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associated co-morbidities using advanced personalized models and advanced interventions

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Exploitation Report and FrailSafe Business Models (vers a)

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Lead Author: Kosmas Petridis (Hypertech)

Lead Partners: Stefanos Makris (Hypertech), Vasilis Megalooikonomou,

Yannnis Elloul, Dimitirs Vlachakis (UoP), Konstantinos Votis, Andreas Vasilakis (CERTH), Roberto Orselli, Carlo Mancuso (Smartex), Enric Montesa, Javier Montesa (Brainstorm), Cristiana Degano, Luca Bianconi (Gruppo SIGLA), Marina Polycarpou, Ioanna Petridou (Materia Group), Athanasios Benetos, Marina Kotsani (INSERM)



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1.0	30/06/2017	final	Kosmas Petridis, Stefanos Makris (Hypertech)	Deliverable finalized taking into account internal review's comments.

EXECUTIVE SUMMARY

The deliverable "D8.6: Exploitation Report and FrailSafe Business Models (vers a)" reports the first version of the exploitation report and the business models of the integrated system produced by the FrailSafe project. This document is part of WP8 and capitalizes on the results of WP1-WP7 and WP9 focusing on the exploitation of the produced system, the eventual business models, the contribution of each partner to the exploitation process and the market analysis concerning the commercialization of the final system.

This document represents the first version of the exploitation report and business plans of the FrailSafe project and is based on the collaborative work of the FrailSafe project partners, who have reviewed and delivered their comments and exploitation intentions.

The report provides a road map and different choices concerning exploitation, which will be evaluated throughout the project's duration and lead to the final complete plan to be used once the project is finalized and the integrated system is implemented and becomes mature for exploitation.

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Contributing authors (beneficiaries)	Vasilis Mega Konstantinos Roberto Orse Enric Montes Cristiana Deg Marina Polyc	kris (Hypertech) looikonomou, Yai Votis, Andreas V elli, Carlo Mancus a, Javier Montes gano, Luca Bianc arpou, Ioanna Pe enetos, Marina K	/asilakis (so (Smarte a (Brainst oni (Grup etridou (Ma	ex) orm) oo SIGLA) ateria Group)
Responsible	Kosmas Petr	idis	Email	k.petridis@hypertech.gr
author(s)	Beneficiary	Hypertech	Phone	+30 2310 262201

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1 Introduction

1.1 Purpose and Scope

This document is part of Work Package 8 (WP8) of the FrailSafe project and concerns the exploitation report of the integrated system implemented during the project, as well as the respective business models which might be used for the final exploitation. It is based on the work done by the project partners throughout the first 18 months of the project implementation and takes into account all the results already produced during this period.

This version of the document is the first one and summarizes the main exploitable products and the road map for future use in the process of exploitation. It contains an overall description of the project, the anticipated final products, an analysis of the targeted market and end users, an overview of the existing competitive solutions and the main advantages of the integrated system currently under implementation. The available solution for exploitation is also further evaluated and different exploitation strategies are proposed, along with business models to be followed after the project completion.

The document will be reviewed and enriched throughout the project duration according to the on-going results and products evolution, and it will be followed by a second and final version at the end of the 3-year project.

1.2 Structure of the Document

The document is structured as follows:

Section 2 summarizes the whole FrailSafe project, outlining its general aspects, the main exploitable results and the break-through characteristics of the final implemented system which will be promoted during the exploitation phase.

Section 3 presents the market where the project products will be positioned, analyzing its main features, the recent market trends, the targeted end users and the market segmentation to be used for expansion.

Section 4 overviews the existing competition to be faced, including the available competitive solutions and the appropriate positioning of the project products once launched.

Section 5 summarizes the exploitable outputs of the project and discusses major factors to be taken into account by the project partners, while presenting the unique selling proposition of the project based on its novelty.

Section 6 presents the business models, analyzing the proposed exploitation scenarios to be selected, and the business plan to be executed during exploitation.

Section 7 presents future work and related projects which could be carried out in parallel with the exploitation strategy.

Section 8 summarizes the conclusions of this report regarding exploitation and business models.

2 Presentation of the Project

2.1 General Aspects

The FrailSafe project addresses the issue of active ageing in modern societies, where population's clinical condition is steadily decreasing after a certain age. This has physical, psychological and behavioral effects on older people, while in societal terms there are risks related to social exclusion, isolation, severe accidents (falls, death etc.) and cost of hospitalization and rehabilitation.

The above-mentioned factors are a direct consequence of ageing and increase of life expectancy in modern societies, where people live longer and spend the last years of their lives inactively while facing multiple diseases which render them vulnerable. This state of morbidities, co-morbidities and disabilities, referred to as frailty, is the primary subject of the project, researching ways and technologies which will facilitate patients (as well as their doctors, caregivers and families) to evaluate, measure and sustain their condition throughout their older years.

Considering that frailty and functional disabilities are dynamic, preventable and reversible processes, the project aims at developing technologies based on machine-human interaction in order to measure those declining factors and proactively help the involved parties to design personalized interventions for counteraction. Given that those declines and changes may not be captured by conventional clinical assessments, the FrailSafe project addresses all the above challenges and is implementing real-life tools for assessment and improvement reasons.

The first goal of the project is in better understanding frailty, quantifying its effects and suggesting vertical interventions per patient, by collecting and evaluating his/her personal real-life data. The FrailSafe consortium is composed of heterogenous competences and includes medical institutions, active-ageing organizations, technology experts, equipment manufacturers, information systems specialists etc.

The main product to be developed is a digital patient model of frailty which is sensitive to several dynamic parameters, including physiological, behavioral and contextual ones. Different equipment and sensors will be integrated to collect real-life data from the patients and introduce them into the model, which will provide assessments, reports and suggestions of personalized treatment programmes, alerts and guidance to the doctors and caregivers in charge of each patient's health.

2.2 Project Components

The project components, the combination of which constitutes the FrailSafe integrated system are:

- Wearable WBan System (WWBS)
- Signal Processing and Data Analysis tool
- Social Media Sensing tool
- Risk Assessment tool
- Virtual Patient Model (VPM)
- Dynamically Synthetized Games
- Virtualization and DSS module
- Clinical Web Platform (eCRF)
- Virtual Community Platform (VCP)

2.3 Innovation within FrailSafe

Most of the products developed by the project partners are not unique in the market in the sense that there are other competitive ones with similar features and characteristics, but the novelty of the FrailSafe project is that the components themselves and the integrated system are addressing and solving frailty-related issues unlike any other existing product. The main innovative aspects of the project are listed below:

- A novel smart garment has been developed equipped with fabric electrodes and sensors, which can acquire an electrocardiogram (ECG), a respiratory signal and data from three inertial platforms (IMUs), providing feedback on the patient's physical activities.
- The project generates and studies continuous real-life data of frailty, such as cognitive, functional, psychological and social data in addition to physical ones. Through these continuous real-life measurement data will be collected and analyzed and a tool has been created which helps assessment, risk stratification and rehabilitation of frailty, leading to the development of a model providing preventive interventions.
- A dedicated patient model has been developed, which simulates the patient's activities and provides a reliable and realistic representation, allowing adaptation of the intervention strategies and a personalized feedback for the patient and the caregivers.
- The evolving virtual patient model also provides a quantifiable analysis and assessment of frailty levels, detecting frailty risks and triggering alarms in case of emergency situations, such as falls, loss of orientation etc.) based on the collected real-life data.
- The project collects heterogeneous information based on linguistic and emotional content of texts (e.g. tweets) and deducts an emotional analysis of the patient's state.
- Innovative sensing VR (Virtual Reality) and AR (Augmented Reality) games have been developed within the project, which quantify the patient's reactiveness and strength using special dynamometers designed to measure hand grip strength, implementing crucial stimuli (force sensing, visual information etc.) together to have a real impact on the game task completion performance.

2.4 Handling of IPR Issues

As it has been stated in the deliverable D8.8 "IPR Protection Plan", each project partner has different contributions to the development of each component, and this is shown in Table 1 below.

Project Output	NoP	BRAINSTORM	SMARTEX	AGE	СЕКТН	MATERIA	SIGLA	HYPERTECH	INSERM
1. WWBS system	✓		\		✓				✓
Signal Processing & Data Analysis tool	√		√		√				

3. Social Media Sensing tool	✓				✓			✓
4. Risk Assessment tool	√				✓			✓
5. Virtual Patient Model (VPM)	√			✓	✓		√	✓
6. Dynamically Synthesized Games	√	√		√	√			✓
7. Visualization & DSS module	√			√			√	
8. Clinical Web Platform (eCRF)	✓			✓	✓	✓		✓
9. Virtual Community Platform (VCP)	√					√	√	
10. Integrated FrailSafe system	√	✓	√	✓	√	√	√	✓

Table 1 - Contribution of Partners to Project Outputs

Based on these contributions and the IP rights owned by each partner before the beginning of the project, there are restrictions regarding IP rights, as well as required licenses which need to be obtained for the proper functioning of each component. All the above is presented in Table 2 below.

Project Output	IPR Restrictions	Required Licenses
1. WWBS system	Hardware and firmware developed by SMARTEX are owned by the company, but libraries for management of data are open for the consortium and could be open also to third parties.	No license required
2. Signal Processing & Data Analysis tool	Open-source or Commercialized	No license required
3. Social Media Sensing tool		Facebook and Twitter developer tokens (free)
	The Twitter crawler can retrieve tweets and retweets from any Twitter account on the condition that the appropriate developer credentials have been obtained prior to crawler launching.	

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4. Risk Assessment tool	Open-source or Commercialized	No license required
5. Virtual Patient Model (VPM)	Open-source or Commercialized	No license required
6. Dynamically Synthesized Games	Open-source or Commercialized	BRAINSTORM's real- time graphics engine (background knowledge)
7. Visualization & DSS module	Open-source or Commercialized	No license required
8. Clinical Web Platform (eCRF)	Commercialized. Software developed by SIGLA is owned by the company, but access to data is open for the consortium and could be open also to third parties via APIs.	No license required
9. Virtual Community Platform (VCP)	Open-source or Commercialized	No license required
10. Integrated FrailSafe system	Commercialized	BRAINSTORM's real- time graphics engine (background knowledge)

Table 2 - IPR Restrictions and Required Licenses

3 Market Analysis

3.1 The Active-Ageing Market

The proportion of population over 65 years-old is steadily increasing in the EU and will increase further within the next decades according to relevant studies, as this is depicted in Figure 1 - Increase of Polupation over 65 years in EU below.

Percentage of population above 65 years in the EU region

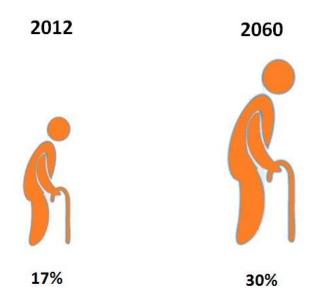
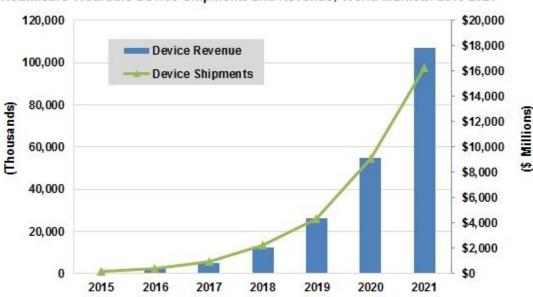


Figure 1 - Increase of Polupation over 65 years in EU

The positioning of the frailty-related products and solutions within the existing market in the EU is an overlapping combination of the following distinct markets:

- Fitness
- Wellness
- Healthcare
- Medical

The above markets are served by products and services which range from wearable sensors to specialized medical equipment. Particularly, the wearable technology market in healthcare and medical sectors is increasing in numbers of units and revenues steadily the last years and will continue to do so, as it is shown in Figure 2 - Healthcare Wearable Devices Units and Revenues below.



Healthcare Wearable Device Shipments and Revenue, World Markets: 2015-2021

Figure 2 - Healthcare Wearable Devices Units and Revenues

3.2 Market Potential for FrailSafe

The partnership has identified several distinct or overlapping markets where the FrailSafe solution, in particular the integrated FrailSafe system, might have high success opportunities, due to the nature of those markets.

Based on the features offered by the FrailSafe solution and the additional services which could be provided, the potential markets where exploitation and promotion will be directed are the following:

- Business-to-Business: The B2B market will be an ideal first step for exploitation, since manufacturers of medical equipment already have a wide variety of products and a large distribution network to promote the FrailSafe solution. These manufacturers might be interested in licensing the integrated system or adding it into their portfolio as a benchmark solution. In this way, the partnership will be given access to a client base difficult to reach otherwise, which is estimated to have high chances of success with minimum initial investment cost.
- Pharmaceutical Industry: The fact that the FrailSafe solution is non-intrusive
 makes it complementary to the pharmaceutical industry, not competitive to it. This
 industry is led by companies investing large percentage of their funding to
 research and development and the integrated FrailSafe system might be the ideal
 solution for part of their difficult-to-reach clients who are not treated using drugs.
 In this respect, pharmaceutical companies might be interested in investing or
 licensing the solution in order to access a broader client base using non-intrusive
 methods.
- National Health Services: National health institutions, including hospitals and clinics, need to reduce the treatment costs for older people who face problems of co-morbidities and frailty-related diseases. The FrailSafe solution, both its separate components and the integrated system, can help these institutions to decentralize the treatment and move it from their high-cost premises to the patient's house with frequent visits for monitoring and evaluation at the hospitals. This will not only drastically reduce costs but it will also improve the effectiveness of the treatment, since new non-intrusive methods will be used and the patient will have a more active role in the treatment process.

- **Insurance Companies:** The cost of in-hospital rehabilitation or treatment for frailty-prone patients is covered by their insurance company, either public or private one. It is in the interest of these companies to alleviate the costs of casual treatment and health monitoring by automated methods which don't require constant in-hospital visits and, thus, provide long-term benefits as far as insurance coverage is concerned.
- Older People: The stand-alone or retail clients (B2C market) will be an
 interesting market to investigate, since only a small percentage of this group
 could afford the high cost and additional required services of the solution. On the
 other hand, intense marketing and promotion campaigns should be carried out in
 order to attract these customers, which could possible enlarge the number of
 produced units and consequently lead to an economy of scale.

3.3 Market Segmentation

Since the FrailSafe solution is implemented by EU companies and institutions under EU grants, it is primarily addressing the European market of active-ageing. The market segmentation which is proposed here is divided into a sectorial one based on the industries it might interest and a geographical one based on the geographical distribution of the markets. Both market segmentations are presented below:

> Sector-based segmentation

- Rehabilitation
- Pathological
- Orthopedics
- General surgery
- Pain management

Geographical segmentation

- France
- Italy
- Belgium
- Spain
- Greece
- Cyprus

Since sectorial segmentation is too narrow and specialized, the most appropriate market segmentation for the exploitation period is proposed to be the geographical one. The means and methodology to be applied in order to enter into these market segmentations are further discussed in section 4.2 below.

4 Competition Analysis

4.1 Competitors and Competitive Solutions

The integrated FrailSafe system is a novel and beyond state-of-the-art solution, tackling numerous issues of the active-ageing and frailty-related market. In this regard, there are no direct competitors in the market now, not even indirect competitive solutions which address the wide variety of problems that this solution does.

On the other hand, the FrailSafe project is based on findings and research outputs of past projects, such as VERITAS, OpenEHR, KINOPTIM, NoTremor, PatientCoach etc., so there are some links with these platforms. However, the technologies and applied knowledge which has been developed within the FrailSafe project are unlike any other related system due to the degree of integration implemented in the current project.

Different markets have presented equipment and online platforms which might be used with limited functionalities in the specific field of active-ageing addressed here, so their products and services could be considered as indirect competitors to the FrailSafe solution. These indirect competitors, which are specialized and addressing complementary or adjacent markets, are the following:

- Wearables
- Health Monitoring Systems
- Medical Reminder Platforms
- Virtual User Models
- AR and VR Games
- Personal Guidance Systems
- Health Data Management Solutions

In Table 3 below, the different competitive solutions are presented, divided into thematic categories according to the original market they have been developed for. In addition, each solution is evaluated and benchmarked using criteria, such as sensing capabilities, personal guidance functionalities and awarded certifications.

		Sens	sing		Personal Guidance							FDA CE	
	Supported Functionalities	Physiological & Environmental	Behavioural	Social	Reminder	Caregiver Interaction	AR Serious Games	Digital Patient Models and Predictive DSS	Medical Visualization	Education and Feedback Support	Personalized Treatment	Frailty Quantification	FDA/CE
Wearables	Fitbit Larklife Apple Watch Jawbone	√	✓						√		2		
>	Preventice Bodyguardian	√	✓						✓		1		✓

			T	1		T .		I	I			I	1
	Carré Technologies Hexoskin	✓	✓						✓		1		✓
	InteleSens	✓	✓						✓				
th ring	Tactio Health	✓	√			√	√		√				
Health Monitoring	Daily Check Cardio Health	✓			✓				√	✓	1		
ation nder	MedCoach				✓				✓	√			
Medication Reminder	Medication Tracker				✓				✓	✓			
Virtual User Models	VERITAS	✓	✓				✓	✓	✓	✓			
Vir User I	OpenEHR	√	✓					✓	✓				
	WiiSports WiiFit	✓	✓				✓	*					
VR	NACODEAL	✓	✓				✓	✓	✓			✓	
AR/VR Games	Dance! Don't Fall	✓	✓				✓	✓	✓	✓	1	*	
	Neumimic	✓	✓				✓	✓	✓	✓	1	*	
	Rewire	✓	✓				✓	✓	✓	✓			
nce	ALFRED	✓		✓			✓		✓	✓		*	
Personal Guidance Systems	DoReMi		✓	✓			✓	✓	✓	✓		*	
sonal Gui System	Miraculous Life		✓	√				✓			3	✓	
Per	MobiGuide	✓	✓					✓	✓	✓	1	*	
ata ient	MyHippocrates							✓	✓	✓			
Health Data Management	eHealthMonitor							✓	✓	✓			
Маг	PatientsLikeMe							✓	✓	✓		*	
	FrailSafe Integrated System	✓	✓	✓	✓	✓	✓	√	√	✓	3	✓	?

Table 3 - Competitive Solutions

1	suggestions	*	partially supported
2	self-progress	?	possibly supported
3	design of interventions		

The competitive solutions mentioned above have been analyzed based on the technical and functional features found on their respective websites, which are stated in references [7] through [37].

As it can be seen from the comparative Table 3 above, most of the indirect competitive solutions have been designed to address issues and give solutions to very specific categories of problems, contrary to the wide variety of solutions given by the FrailSafe Integrated System. Particularly, the different functionalities supported by various competitors are described below:

Sensing

Most of the competitive solutions have sensors to detect physical, environmental and behavioral activity, but very few can detect and analyze social activities of the patients

Interaction

Very few of the competitive products, with the main exception of AR/VR games, provide messages or alerts for humans based on detected variables, such as reminders, messages for the caregivers or synthetized interactive games.

User Models/Visualization/DSS

Most of the presented solutions have developed a virtual patient model and provide visualization of collected data, as well as decision support systems for the patient or its caregivers.

Feedback and Personalization

Most of the solutions provide some type of feedback to the patient based on the collected data, but only one of them (Miraculous Life) designs and offers personalized interventions to follow according to the patient's state.

Frailty Measurement

Many recent projects have been addressing problems related to frailty, leading to quantitative measures of defining it. Some other solutions have developed algorithms of quantification which are not specific to frailty but to the generic health and medical field.

Certifications

Except of two wearables (BodyGuardian and Hexoskin), no other product is certified by FDA or EC for use as medical device, nor is the FrailSafe solution for the time being. The active-ageing market overlaps or is a segment of the general medical industry, meaning that such a certification would be an important asset for the FrailSafe solution in terms of validity for penetration into this market.

The FrailSafe solution, consisted of its different interconnected components, complies with all the above-mentioned criteria except of the FDA/CE certification which could be obtained in the future. It is designed to address all of these issues and in terms of functionalities and capabilities is superior to any other indirect competitive solutions already existing in the market.

4.2 Competitive Positioning

As already discussed in section 3.3 above, the geographical market segmentation is proposed over the sectoral one. Based on this scheme, the partnership is suggested to

use existing channels and connections of their members in order to proceed. Entering a new market is challenging and the first penetration attempt is crucial for the success of the overall process. In this regard, it is proposed that the partnership focuses at first on a high-prospect market (e.g. France, Italy or Belgium) instead of investing high budget on trying to do all at once.

A high-prospect geographical market might provide potentials for acquisition of a small but significant market share, which will therefore lead to synergies with key players and access to more clients using chain-selling techniques. It would be suggested to initially launch promotion and marketing campaigns in one of these high-prospect markets, e.g. France, where a reputable partner (INSERM) of the consortium operates and already has access to numerous clients and eventual key cooperators. This will enable the partners to benchmark the solution and evaluate the results, having the support and industry connections of an involved project partner with high interest in the success of the venture.

4.3 Targeted Markets

The results of the FrailSafe project are expected to attract interest in several specific communities which should be used by the partnership in order to update, improve and further develop the implemented components and system.

In particular, the stakeholders to be targeted will be:

- Scientific Communities: focused on signal processing, data mining, knowledge discovery, knowledge management (e.g. in private, medical and health contexts), user profiling, symptom modelling, frailty definition and therapy, medical interventions in the context of social care; etc.
- **Technical Communities:** medical equipment technicians and engineers, manufacturers and distributors who need to stay up-to-date with new technological solutions in their respective field.
- Business and Medical Entities: external companies which would like to use the
 project results in order to improve their own medical services and treatments to
 become more competitive or to distinguish themselves from similar services.
- Care Organizations: in particular not-for-profit organizations and institutions which understand the power of independent living and social inclusion as viable strategies to heal patients and integrate them into their respective communities.
- **General Public:** people related to older adults and frailty-prone people, such as their families, friends, caregivers etc., who wish to have a better understanding of their situation and improve their physical and cognitive state.

5 Exploitation Strategy

5.1 Exploitable Results and Outputs

The FrailSafe project outputs consist of separate components which could be used as stand-alone products, but all together form an integrated system which provides unified measurements, evaluation of condition and personalized interventions for older people.

The project partners have been working on the different components in working groups and contributing to the development of multiple components each. This has been summarized in Table 1 in section 2.4 above, which shows the project's outputs and exploitable results, and the contribution of each partner to their development.

These outputs are part of the project development process and are evolving throughout its duration. Each partner might opt to exploit a component separately or jointly with other partners as far as they own the IP rights for this component. In aggregate, the components which are considered exploitable by the project partners are shown in Table 4 below.

Project Output	UoP	BRAINSTORM	SMARTEX	AGE	СЕКТН	MATERIA	SIGLA	HYPERTECH	INSERM
1. WWBS system	√		√		✓	✓	✓	√	✓
2. Signal processing & Data Analysis tool	√		√		√				✓
Social Media Sensing tool	✓								
4. Risk Assessment tool	√					√			√
5. Virtual Patient Model (VPM)	√			√	\	√	√	✓	✓
6. Dynamically Synthesized Games	√	✓	√		\	√	√	✓	✓
7. Visualization & DSS module	√		√		>	√	√	✓	✓
8. Clinical Web Platform (eCRF)	√		√	√	√	√	√	✓	√
9. Virtual Community Platform (VCP)	✓								

10. Integrated									
FrailSafe system	✓	✓	\checkmark	✓	\checkmark	\checkmark	\checkmark	✓	\checkmark

Table 4 - Preference of Partners regarding Exploitable Outputs

Each partner has a different strategy concerning exploitation of the separate components and the integrated system which depends on these independent products. The available strategies for final exploitation will be further discussed in section 6.1 below, where different exploitation scenarios will be presented along with all their features, advantages, disadvantages and challenges.

5.2 Key Success Factors

The major factors which will determine the success of the exploitation strategy for the project and its outputs after its completion are based both on the market competition and the decided positioning of the solution in the market. These factors are:

- Commitment of the involved partners to the product exploitation and assignment of appropriate resources
- Finalization of the IPR framework among the partners which manages the IP rights which are required for the integrated system
- Initial market entry derived from the decided market segmentation is also considered crucial since an unsuccessful launch in a market might jeopardize the whole exploitation plan
- Utilization of the existing distribution channels of the project partners for the initial launch in targeted markets, instead of trying to set up new ones
- Reputable people to collaborate with in promotional and marketing campaigns at the early stages
- Continuous funding from the partners for the initial attempt to exploit the integrated system into a market

5.3 Unique Selling Proposition

The Unique Selling Proposition of the integrated FrailSafe system should be based on the uniqueness and novelty of the unified system, and the additional features it provides for the assessment and personalized intervention in the lives of older people.

Taking the above into consideration, the Unique Selling Proposition for the exploitation of the integrated system will be as follows:

"The integrated FrailSafe system is a unified system which can proactively help older people improve their everyday life by measuring and evaluating their frailty levels and providing them and their caregivers with personalized suggestions for improvements. This is done using wearable equipment, AR/VR interactive games and sensors, along with a platform which helps decision-making for everyone involved with older people. The system collects real-life data from everyday activities, detects events, sends feedback and provides valuable suggestions for improvements."

6 Business Models

6.1 Exploitation Scenarios

The partners of the FrailSafe project have identified different scenarios which can be used for the final exploitation of the project outputs and, particularly, the integrated FrailSafe system. These scenarios will define the exploitation plan to be followed based on the special features of each scenario and the challenges it poses.

Partners will finally choose one of those scenarios as the most appropriate one and try to follow the basic steps in order to implement and promote it.

6.1.1 Create a Company

This scenario highlights the ultimate commercial exploitation plan, which is based on the creation of a new company by project partners and joining it collectively as partners and shareholders. The IPR of each partner according to the Joint Ownership Agreement will still be valid concerning separate components, but the promotion and distribution of the integrated FrailSafe system will be executed by this new company. In this scheme, the partners might opt to keep a certain percentage in order to allure external investors or complementary companies into the partnership. This will lead to financial benefit for the new company and assure the required initial investment, while it will help the company evolve using the know-how and connections of the new investors.

A business plan will be studied and implemented for this new company, which will address the following topics related to the selected scheme:

1. Internal analysis

- Structure: organization, human resources, management team
- Products or services: different components, functionalities, technical features
- Production: production process for components, development for software
- Financial: investment, budgets, resources
- Vision: Key Success Factors, short-term and long-term goals

2. Market analysis

- Market data: size, segmentation, new emerging markets
- PESTLE analysis
- Impact on the market
- Market positioning
- Demand and supply
- Competition: competitors, solutions, marketing mix

3. Marketing plan

- Overall FrailSafe offer
- Promotion channels
- Publicity plan
- Development strategy

4. Implementation

- Budget per activity
- Financial planning: income, expenses, balance sheet
- Forecasts: sales, investment, cash-flow
- Action plan: time planning, roles

Summarizing, the advantages and disadvantages of creating a company as an exploitation strategy are the following:

Advantages

- Controlled entirely by project partners
- High motivation for every project stakeholder
- The FrailSafe project and its outputs will be sustained through the new company
- Possible participation of external investors for capital raising reasons

Disadvantages

- High initial investment will be required by project partners
- Commitment from partners must be ensured throughout exploitation
- Definition and assignment of roles and responsibilities will be challenging
- IPR issues should be dealt with and agreed upon by all partners very quickly

6.1.2 Sell the Work and IPR to Another Company

In this scenario, the project consortium is selling the whole work done until the end of the project and every IPR related to separate components or the integrated FrailSafe system to another company, including all the IPR of different partners over the components before the beginning of the project. The company which will buy the whole solution should preferably be a market leader or a company dynamically entering the market and needing the solution to complete its product line.

This is a much less complicated exploitation strategy since it alleviates all the resources and funding from partners, while they will have a financial benefit for the work so far. On the other hand, the difficult task for the partners will be to effectively promote the solution to potential investors and conduct the negotiations. This might be challenging for most partners, since specialized knowledge on negotiations might be needed and there might arise the need to hire external specialists, while the process will be lengthy.

In aggregate, the advantages and disadvantages of this exploitation scenario are listed below:

Advantages

- Early financial reward for project partners
- Commercial expertise of the buying company leads to better chances of success
- Future contracts with the company might be needed for expansion projects
- Sustainability of the FrailSafe project is ensured through the company

Disadvantages

- Commercial success depends on market factors which are not controllable
- Complicated IPR handling, unless there is unanimous agreement from all partners
- Special expertise needed in order to promote the solution and attract investors
- Lengthy and demanding process for closure of selling negotiations

6.1.3 License the FrailSafe Solution and Keep the IPR

In this scenario, partners will only license the solution to another company, while keeping the IPR and receiving licensing fees on the company's sales. In this way, the partnership will keep ownership of the solution and financially share the company's eventual commercial success.

Since the solution will still belong to the partners, they might decide to upgrade it in the future and offer updated and improved features, so that their share is increased and the licensing fees are more alluring for the years to come.

Similar to the second scenario, the most difficult part of this option is to promote the solution and attract investors to buy into the solution's success.

Summing up, this scenario's advantages and disadvantages are shown below:

Advantages

- No significant initial investment is needed from the partnership's side
- The partners keep the IPR
- Risk exposure is very low and shared with the other company
- Profit prospects will be high related to the involved risk in case of commercial success of the solution
- The integrated FrailSafe system and the developed solution will be sustained in the future

Disadvantages

- High difficulty in promoting the solution and attracting external investors to buy in
- Lengthy process of negotiating both internally about IPR and with the company about the licensing fees and licensee obligations
- Partners might lack expertise in licensing procedures and negotiations
- An experienced external legal consultant might be required in order to conclude on the best-fitted scheme of licensing and the technical terms of the agreement

6.1.4 Open-Source Exploitation and Provision of Value-Added Services/Products

This scenario entails a free-of-charge provision of the whole FrailSafe solution through open-source exploitation. This method will attract many researchers, industry companies and not-for-profit organizations in using the solution and taking advantage of its features. There will be no fee collected by this exploitation, but additional valued-added services and/or products may be provided to the actual users for a low service fee, such as consulting and training on the proper use of the solution and its extensions.

Although the partnership will not acquire any financial benefit, partners will attract a large number of interested users who might be interested in low-cost value-added services concerning the solution, so that the partners will have the chance to broaden their client base and offer these services.

In aggregate, the advantages and disadvantages of this scenario are shown below:

Advantages

- Very easy to implement process
- Opportunity for financial benefit from the provision of additional services to users
- Required expertise already acquired during the project implementation
- Negligible initial investment needed and low-cost future maintenance
- Attraction of numerous future customers and researchers to work on the solution
- IPRs are kept by the partners and not shared with any other organization

Disadvantages

- The FrailSafe solution might not be sustained, since there are no guaranteed exploitation profits
- Difficult IPR handling if a partner is not interested in this exploitation method
- The integrated FrailSafe system may not be adequate to attract mass-base clients if marketed as a stand-alone solution, so additional solutions, systems and products must be combined with it in order to have better chances of market success.

6.2 Exploitation Plan

6.2.1 Partnership Exploitation Preferences

Based on the proposed exploitation scenarios analyzed above in section 6.1, each partner has a different preference as to the direction that the FrailSafe project's exploitation should be pointed. In Table 5 below, each partner's preference is shown regarding exploitation.

Exploitation Scenario	Preferred by Partner
Create a Company	UoP, SMARTEX, CERTH, HYPERTECH
Sell the Work and IPR to Another Company	BRAINSTORM
License the FrailSafe Solution and Keep the IPR	UoP, BRAINSTORM, CERTH, INSERM
Open-Source Exploitation and Provision of Value-Added Services/Products	UoP, CERTH, MATERIA, HYPERTECH, INSERM, SMARTEX

Table 5 - Exploitation Scenarios Preferences for the Project Partners

A different scenario could have been proposed above, where each partner could exploit specific project outputs, which can be done without a joint agreement from all partners, but through independent negotiations among the partners who hold the respective IPRs. In this respect, this scenario has not been analyzed above, but it is only mentioned in Table 6 below which shows the preferred role of each partner in a future joint exploitation scheme. Nevertheless, this report currently focuses on the eventual exploitation models of the integrated FrailSafe system by the consortium and will also examine any active exploitation of specific components at a later stage of the project.

Project Partner	Active Exploitation of the integrated FrailSafe system		Passive Exploitation (sell or license the solution)	Value-Added Services (open-source)
UoP	✓	✓	✓	✓
BRAINSTORM			✓	✓
SMARTEX	✓	✓		✓
AGE				
CERTH	✓	✓		✓
MATERIA				√
SIGLA		√		✓

HYPERTECH	✓	✓	✓
INSERM	✓	✓	✓

Table 6 - Identification of Partners' Roles in Exploitation

6.2.2 The Freemium App Model

As it can be clearly seen from both Table 5 and Table 6 above, there is not a unanimous preference of the partnership regarding future exploitation, but only a clear preference promoted by the majority of partners to have the opportunity of providing value-added services to future users of the solution. This implies an open-source exploitation model, which generates zero to very low income throughout exploitation.

An alternative model, which combines both the preference for provision of services and the straight-forward solution of creating a company for commercial exploitation, would be the Freemium App model.

The Freemium App is a hybrid model, based on the assumption that a company is created by all interested partners and the solution is offered as an application accessible to any web-based device. This applies to the software and services of the solution, which consist the basic online platform of the system. On this platform, the basic functional services will be offered free-of-charge to anyone upon signup, covering most daily activities of interested users. On top of these services, additional value-added features may be offered for a financial fee depending on the complexity and the personalization required by the user.

It should be noted that the integrated system consists of multiple devices and hardware which cannot be offered for free and, hence, the user should buy them directly from a collaborating distributor to enable access to the functionalities of the platform. This implies a minimum cost per user, which highly depends on manufacturing costs related to procurement of required sensors and materials. Although the partnership will try to reduce this cost as much as possible, it is not negligible and the end user may have to buy at least one of these devices in order to use effectively the online platform.

After analyzing the market and potential customers, there are two distinct audiences who should be offered different solutions and services regarding this business model. An indicative example of the potential features of this model follows:

- ➤ Individual end users: they are the older people who use the platform for personal data collection, visualization and interaction. They could be offered the basic features of the application for free, such as:
 - physical, social and environmental sensing
 - · automatic reminders for any setup event they need
 - interaction and alerts towards their caregivers and family
 - access to a wide range of AR and VR synthetized interactive games
- Doctors and Medical Professionals: these are the professionals who examine and evaluate the information provided by the platform using their patient's data. They could be offered the premium features of the application for a monthly or annual fee, such as:
 - real-time representation of the virtual patient model
 - access to the predictive DSS model for each patient
 - · visualization models of patient's medical data
 - suggestions of improvements and proposals of personalized treatment

- metrics of quantified results on specific categories of frailty
- event detection alerts and emergency alarms from the patient's devices

In summary, the Freemium App model is based on free basic features for the individual older end users and premium paid features for the medical professionals who treat those users. This will benefit all involved groups:

- The partnership will attract numerous free end users and have the opportunity to capitalize on the model.
- The individual end users will be able to try the solution for free to have some input on their state and the possibility to share the data with a professional.
- The medical professionals will have the opportunity to change their treatment method, where patients will not have to visit them so frequently for treatment but only grant them access to their medical data through the platform and evaluate their condition based on this. This will enable them to have more real-life data for assessment and propose a monthly fee to their patients for remote medical monitoring using the online platform.

Based on the current facts, this exploitation model seems to be the most suitable for the FrailSafe case. However, since the project execution is still at an early stage especially concerning system integration, there hasn't been a certain agreement inside the consortium yet. For this reason, further analysis and discussion among the partners will be encouraged during the next project period in order to reach to a final decision.

6.3 Business Plan

The most crucial part of the FrailSafe project exploitation is the selection of the appropriate model which corresponds to the preferences of these partners and is fitted for the purpose they want to serve. Once this is selected and agreed upon, a business plan must be detailed including the operational framework for exploitation, its objectives, involved parties and market planning.

Different parameters have to be decided and clarified for a successful commercial exploitation of the projects' outputs. These parameters are presented in the sections below and graphically depicted in Figure 3 into a Canvas Model which shows, at a glance, the business model's key points.

Key Partners	Key Activities	Value Propos	sitions	Customer Relationships	Customer Segments	
Project Partners members of the implementation team Research Groups contributing new outputs and solutions of the integrated system Business Specialists contributing expertise in market penetration and expansion Opinion Formers strong reputation in communities and able to promote the solution Advisory Board active support and feedback in different fields External Investors financial contribution and business know-how	To be defined. Issues to be clarified: - required key activities - distribution channels - revenue streams Key Resources To be defined. Issues to be clarified: - required key resources - customer relations - collaborators	The integrated system is a unif which can proa older people in everyday life b and evaluating levels and prov and their caregi personalized su for improvement done using wea equipment, AR/ interactive gam sensors, along platform which decision-making everyone involvolder people. Ti collects real-life everyday activit events, sends fi provides valuab suggestions for improvements.	ctively help mprove their y measuring their frailty iding them vers with yggestions ts. This is rable VR es and with a helps g for ved with he system data from ies, detects eedback and	To be defined. Questions to be answered: - what type of relationship does each of the customer segments expect? - which type of relationship has already been established? - how are they integrated with the rest of the business model? - how costly is it to maintain these relationships? Channels To be defined. Issues to be clarified: - channels to reach customers - efficiency of used channels - best combination of channels - adaption to customer's routines	Business-to-Business manufacturers of medical equipment Pharmaceutical Industry complementary sector, not a competitive one National Health Services hospitals and clinics aiming at cost reduction Insurance Companies proactive non-invasive methods in order to reduce rehabilitation costs Individual Older People stand-alone users who afford to buy the devices and willing to use the system's online services	
Cost Structure To be defined.			Revenue Streams To be defined.			
Questions to be answered: - what are the most important costs inherent in the business model? - which key resources are most expensive? - which key activities are most expensive?			Questions to be answered: - which are the revenue streams? what is the revenue contributed by each? - what price are the customers willing to pay? what they currently pay? - how do the customers want to pay? how do they currently pay?			

Figure 3 - FrailSafe Business Model Canvas

6.3.1 Objectives

The major objectives of the business plan for the exploitation of the FrailSafe solution is the identification and agreement on a successful execution plan, considering the exploitable outputs of the project and the competitive advantages of the overall integrated system. The objectives could be divided into short-term ones which refer to the last months of the project implementation and the long-term ones which will be pursued after the project is finalized and exploitation has begun.

The short-term objectives of the FrailSafe exploitation plan are the following:

- Ensure that the FrailSafe project is sustained after its finalization, while the various components are updated and kept competitive in the market
- Secure exploitation budget funding either from the partners or from external investors who will be attracted to join forces with the partnership
- Motivate all project partners to be actively involved in the exploitation process and contribute to the success of the new venture
- Clarify IPR issues both among partners and towards potential investors who
 might be willing to buy or license the solution, or alternatively be involved in the
 organizational scheme
- Organize and structure all involved partners into a new scheme of work, where
 different roles are assigned to the partners' team members in order to establish
 a new entity the goal of which is to commercialize and sustain the implemented
 solution

The long-term objectives of the FrailSafe exploitation plan are the following:

- Achieve a viable and sustainable plan for the project outputs and solution
- Motivate project partners to collaborate in the new organizational structure and produce new competitive results

- Collaborate with distributors and retailers for the commercialization of the solution
- Successfully enter and grow into competitive markets
- Establish a successful corporate model and achieve profitability which will lead to a strong brand name in the active-ageing and frailty market.
- Expand the activities of the venture to additional solutions within the same market or divert the product-line into new markets

6.3.2 Key Roles

The relations among project partners throughout implementation and especially into the exploitation period play a crucial role in the commercial success of the project. If case any external investors or licensees enter the new organization structure, then their role will also be significant for the commercial success. In this regard, the different roles to be identified and taken into consideration for exploitation are the following:

- Project partners who have a significant role during the implementation phase, especially industrial partners
- Research groups related to any of the project partners, who could contribute new outputs and solution to the FrailSafe system during exploitation
- Business specialists related to the project partners, who will contribute with their expertise in terms of market penetration and expansion
- Opinion-formers with strong reputation in their respective communities who can self-promote the solution through their networks of influence
- Advisory Board of the project who have actively supported and provided useful input on major exploitation decisions so far
- External investors who will be attracted by the novelty of the solution and the competitiveness of the exploitation plan, and might be willing to contribute financially and in business terms

6.3.3 Marketing Mix

A major part of the exploitation plan for the FrailSafe solution is the definition of the marketing mix which will be used throughout the process. This includes the identification of the following:

- Product or service: Decision on the exploitation model to be used for the integrated FrailSafe system is still pending
- Price: since the components and integrated system have not been fully developed yet, there can be no estimation of their final price or cost
- Distribution channels: as an online platform, the main channel of the integrated FrailSafe solution will be the Internet, through online stores like App Store, Google Play etc.
- Promotion: target rehabilitation centers or clinics, email marketing, social media marketing, major retailers and distributors

6.3.4 Financial Aspects

An important part of the business plan is the estimation of crucial financial aspects of the exploitation process. Since the components are still at the development phase and exploitation will start at the end of implementation in 18 months, there can be no credible estimation of related values.

The variables which will be estimated for the financial forecast of the exploitation period are the following:

- Number of free users
- Number of premium users
- Average revenue per client (integrated system)Average revenue per client (additional services)
- Personnel cost
- Marketing and sales costs

These estimations will be made near the end of the implementation period, when the system will be fully developed and under testing.

7 Future Work

In the next 18 months, the project partners will have to further work on and specify the following main aspects of the exploitation process:

Joint Ownership Agreement

The IPR of each individual component must be clarified and the partners have to agree on specific aspects of each output and the integrated system as a whole. The initial IPR analysis (deliverable D8.8) will provide partners with all the information and guidance needed to conclude to a viable and simple scheme for future use into exploitation.

Costs and Financial Aspects

Since both components and the integrated system are still under development and continuous improvement, the costs and expected pricing cannot be estimated yet. Partners, along with their implementation responsibilities, should make financial calculations and research in the market in order to have a final cost reporting and come up with a competitive pricing for the final solution.

• Freemium App Model

The exploitation scenario proposed above in section 0, i.e. the Freemium App model, has to be analyzed further in terms of provided services and pricing. After the major components have been implemented in the next months and case studied in real situations, the partners will have a clearer overview of those services which should be considered as basic and, hence, offered in the free version, and which ones are more advanced and will be provided in premium packages for a fee. In addition, pricing for each premium service package should be proposed based on its novelty and the foreseen market potentials.

Selection of Exploitation Scenario

After reviewing and evaluating the different exploitation scenarios which have been proposed above in sections 6.1.1 through 6.1.4 and considering the suggested Freemium App model, the partners will have to decide on the final exploitation scenario which will be considered as the most appropriate for a successful launch in the targeted market.

8 Conclusions

In this report, the major exploitation scenarios and the business models to be followed have been presented with regards to the FrailSafe project. The project's main outputs have been listed and evaluated by the partners and each partner's role in future exploitation has been identified. Based on these factors, different exploitation scenarios have been analyzed, a combination of which is proposed as the ideal exploitation scenario, the Freemium App model.

Market and competition analysis have offered an overview of the current industry situation and will be evaluated in order to promote and position the FrailSafe solution in better and more successful ways.

Future work has still to be made, not only in implementation which will affect the exploitation process, but also in terms of agreement on IPR handling which plays a significant role in future strategies.

Summarizing, this deliverable presents the first approach of the FrailSafe exploitation plan and it is expected to evolve as the project execution proceeds and the FrailSafe results become mature. The final exploitation report is expected to be delivered at the end of project (M36).

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