business potential of FrailSafe, its innovative aspects and the added value compared to the current market state. 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).

16 Updates of the data management plan

The first version of the Data Management Plan (DMP) (deliverable D8.12) is submitted in M6, together with the current report. 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. Nevertheless, all three clinical centers have already managed to start the clinical part of the study. INSERM obtained approval from their local Ethics committee on Oct. 6th 2016. 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., parallel recruitment of groups A and B) has been communicated to the Project Officer.

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 analysing 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 amandment 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 - Main concepts related to FrailSafe - Expected contributions - First timeline and deadlines set - Administrative matters	**UoP**: Vasilis Megalooikonomou (FrailSafe coordinator), Yannnis Elloul, Kyriakos Sgarbas, Christos Makris, Andreas Kanavos, Georgios Drakopoulos, Evangelia Pippa, Pantelis Vikatos **CERTH**: Nikos Fakotakis, Konstantinos Moustakas, Konstantinos Votis, Aris Lalos **Hypertech**: Kosmas Petridis **Gruppo SIGLA**: Luca Bianconi **Inserm**: Athanasios Benetos (FrailSafe scientific coordinator) **Materia-AgeCare**: Marina Polukarpou, Kimon Volikas, Ioanna Petridou **SMARTEX**: Roberto Orselli, Carlo Mancuso **BrainStorm**: Javier Montesa **AgePlatform**: Maude Luherne
2nd Plenary meeting	01-02/06/2016, Thessaloniki Greece	- FrailSafe project progress - Project report on all working packages - Medical partners meeting	**UoP**: Vasilis Megalooikonomou (FrailSafe coordinator), Yannnis Elloul, Andreas Kanavos, Konstantinos Deltouzos, Georgios Drakopoulos, Eirini Tsiamaki, Maria Dimopoulou, Rafaela Sibola **CERTH:** Konstantinos Moustakas, Andreas Vasilakis,

Title	Date and Place	Main conclusions	Participants
		- ICT partners meeting - i-PROGNOSIS Project presentation - Next steps	Dimitrios Tzovaras, Konstantinos Votis, Elias Kalamaras, Konstantia Kotta, Fotini Trikka, Anastasia Chatzidimitriou, Christina Karamanidou, Smerla Stavroula, Hatziioannou Diane **Hypertech**: Kosmas Petridis **Gruppo SIGLA**: Cristiana Degano, Luca Bianconi, Fabio Podda **Inserm**: Jirar Topouchian **Materia-AgeCare**: Kimon Volikas, Ioanna Petridou **SMARTEX**: Roberto Orselli, Carlo Mancuso **AgePlatform**: Nathalie de Craecker, Nhu Tram
3rd Plenary meeting	December, Italy	- FrailSafe project progress - Project report on all working packages - Evaluation of the first year - Next steps	**UoP**: TBA **CERTH**: Andreas Vasilakis, Elias Kalamaras **Hypertech**: TBA **Gruppo SIGLA**: Cristiana Degano, Luca Bianconi, Fabio Podda, Matteo Toma **Inserm**: TBA **Materia-AgeCare**: TBA **SMARTEX**: TBA **BrainStorm**: TBA **AgePlatform**: TBA

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 - Technical issues (data transmission, battery consumption, architecture) - Prepare website and logo - Discussion about falls (detection vs prevention)	Vasilis Megalooikonomou, Yiannis 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 - 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,	Vasilis Megalooikonomou, Yiannis Ellul, Andreas Kanavos (**UoP**), Konstantinos Moustakas, Konstantinos Votis, Ilias Kalamaras (**CERTH**), Luca Bianconi (**SIGLA**), Roberto

Title	Date and Place	Main conclusions	Participants
		blood pressure monitor, mobilograph, impedance scale)	Orselli, Carlo Mancuso (**SMARTEX**), Javier Montesa (**BrainStorm**), Kosmas Petridis (**Hypertech**), Thanos Benetos, Jirar Topouchian (**INSERM**), Kimon Volikas, Ioanna Petridou (**MATERIA**)
ICT Partners meeting	11/03/2016	- Discussion on the architecture of the FrailSafe project - Discussion on the use cases	Vasilis Megalooikonomou, Yiannis 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, Yiannis 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	20/04/2016	- Update on the progress	Vasilis Megalooikonomou, Yiannis Ellul, Andreas Kanavos,

Title	Date and Place	Main conclusions	Participants
meeting		of each WP - Feedback from INSERM about the vests	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**)
WP Leaders meeting	04/05/2016	- Additional discussion on the budget to acquire the devices	Vasilis Megalooikonomou, Yiannis 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

Title	Date and Place	Main conclusions	Participants
			Montesa (**BRAINSTORM**), Nhu Tram (**AGE**), Marina Kotsani (**INSERM**)
Clinical meeting	13/05/2016	- Discussion on clinical assessment completed - 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 -	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**)
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	J. Ellul, M. Kotsani (**INSERM**), 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	22/06/2016	- Generation of the eCFR platform	Luca Bianconi (**SIGLA**), Matteo Toma (**SIGLA**), Fabio Podda (**SIGLA**), Marina Kotsani

Title	Date and Place	Main conclusions	Participants
meeting			**(INSERM)**
ICT and medical Partners meeting	22/06/2016	- 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 - Purchase of devices - Project name conflict - Update from the Work	Vasilis Megalooikonomou, Yiannis Ellul, Andreas Kanavos, Konstantinos Deltouzos **(UoP)**, Andreas Vasilakis, Ilias Kalamaras, Konstantinos Moustakas **(CERTH)**, Roberto Orselli **(SMARTEX)**, Luca

Title	Date and Place	Main conclusions	Participants
		Package leaders	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 36. Update from the Work Package leaders	Vasilis Megalooikonomou, Yiannis 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 - Amendment - Project name conflict 37. Update from the Work Package leaders	Vasilis Megalooikonomou, Yiannis 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)** Marina Kotsani, Thanos Benetos, Sylvie Gautier, Jirar Topouchian

Title	Date and Place	Main conclusions	Participants
			(INSERM)
WP leaders meeting	11/10/2016	- General update by the Coordinator concerning the amendment request, the workshop he attended - Next plenary meeting - Review meeting - Device loan document 38. 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 -plans for the near future 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)**

Title	Date and Place	Main conclusions	Participants
WP leaders meeting	09/12/2016	-Discuss the comments and recommendations that received fron the review panel -The leaders that asre responsible for the Deliverables, informed about the status of the deliverable. 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**

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.

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.

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.

As FrailSafe is still at its first year with little concrete outcomes, it is difficult for example at this stage to organise joint activities with other H2020 projects. However, we do keep track of their activities and FrailSafe coordinator remains in contact with them, as there are potential synergies from a technical but also medical point of view.

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) A.2 Natural Persons under direct contract A.3 Seconded persons (A.6 Personnel for providing access to research infrastructure)		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment 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: XX Euro/Hour		Actual	Actual	Actual	Actual	FlatRate[5] 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															
BRA															
SMARTEX															
AGE															
CERTH															
MATERIA															
SIGLA															
HYPERTECH															
INSERM															

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

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	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) Server (1)	Equipment				3.465.54 euro
MATERIA CYPRUS	Review meeting Brussels	travel				Tickets= 486.07 euro Accommodation: 374 euro Food: 127.48 euro Taxi&bus 75 euro
MATERIA CYPRUS	Plenary meeting Genova	travel				Tickets= euro Accommodation:

						1.244.9 Food: 219.50 euro Trains: 179.66 euro
SIGLA	Kickoff meeting in Patras (19-20/01/2016)	Travel costs and accomodation for 1 resource	WP6	YES		464,59 Euros
SIGLA	Plenary meeting in Thessaloniki (01-02/06/2016)	Travel costs and accomodation for 3 resources	WP6	YES		1.320,18 Euros
SIGLA	Technical meeting in Nancy at INSERM	Travel costs and accomodation for 2 resources	WP6	YES		776,42
SIGLA	Workshop in Bruxelles and technical meeting (3 – 4/10/2016)	Travel costs and accomodationf for 1 resource	WP1	YES		438,32
SIGLA	1st Project Review in Bruxelles (25/10/2016)	Travel consts and accomodation for 2 resources	WP9	YES		1363,21 Euros
SIGLA	2nd Project plenary	Dinner costs for 4	WP6	YES		140,00

	meeting in Genova – Italy (12-13/10/2016)	resources				Euros
SIGLA	IARIA Conference – MATH - Symposium in Venice (25-27/04/2016)	Travel costs and accomodation for 2 resources	WP8	YES		1.084,40 Euros
SIGLA	Purchase of 6 Google Pixel C tablets for trials sites	Equipment	WP2	YES		2545,20 Euros
SIGLA	Cost related to the rent of Meeting Room and catering (coffee breaks and lunches) for the plenary meeting held in Genova on the 12 and 13 of December 2016	Services	WP1	YES		3673,99 Euros
SIGLA	Purchase of 6 Google Pixel C tablets for trials sites	Equipment	WP2	YES		3.224,96 Euros
SMARTEX	Kickoff meeting in Patras (19-	Travel costs for 2 resources (C.	WPs 1,3,9	YES		Flights and transportation: €

	20/01/2016)	Mancuso, R. Orselli)				715,57, Hotel: 208,00 Food: € 89,63 TOTAL: € 1.013,20
SMARTEX	Disseminati on activity in Genoa (06/04/16)	Travel costs for 1 resource (R.Orselli)	WP8	YES		Car rental + Gasoline + Motorwa y 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 transport ation: € 969,72, Hotel: 296,08 Food: € 170,97 TOTAL: € 1.436,77
SMARTEX	Electronic component s	Other goods and services	WP3	YES		€ 1.061,61
SMARTEX	Tablets	Other goods and services	WP3	NO	SMARTEX will request for a budget allocation for Other Direct Costs (*1)	€ 2.762,39
AGE	Kick Off meeting	Travel		YES		586,88 EUR
AGE	Consortium meeting –	Travel		YES		693,94

	Thessaloniki (2 PAX)					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 Hotel: 762 EUR Per Diem: 446.50 TOTAL: 1862,50 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 & 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		889,75 Euros
BRAINSTORM	Purchase of 3 Google Pixel C tablets and 2 covers for trials sites	Equipment	WP2	NO	Bainstorm will request for a budget allocation for equipment. (*1)	1267,09 Euros

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.

SIGLA:
Personnel cost for the reporting period is 127.339, 98 Euros. Other costs are 11.806,31 that is less than 15% of personnel cost.

UoP:
Personnel cost for the reporting period is 138.082,50 Euros. Other costs are 20.338,61 Euros which is less than 15% of personnel costs.

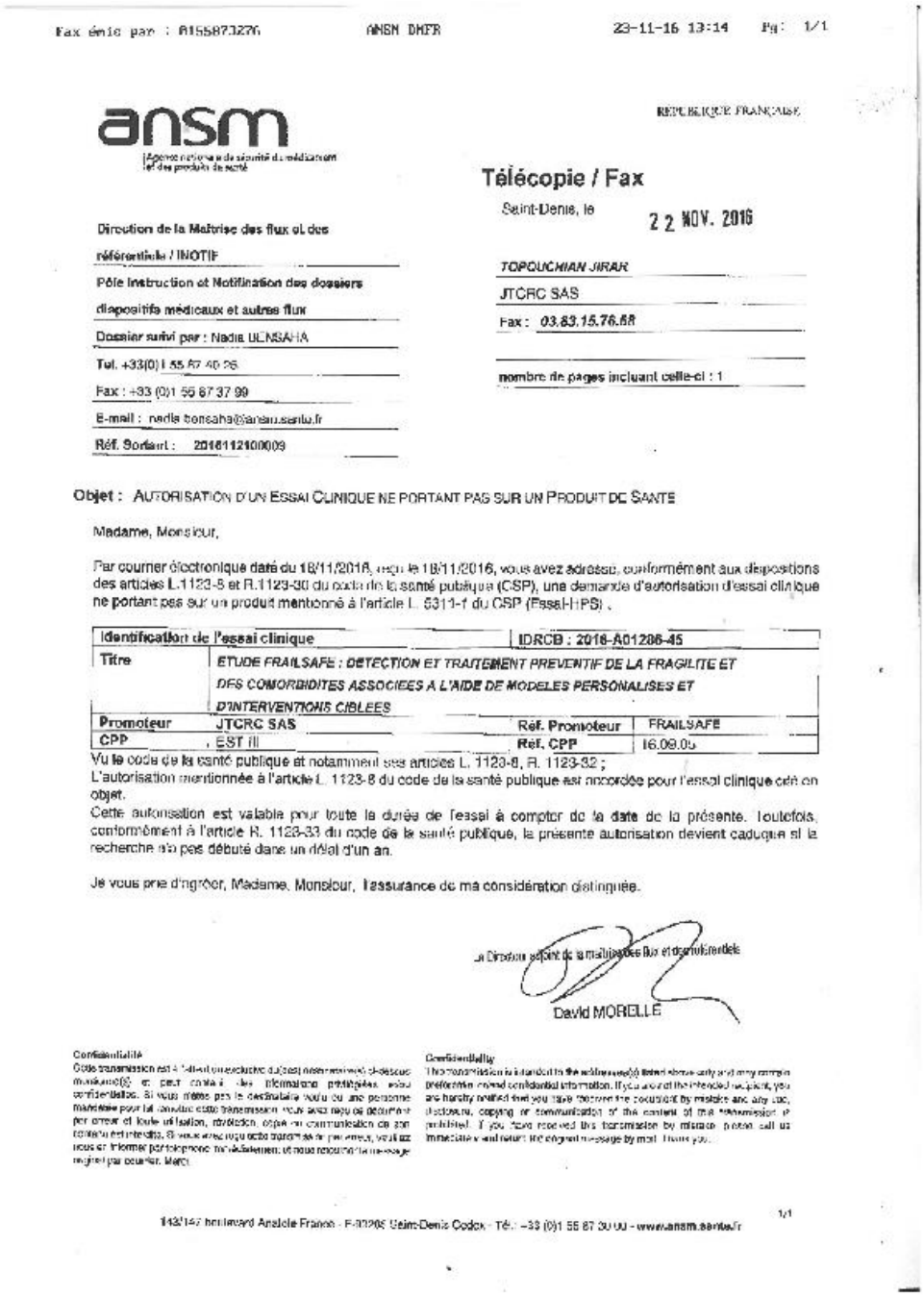
21.7 Other directs costs reported as use of in kind contribution from third party

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 - Ethical approvals



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Agence nationale de sécurité du médicament et des produits de santé

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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 26
Fax : +33 (0)1 55 87 37 99
E-mail : nadia.bensaha@ansm.sante.fr
Réf. Sortant : 20161121000009

TOPUCHIAN JIRAR
JTCRC SAS
Fax : *03.83.15.76.58*

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

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1/1

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COMITÉ de PROTECTION des PERSONNES EST-III

116pital de Brabois, Rue du Morvan 54511 VANDOEUVRE-LES-NANCY Cedex

Téléphone : 03.83.15.43.24 - Télécopie : 03.30.62.16.02 - Courriel : cppest3@chru-nancy.fr

Nancy, le jeudi 6 octobre 2016

Mr le Pr Alexandre 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).

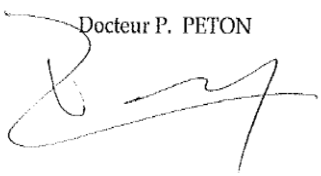
Le Comité a adopté la délibération suivante : **AVIS FAVORABLE** pour :

- 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



Consent forms and information forms

v/réf : version 2 /19.09.2016

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 compose 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.

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.

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 2 /19.09.2016

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 compose 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.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.

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.

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

From Patras - Ethical approval

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. Α2β/Γ.Π.: 100428/15 (ΦΕΚ 40/ΥΟΔΔ/27.1.2016), και ΔΥ1δ/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. προς τα τακτικά, αναπληρωματικά μέλη και εισηγητές, παρέστησαν οι :

1.ΚΟΝΣΤΑΝΤΟΠΟΥΛΟΥ 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: 6ΥΠΝ7693ΟΓ-ΘΩΨ
Θέμα 5ο

Η Αντιπρόεδρος θέτει υπόψη των μελών του Δ.Σ το αριθ. πρωτ. 6954/11-4-16 διπλωματικό 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 Deontology.

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 Ελληνά

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 Ελληνά.

Η ΑΝΤΙΠΡΟΕΔΡΟΣ ΤΟΥ Δ.Σ **ΤΑ ΜΕΛΗ**

ΚΩΝΣΤΑΝΤΟΠΟΥΛΟΥ ΕΙΡΗΝΗ

ΤΖΟΥΤΗ ΑΘΗΝΑ
ΜΑΛΛΙΩΡΗ ΣΤΑΘΑΚΗ ΑΙΚ.
ΑΝΘΡΑΚΟΠΟΥΛΟΣ ΜΙΧΑΛΗΣ
ΛΑΖΑΡΟΥ ΝΙΚΟΛΑΟΣ

ΑΚΡΙΒΕΣ ΑΠΟΣΠΑΣΜΑ
Η ΑΝΤΙΓΡΑΜΜΑΤΕΑΣ ΤΟΥ Δ.Σ

ΜΑΚΡΗ ΚΑΛΛΙΟΠΗ

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:

From Cyprus - Ethical approval

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

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 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

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 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 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

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ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ

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Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

Επίθετο:	……	Όνομα:	……
Υπογραφή:		Ημερομηνία:	

ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ

ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΜΕΓΑΛΗ ΤΕΛΙΚΗ ΟΜΑΔΑ

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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)

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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

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ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ

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Ονοματεπώνυμο ερευνητή: _____

Ημερομηνία:

Υπογραφή:

Ονοματεπώνυμο συμμετέχοντα: _____

Ημερομηνία:

Υπογραφή:

Επίθετο:	……	Όνομα:	……
Υπογραφή:		Ημερομηνία:	

ΠΕΡΙΓΡΑΦΗ ΤΗΣ ΜΕΛΕΤΗΣ

ΓΙΑ ΤΟΥΣ ΣΥΜΜΕΤΕΧΟΝΤΕΣ ΣΤΗΝ ΟΜΑΔΑ ΕΛΕΓΧΟΥ

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ΕΝΤΥΠΑ ΣΥΓΚΑΤΑΘΕΣΗΣ για συμμετοχή σε πρόγραμμα έρευνας (Τα έντυπα αποτελούνται συνολικά από 2 σελίδες)
Σύντομος Τίτλος του Προγράμματος στο οποίο καλείστε να συμμετάσχετε
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ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ

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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