Project Title:	**Sensing and predictive treatment of frailty and associated co-morbidities using advanced personalized models and advanced interventions**
Contract No:	690140
Instrument:	Collaborative Project
Call identifier:	H2020-PHC-2014-2015
Topic:	PHC-21-2015: Advancing active and healthy ageing with ICT: Early risk detection and intervention
Start of project:	1 January 2016
Duration:	36 months

Deliverable No: D9.3

Periodic Management Report (vers. a)

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Change History

Ver.	Date	Status	Author (Beneficiary)	Description
0.1	01/06/2016	draft	Vasileios Megalooikonomou (UoP)	First draft
0.2	06/06/2016	draft	Kosmas Petridis (Hypertech), Vasilis Megalooikonomou, Yannnis Elloul, Konstantinos Deltouzos, Andreas Kanavos (UoP), Konstantinos Moustakas, Andreas Vasilakis (CERTH), Roberto Orselli (Smartex), Javier Montesa (Brainstorm), Luca Bianconi, Cristiana Degano (Gruppo SIGLA), Ioanna Petridou (Materia Group), Marina Kotsani (INSERM)	1st round of contributions received by all partners.
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0.6	22/06/2016	draft	Kosmas Petridis (Hypertech), Vasilis Megalooikonomou, Yannnis Elloul, Konstantinos Deltouzos, Andreas Kanavos, Georgios Drakopoulos, Evangelia Pippa (UoP), Elias Kalamaras, Konstantinos Votis, Dimitrios Tzovaras (CERTH), Roberto Orselli (Smartex), Javier Montesa (Brainstorm), Cristiana Degano (Gruppo SIGLA), Ioanna Petridou (Materia Group), Marina Kotsani	3rd round of contributions received by all partners.

			(INSERM)	
0.7	24/06/2016	draft	Konstantinos Deltouzos (UoP), Andreas Kanavos (UoP)	Feedback by deliverable responsible: 3rd draft sent out to all partners.
0.8	30/06/2016	draft	Konstantinos Deltouzos, Andreas Kanavos, Vasileios Megalooikonomou (UoP)	Final revisions before sending for internal review
0.9	04/07/2016	draft	Yiannis Ellul (UoP)	Final internal review comments
1.0	07/07/2016	final	Vasileios Megalooikonomou (UoP)	Deliverable finalized taking into account internal review's comments.

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 report, an extensive list of the, so far, provided deliverables was provided together with the expected milestone achievements. A review has been conducted of the current practices in all frailty domains. Technical aspects, 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 architecture. A comprehensive clinical assessment was agreed including a face-to-face clinical assessment, self-administrated questionnaires, text sampling, and phone follow up assessment. Physiological parameters to monitor have been listed and the specifications of the devices have been described. A data flow and initial drafts of the FrailSafe architecture and specifications, detailing the distinct system components, their interconnections and security features were devised.

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 the person's right to be forgotten. Minor unforeseen risks were identified, which are causing delays, but mitigation procedures were placed. Dissemination strategies are already in place with measurable results, which we are also reporting. Intellectual property rights are also discussed, whilst open research data are guaranteed. Finally, all current technical progress from all work packages is fully explained.

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. Ramón Sanmartín Sola		

Deliverable number:	9.3	**Title:**	Periodic Management Report
Work package number:	9	**Title:**	Management & Ethics

Date of delivery	**Contractual**	**30/06/2016 (M6)**	**Actual**	**7/7/2016**
Status	Draft ☐		Final ☒	
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 not covered by the documentation in the individual working groups.			
Keywords	Periodic progress report, periodic technical report, periodic financial report			

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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. These preparatory steps will ultimately lead to the design of the requirement extraction and use case formulation methodologies, following well-known practices. Regarding T1.3, current practices for acquiring user feedback and allowing user participation for the purpose of UCD methodologies have been reviewed, such as questionnaires, interviews, participatory design and usability testing. 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". 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 in order to detect changes, as well as progression form one frailty state to other.

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

Moreover, WP2, in cooperation with other WPs, has contributed to: a) a preliminary version of an operational procedures' check list defining the FrailSafe system installation home 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.

In the context of WP3 and as described in D3.1, a search for sensors has been performed on the basis of parameters defined and described within the GA and the devices and related monitored parameters have been selected. Bio-impedance scales, Mobil-o-graph, blood pressure monitors and dynamometers have been or will be soon purchased to be used on the start-up group during the initial phase of the project. 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 two years of the project and 15 systems will be finally delivered only at M24, and on the base of a request of PO after a telco review, some sets of commercial inertial platforms have been selected 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 not been taken at the time of this report delivery.

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. 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. 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 so as to address critical issues of FrailSafe' human-computer interaction as well as to provide older persons and caregivers with interface and tools fitting to their specific needs. The identification and classification of the entities/concepts of interest relevant to FrailSafe is initially offered including monitored parameters, clinical data, diagnosis results, risk factor, action plans, interventions, patient record, etc., in order to meet the defined requirements.

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 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. 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 as part of Task 4.5 - "Processing social media". 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 - "Signal Processing for extraction of frailty-related indicators" aims at extracting frailty-related indicators from signal processing. In this way, as FrailSafe data are not available, we evaluated a preliminary analysis and evaluation of the accelerometer and gyroscope signals regarding the problem of motion identification using multi-parametric data from the UCI HAR Dataset. 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.

WP5 has focused mainly on the analysis of smart devices, operative systems, end game engines to be used in FrailSafe. As a result 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 operative systems. Regarding developments, the design of the FrailSafe Games Framework has been started and the first tests based on Unity have been performed, accessing device sensors, accelerometers or GPS, 3D rendering, and tactile screen.

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 in order to provide WP2 the possibility to collect digitalized data (instead of the paper one) since the beginning of the project to better rationalized the 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 elderly families and caregivers.

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

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

During this period, a first approach to the FrailSafe business model issue has been faced in T8.2. Firstly, we started to investigate different approaches to business modelling to promote the adoption of ICT-based solution for study, supporting and contrast frailty and co-morbidities. This is done by combining the specific basic components of the traditional business models (user/customer, application/services offering) to maximize the impact on the healthcare ecosystem, according to the following main topics: (a) User's/customer's central role in the definition of FrailSafe

Business Model; (b) Opportunities to FrailSafe business modelling; (c) Threats to FrailSafe wrong business modelling; (d) Earnings logic; (e) Key resources; (f) Orchestration of FrailSafe business model.

Then, the activities performed concentrated on how to develop a business framework with illustrative business models and their interfaces between actors to understand how the services can be created and delivered in the FrailSafe marketplace. Furthermore, the model Canvas and the Customer Development Model (by Steve Blank) are currently under evaluation in order to verify their usefulness to start to design the business model and, consequently, the FrailSafe business plan.

Additionally, the Intellectual Property Rights (IPR) Working Group was defined inside the project to work towards the compilation of the IPR agreement (T8.3). Discussions on the technical architecture of the FrailSafe platform are currently underway and are expected to be finalized pretty soon. In this architecture, the various exploitable components expected to be developed during the project lifecycle are also included (WWBS, games, data analysis and visualization tools, Virtual Patient Model, clinical and community platform etc.). The IPR agreement 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 six 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 a number of 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 a large number of 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].

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.

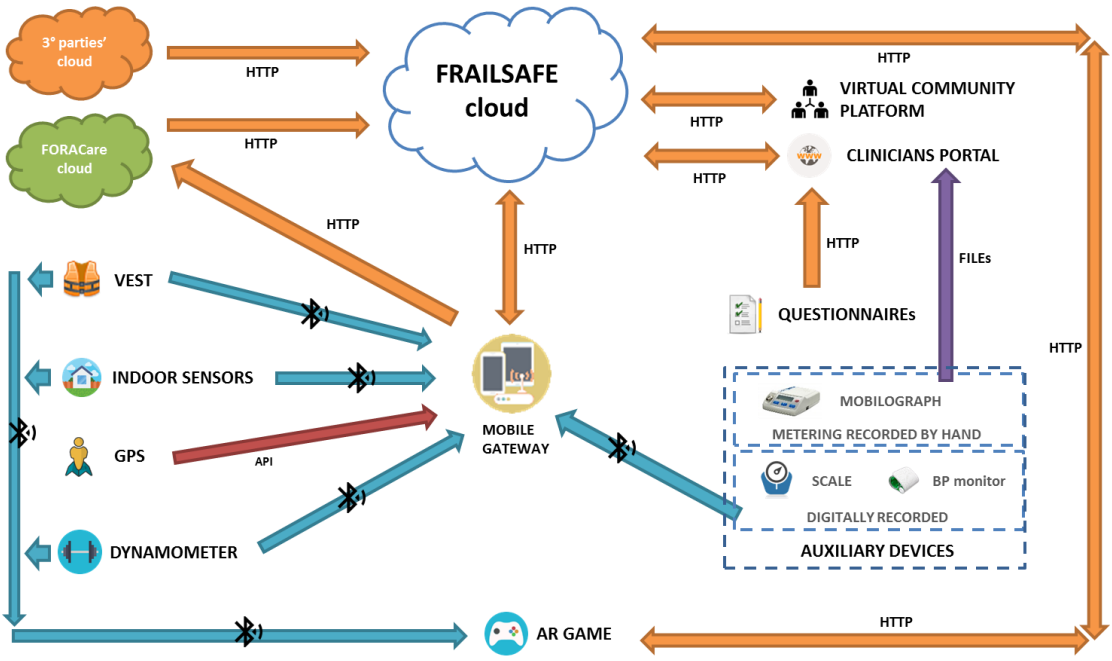

Figure 1 Data flows based architecture

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 in order 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.

References:

[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, Rome, Italy, 2016*

[2] Drakopoulos, Georgios, and Vasileios Megalooikonomou. "A Graph Framework for Multimodal Medical Information Processing.", *In Proceedings of 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)*

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,M12, M24, M36	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)
D8.5	Project Web presence	8	HYPERTECH	OTHER	PU	M3	M3		Submitted	Creation and launch of the FrailSafe 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	9	UoP	R	CO	M6, M12,	M6		Submitted	This report

	Reports					M24, M30				
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 the area of knowledge management systems and sensors for monitoring physical and cognitive capabilities as well as AR serious games and rehabilitation programs
D2.1	Clinical study methodology	2	INSERM	R	PU	M6	M6		Submitted	This report will be a living document and will provide 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	4	CERTH	R	PU	M6	M6		Submitted	It reports on the user-

	Profiling models and Patient modeling and representation framework (vers. a)									profiling models developed based on data collected from participants belonging to different frailty stages plus healthy participants.
D5.1	Analysis of hardware devices and software tools. Game hardware and software design.	5	BRA	R	PU	M6	M6		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 also 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.

3 Milestones

Table 2: List of FrailSafe milestones

Milestone No	Milestone Title	Related WP(s) no	Lead Beneficiary	Delivery date from Annex I	Means of verification	Achieved Yes / No	If not achieved Forecast achievement date	Comments
Ms1	Web site available	WP8	HYPERTECH	M3	Web site available on the internet	YES		

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 UoP and Materia	N/A	Final ethical approval is pending in INSERM
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	Has been appointed
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 taken into account. 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 in order 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.

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.

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.

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	Repeated applications after required adjustments in the questionnaires, information and informed consent forms
2	Technical imperfections of FrailSafe system	1-6	Continuous interactions between all WPs, prevention of possible practical obstacles and adaptation of devices in the target population's specificities
3	Recruitment rate delay	1-6	Recruitment campaigns intensification and study's beginning shifting
4	Use of augmented reality glasses may be difficult for some of the subjects	WP5	To a technical hands-on evaluation of existing glasses in our labs before choosing the product to purchase

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	Next application for Ethical Committee's approval to be examined in its following session
2	M1-	Yes	Yes	Continuous interactions and effort to adapt the material proposed and to develop

	M6			ameliorated devices in terms of both performance and tolerance/usability.
3	M4-M6	Yes	Yes	The delay of the study's beginning for 2-3 months, will be 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. Also, we had anticipated a delay for the first steps of the study, and thus we had ta 2-month "free" period between the Starting Group and the Main Group (M8-M10)
4	1	Yes	Not yet	Final outcome to be evaluated by end of October

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,*	*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				*and 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
FORESEEN ACCEPTED PUBLICATIONS													
1.	Conference proceedings paper	*Regularizing Large Biosignals with Finite Differences*	N/A	N/A	Vasileios Megalooikonomou; Georgios Drakopoulos	*7th International Conference on Information, Intelligence, Systems, and Applications (short name: IEEE IISA 2016)*	IEEE		*2016*	*(accepted to appear)*	*both*	*yes*	*no*

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	0
Press release	2
Non-scientific and non-peer reviewed publications (popularized publications)	0
Exhibition	0
Flyers training	0
Social media	2 (Twitter, Facebook)
Web-site	http://frailsafe-project.eu/
Communication campaign (e.g. radio, TV)	1
Participation to a conference	3
Participation to a workshop	0
Participation to an event other than a conference or workshop	7
Video/film	0
Brokerage event	0
Pitch event	0
Trade fair	0
Participation in activities organized jointly	0

with other H2020 project(s)	
Other	0
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	500
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.	*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*		*Europe*
2.	*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*
3.	*Article*	*AGE*	*Frailty, what is it?*	*11 April 2016*	*Brussels*	*Civil Society, Clinicians, ICT, policy-makers*		*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.

4.	*Meeting*	*INSERM*	*Informative meeting with ONPA*	*22 April 2016*	*Nancy, France*	*Older people*	*50*	France
5.	*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
6.	*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*
7.	*Article*	*European Commission*	*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*
8.	*Meeting*	*INSERM*	*Join the FrailSafe Study*	*25 May 2016*	*Nancy, France*	*Older people*	*25*	France
9.	*TV interview*	*UoP*	*Σύνδρομο ευθραυστότητας των*	*26 May 2016*	*Greece*	*General Public*	*1000+*	Greece

			ηλικιωμένων (Syndrome Frailty of the older people)					
10.	*Meeting*	*INSERM*	*Join the FrailSafe Study*	*6 June 2016*	*Nancy, France*	*Older people*	*25*	France
11.	*Meeting*	*INSERM*	*Join the FrailSafe Study*	*7 June 2016*	*Nancy, France*	*Older people*	*25*	France
12.	*Meeting*	*INSERM*	*Join the FrailSafe Study*	*16 June 2016*	*Nancy, France*	*Older people*	*25*	France
13.	*Meeting*	*INSERM*	*Join the FrailSafe Study*	*29 June 2016*	*Nancy, France*	*Older people*	*25*	France
14.	*Open House*	*INSERM*	*ONPA Open House Event*	*30 June – 1 July 2016*	*Nancy, France*	*Older people*	*50*	France
15.	*Newsletter*	*AGE*	*Newsletter #1*	*30 June 2016*	*Brussels, Belgium*	*Civil society, Medical, technical, policy makers*		Europe
FORESEEN ACTIVITIES								
1.	*Workshop*	*European Commission*	*Towards early detection of age-related health risks: understanding users' needs, unobtrusive sensing and data analysis*	*4 October 2016*	*Brussels, Belgium*	*ICT*	*50*	Europe
2.	*Summit*	*European Commission*	*European Summit on Innovation for active and healthy ageing*	*5-8 December 2016*	*Brussels, Belgium*	*ICT*	*500*	Europe

			"Transform the future of health and care in Europe"					

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.

Additionally, discussions on the technical architecture of the FrailSafe platform are currently underway and are expected to be finalized pretty soon. In this architecture, the various exploitable components expected to be developed during the project lifecycle are also included (WWBS, games, data analysis and visualization tools, Virtual Patient Model, clinical and community platform etc.).

The IPR agreement will focus exactly on these components. 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 section 16 of the current document.

9 Gender analysis

Beneficiary	Number F (Female) including third parties (if appropriate)	Number M (Male) including third parties (if appropriate)	Total including third parties (if appropriate)
UoP	1	9	10
BRA	2	4	6
SMARTEX	3.6	4.6	8.2
AGE	2	0	2
CERTH	4	6	10
MATERIA	7	3	10
SIGLA	3	7	10
HYPERTECH	1	1	2
INSERM	1	0	1
Total	24.6	34.6	59.2

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 privacy issues	Design of components is being performed, while selection of off-the-shelf components is almost finalized. This activity has to close within the first year, while implementation of new components will be finalized within year 2	20%
TO2	Design and development of efficient signal processing algorithms for low level processing including signal enhancement, activity classification, energy expenditure, and behavioral monitoring	Several algorithms for signal enhancement and activity classification have been developed	10%

		based on existing datasets since FrailSafe data are not available yet	
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 health preservation based on a personalized patient profile	The VPM has been designed and the parameters to be included have been defined. The real-time update and communication with the FrailSafe system is to be implemented	20%
TO4	Development of a generic monitoring and management infrastructure on which modular services and patient-specific applications will be built	Requirements of the data management infrastructure are discussed and database has been designed	10%
TO5	Development of novel methods for the offline management, fusion and analysis of multimodal and advanced technology data from social, behavioral, cognitive and physical activities of frail older people and application of these methods to manage and analyze the large amounts of data collected leading to integrative interpretation and better understanding of frailty, introduction of new quantitative frailty biomarkers as well as frailty metrics, correlation of co-morbidities and frailty, advanced decision making capabilities (DSS) assisting diagnosis by medical professionals	Part of the fusion and analysis methods for social and physical activities have been developed	5%
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) based on minimal processing of real-time multi-parametric streaming data and economical personalized monitoring guided by a minimal number of sensors and parameters	Several methods for real-time data management and analysis have been investigated.	5%

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 results from the offline data mining of multi-parametric data to make real-time analysis more efficient and targeted	Investigation of real-time trade-offs has started.	5%
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 behavioral, cognitive and physical domain while implementing various intervention strategies	Requirements discussed, hardware prerequisites analyzed, plans available	5%
TO9	Extensive testing of the FrailSafe integrated system in several validation scenarios while ensuring compliance with ethics standards	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.

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 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.	15%
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.	15%
MO5	Provide a model sensitive to change in order that will facilitate the testing	Not yet started	0%

	of 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, 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	Not yet started	0%

11 Success Indicators as Related to the FrailSafe Main Objectives

WP No.	Indicator	Success Criteria
		1st six month 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.	80%
	User requirements and system specifications clearly address FrailSafe needs	30% 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	5%
	Standardization of the procedures and protocols for the clinical studies and objective measurements of performance collected through various means and analyzed	80%

WP3 (Smart Sensing, data acquisition and signal processing)	Integration of sensors and definition of the communication framework	20%
	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	10%
	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	10%
	Number of physiological variables of the elderly models linked to frailty	5%
WP5 (Dynamic Intervention Services)	Review and comparative benchmarking of available Game hardware devices and software tools	70%
	Development of the game controllers and of the visualization interfacing	5%
	Graphical users interfaces customizable to the user requirements/needs	10%
	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 will lead to the formulation of the specific user requirements and use cases, in M12.
- The selection of the User Centered Design (UCD) methodology that will be used throughout the design and development of the FrailSafe components, in order to ensure that the user requirements are met. This will lead to the definition of UCD guideline evaluation protocols and checklists, by M12.
- The design of initial drafts of the FrailSafe architecture and specifications, detailing the distinct components and their interconnections. These drafts will lead to the first version of the FrailSafe architecture, by M12.

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, as well as software components, such as mobile applications, virtual and augmented reality games, data analysis software and visual analytics.
- Existing methods for the acquisition of feedback from the end user groups regarding the use of the various components have been examined, such as questionnaires, interviews, surveys and focus groups.
- 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.
- Three types of use cases for the FrailSafe system 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 viewing the data from a specific patient, and researcher-oriented, describing actions performed by researchers, such as using visual analytics tools for data analysis.
- The above preparatory steps will lead to the determination of the specific user requirements and use cases, by M12.

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.

- The above preparatory steps will lead to the design of the specific UCD guidelines protocols and checklists, to be used throughout the design and implementation phases of the project, by M12.

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, the dynamometer, the VR and AR games, the indoor sensors, the smartphone sensors and the questionnaires. 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, to be delivered by M12.

12.1.3 WP1 – Significant results and achievements

The most significant results and achievements with regard to WP1, in this first period, 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 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 deliverable D1.1, which is the outcome of Task 1.1, has been delivered on time, while the outcomes of the other tasks are preparatory steps for the final outcomes, to be delivered by M12.

12.1.5 WP1 – Use of resources

Smartex Task 1.1 1 PMs, Task 1.2, 0.2 PMs, Task 1.4 0.8 PMs

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

12.1.6 WP1 – Corrective actions

Currently, no corrective actions are needed.

12.2 WP2 – Clinical studies, measurements, clinical analysis

12.2.1 WP2 – Objectives of WP2 during the period

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

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

The Task 2.2-Clinical monitoring of older people was planned to start in M4 and 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.

In the context of Task 2.2, the clinical monitoring of participants has already started in the clinical centers of MATERIA-Cyprus and UoP-Greece. The first part of the initial clinical evaluation has taken place in Patras and Cyprus, subjects have been categorized according to conditions of interest for the study. Although INSERM has not yet started clinically evaluating subjects, all three centers have created an eligible participants' pool from which they are about to draw the study's subjects.

Task 2.3 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.

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, while others, mostly computer-based are still to be investigated and determined after the finalization of the computerized testing and the results of its first practical applications.

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.

The clinical centers of UoP and MATERIA have started the first phase of the clinical evaluation.

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 particularly in INSERM was the delay for obtaining approval from Ethical Committees in Nancy, France. This is mitigated by repeated applications after required adjustments, information and informed consent forms. Al three centers experienced some difficulty in creating a sufficient recruitment pool with eligible subjects. However the study is beginning shifting due by intensifying recruitment campaigns.

12.2.5 WP2 – Use of resources

The allocated resources have been used so far for hiring (full time) one geriatrician Dr Marina Kotsani 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 teleconference and other discussions with the different other partners for the development of this project

12.2.6 WP2 – Corrective actions

INSERM is preparing to re-submit the protocol to the Ethical committees. The case is expected to be examined in the following scheduled session. Recruitment campaigns are going on in all three clinical centers and the demanded number of subjects for the first randomization in groups A and B is expected to be fulfilled up until the end of the summer period.

UoP and MATERIA are going to complete the rest of the clinical evaluation, along with the FrailSafe system installation as soon as they grow the number of subjects needed for the first randomization. These first applications of the FrailSafe system devices will be realized with the material that we already possess in each phase of the study and the rest of the 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) first activities are planned for the development of a

wearable product able to monitor physiological parameters (cardiac and respiratory signals) together with information on user posture, activity and movement.

12.3.2 WP3 – Summary of progress

In the frame of Task 3.1, a set of different devices have been selected and (partly) 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)
Heart rate	
Respiration signal	
Respiration rate	
Posture	
Activity classification	
User localisation at home	Estimote™ iBeacon

On the base of a request of PO after a telco review, some sets of commercial inertial platforms have been selected too 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, but a final decision on which set will be purchased has not been taken at the time of this report delivery.

In the frame of Task 3.2, the motherboard and the components of the electronic device composing the WWBS has been designed, and it will be some assembled for first tests.

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

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 not yet 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 expected to be finished soon (July 2016).

12.3.5 WP3 – Use of resources

Smartex Task 3.1 4 PMs, Task 3.2 2 PMs

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 six 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 design 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.

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 Task 4.3, openEHR, which is a reference model for building VPM (Virtual Patient Models) via archetypes has been adapted so as to address critical issues of FrailSafe' human-computer interaction as well as to provide older persons and caregivers with interface and tools fitting to their specific needs. The identification and classification of the entities/concepts of interest relevant to FrailSafe is initially offered including monitored parameters, clinical data, diagnosis results, risk factor, action plans, interventions, patient record, etc., in order to meet the defined requirements.

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 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.

Task 4.6 aims at extracting frailty-related indicators from signal processing. In this way, as FrailSafe data are not available, we evaluated a preliminary analysis and evaluation of the accelerometer and gyroscope signals regarding the problem of motion identification using multi-parametric data from the UCI HAR Dataset.

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.

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 lightweight time domain algorithm for regularizing and removing outliers from long cardiovascular data sequences has been developed. It is based on the principles of bounded finite discrete differences and Tikhonov regularization. This algorithm will be incorporated to the abovementioned framework in order to be evaluated and further improved.

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).

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, however the inclusion of these parameters to the patient models will be further investigated in the final version of this deliverable. Finally, the last part of this deliverable presents how the identified parameters are translated into existing openEHR archetypes.

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 questionnaire 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).

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.

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

In this task, 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.

T4.7 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 elderly.

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.
- 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.

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 mostly 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.

Regarding development of modules and games, 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.

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).

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.

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*;
- 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 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:

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 4 WP6 Tasks

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

Table 5 WP6 Deliverables and Milestones

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 questionnaires web platform, in collaboration with WP2 and WP4;
- Designed front-end architecture, based on Data Flow, in collaboration with WP1;
- Deeply investigated Data Security and Privacy EU Directives and Regulation;
- 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 DoW, 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.

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.

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 DoW, to start at M16. However, as already mentioned in paragraph 10.1.6.1, the deployment of pre-α 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 (e.g. intervention system?);
  - 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”.

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 pre-α 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 DoW, 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.

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 two months (May-June 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 to be downloaded by visitors. The consortium partners decided to translate the English leaflet into Greek and French. The translated versions will be made available on the website when ready. Another leaflet is in

progress which will be displayed in medical centers for medical stakeholders but also to convince older volunteers to take part in the FrailSafe study.

Poster: A FrailSafe poster is also in progress, which partners can bring to conferences and events.

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 is due 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.

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, which could be found here.

Data Management Plan: The first version of the Data Management Plan (DMP) (deliverable D8.12) is due 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).

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. Research and standardization issues" has been accepted within the "From Research to Standardization" workshop.

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 version of the FrailSafe Dissemination Plan created, as illustrated in deliverable "D8.1: Dissemination plan and FrailSafe dissemination material" (M3).
- First version of the FrailSafe Data Management Plan compiled (Deliverable "D8.12: Data Management Plan" (M6)).
- Scientific dissemination activities took place both to scientific communities and to stakeholders through the participation at events listed in section 6.2.3. State-of-the-art of EU Directives and Regulations on privacy, data security and protection created.

12.8.4 WP8 – Deviations and critical issues

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

12.8.5 WP8 – Use of resources

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

12.8.6 WP8 – Corrective actions

No corrective actions required.

12.9 WP9 – Management and Ethics

The main objectives of this work-package are to guarantee the efficient functioning of the project, the resolution of possible conflicts that may arise and the timely completion of deliverables and milestones. In particular, the efforts here focus on: ensuring the delivery of the project on time and within the budget, coordinating the technological and scientific aspects of the project, guaranteeing high-quality

standards at all levels, guaranteeing the accomplishment of the objectives, ensuring that the project maintains its relevance towards the objectives of the program, managing resources and monitoring the overall project performance, managing ethics and safety issues, as well as establishing appropriate relationships and communication channels with the funding actors as well as between consortium partners.

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

WP9 Tasks	Effort (PMs)	Leadership
T9.1 Project Management	18.5	UoP
T9.2 Risk management and contingency planning	5	UoP
T9.3 Ethics and safety	4	UoP

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

Deliverables	D9.1 Project reference manual and quality plan	M3
	D9.2 Project Quality Plan	M3
	D9.3 Periodic Management Reports	M6: 1st periodic report 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 reporting 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
- The assembling of the 1st periodic progress report

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

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 six month periodic report.

14 Summary of Actual PMs Allocation for the Reporting Period

	Person Months									
Partner short name	**WP1**	**WP2**	**WP3**	**WP4**	**WP5**	**WP6**	**WP7**	**WP8**	**WP9**	**Total**
UoP	2.97	0.69	0.33	4.69	1.96	0.21	-	0.085	1.82	12.755
BRA	0.7	1.5	-	-	5.3	0.6	-	0.6	-	8.7
SMARTEX	2	-	6	-	-	-	-	0.05	0.5	8.55
AGE	-	-	-	-	-	-	-	2.35	0.68	3.03
CERTH	8.25	-	0.21	0.11	2.38	-	-	0.29	0.11	11.35
MATERIA	5	4.5	-	-	0.25	-	-	0.83	0.16	10.74
SIGLA	3.08	-	2	-	-	0.86	-	0.35	0.28	6.57
HYPERTECH	1	-	-	-	-	-	-	1.49	-	2.49
INSERM	1	3	-	-	-	-	-	-	-	4
Total	24	9.69	8.54	4.8	9.89	1.67	-	6.045	3.55	68.185

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.).

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.

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 is the difficulty in creating a sufficient recruitment pool with eligible subjects and some technical imperfections, which delayed the preparation and the integration of all FrailSafe system devices. In the case of INSERM there is still the delay in the 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 are going to be evolved during the development of the study. Nevertheless, two out of three clinical centers, the UoP and MATERIA GROUP, have managed to start the clinical part of the study in M6. Due to the delay in the beginning of the clinical part, tasks 2.2, 2.3 and 2.4, to the extent of their dependence from clinical measurements, are also shifted in time.

17.2 Deviations in the Use of Resources

Nothing to report.

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	**UoP**: Vasilis Megalooikonomou (FrailSafe coordinator), Yannnis Elloul, Andreas Kanavos, Konstantinos Deltouzos, Georgios Drakopoulos, Eirini Tsiamaki, Maria Dimopoulou,

Title	Date and Place	Main conclusions	Participants
		- Medical partners meeting - ICT partners meeting - i-PROGNOSIS Project presentation - Next steps	Rafaela Sibola **CERTH:** Konstantinos Moustakas, Andreas Vasilakis, 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	Mid December, Cyprus	- FrailSafe project progress - Project report on all working packages - Evaluation of the first year - Next steps	**UoP**: TBA **CERTH**: TBA **Hypertech**: TBA **Gruppo SIGLA**: TBA **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**), 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 (**Gruppo 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	Vasilis Megalooikonomou, Yiannis Ellul, Andreas Kanavos (**UoP**), Konstantinos Moustakas, Konstantinos Votis, Ilias

Title	Date and Place	Main conclusions	Participants
		usage (beacons, blood pressure monitor, mobilograph, impedance scale)	Kalamaras (**CERTH**), Luca Bianconi (**Gruppo SIGLA**), Roberto 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 (**Gruppo 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**), 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	V.Megalooikonomou, J. Ellul, Eir.Tsiamaki, M.Dimopoulou (**UoP**), Ath. Benetos, J. Topouchian, M. Kotsani (**INSERM**), I.Petridou (**MATERIA**)

Title	Date and Place	Main conclusions	Participants
		discussed	
WP Leaders meeting	20/04/2016	- Update on the progress of each WP - Feedback from INSERM about the vests	Vasilis Megalooikonomou, Yiannis Ellul, Andreas Kanavos, Konstantinos Deltouzos (**UoP**), Ilias Kalamaras, Kostas Moustakas, Andreas Vasilakis (**CERTH**), 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 (**SILGA**), 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**), Roberto Orselli

Title	Date and Place	Main conclusions	Participants
			(**SMARTEX**), Luca Bianconi (**SILGA**), Kosmas Petridis (**HYPERTECH**), Javi Montesa (**BRAINSTORM**), Nhu Tram (**AGE**), Marina Kotsani (**INSERM**)
Clinical meeting	13/05/2016	- Discussion on clinical assessment completed - 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 (**Gruppo 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 (**Gruppo SIGLA**), Matteo Toma (**Gruppo SIGLA**), Marina Kotsani **(INSERM)**

Title	Date and Place	Main conclusions	Participants
ICT and medical Partners meeting	22/06/2016	- Generation of the eCFR platform	Luca Bianconi (**Gruppo SIGLA**), Matteo Toma (**Gruppo SIGLA**), Fabio Podda (**Gruppo SIGLA**), Marina Kotsani **(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)**

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.

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 actual costs

	Person Months									
Partner short name	**WP1**	**WP2**	**WP3**	**WP4**	**WP5**	**WP6**	**WP7**	**WP8**	**WP9**	**Total**
UoP	2.97	0.69	0.33	4.69	1.96	0.21	-	0.085	1.82	12.755
BRA	0.7	1.5	-	-	5.3	0.6	-	0.6	-	8.7
SMARTEX	2	-	6	-	-	-	-	0.05	0.5	8.55
AGE	-	-	-	-	-	-	-	2.35	0.68	3.03
CERTH	8.25	-	0.21	0.11	2.38	-	-	0.29	0.11	11.35
MATERIA	5	4.5	-	-	0.25	-	-	0.83	0.16	10.74
SIGLA	3.08	-	2	-	-	0.86	-	0.35	0.28	6.57
HYPERTECH	1	-	-	-	-	-	-	1.49	-	2.49
INSERM	1	3	-	-	-	-	-	-	-	4
Total	24	9.69	8.54	4.8	9.89	1.67	-	6.045	3.55	68.185

21.2 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										

21.3 Total Person Months Allocated to Each WP

	Person Months									
Partner short name	**WP1**	**WP2**	**WP3**	**WP4**	**WP5**	**WP6**	**WP7**	**WP8**	**WP9**	**Total**
UoP	8	10	5	42	8	7	14	7	18	119
BRA	1	6	-	-	25	8	8	5	-	53
SMARTEX	4	1	40	-	-	3	-	3	1	52
AGE	3	-	-	-	-	-	-	15	1.5	19.5
CERTH	6	-	20	18	20	4	-	2	3	73
MATERIA	11	12	-	-	3	-	20	7	-	53
SIGLA	12	-	6	-	-	44	3	5	3	73
HYPERTECH	3	-	-	3	3	5	-	14	-	28
INSERM	8	19	-	-	3	-	14	5	1	50
Total	56	48	71	63	62	71	59	63	27.5	520.5

21.4 Use of in kind contribution from third party

No contribution from third parties in the current reporting period

21.5 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.

21.6 Direct costs of providing financial support to third parties

No contribution from third parties in the current reporting period.

21.7 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
SIGLA	Kickoff meeting in Patras (19-20/01/2016)	Travel costs for 1 resource	WP6	YES		464,59 Euros
SIGLA	Plenary meeting in Thessaloniki (01-02/06/2016)	Travel costs for 3 resources	WP6	YES		1.320,18 Euros
SIGLA	IARIA Conference – MATH Symposium	Travel costs for 2 resources	WP8	YES		1.084,40 Euros

	in Venice (25-27/04/2016)					
SIGLA	Purchase of 6 Google Pixel C tablets for trials sites	Equipment	WP2	YES		3.224,96 Euros
SMARTEX	Kickoff meeting in Patras (19-20/01/2016)	Travel costs for 2 resources (C. Mancuso, R. Orselli)	WPs 1,3,9	YES		Flights and transportation: € 715,57, Hotel: 208,00 Food: € 89,63 TOTAL: € 1.013,20
SMARTEX	Dissemination activity in Genoa (06/04/16)	Travel costs for 1 resource (R.Orselli)	WP8	YES		Car rental + Gasoline + Motorway fee: € 160,70
SMARTEX	Plenary meeting in Thessaloniki (01-02/06/2016)	Travel costs for 2 resources (C. Mancuso, R. Orselli)	WPs 1, 3	YES		Flights and transportation: € 969,72, Hotel: 296,08 Food: € 170,97 TOTAL: € 1.436,77

SMARTEX	Electronic components	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 – Thessaloniki (2 PAX)	Travel		YES		693,94 EUR
AGE	Design of logo	Other goods and services	WP 8	No	In order to create the visual identity of FrailSafe, AGE outsourced the creation of the logo to Association Bug	403,20 EUR
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	Equipment	WP2			240 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 first period is 36.480,83 Euros. Other costs are 6.094,13 that is more than 15% of personnel cost.

UoP:
Personnel cost for the reporting period is 61.303 Euros. Other costs are 5363 Euros which is less than 15% of personnel costs.

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

No contribution from third parties in the current reporting period.