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Glossary

MD	Medical Device
MDD	Medical Devices Directive
IPR	Intellectual Property Rights
ICT	Information and Communication Technologies
R&D	Research and Development
TUG	Timed Up and Go
SPPB	Short Physical Performance Battery
EU	European Union
EHR	Electronic Health Record
PPI	Public Procurement of Innovation

1. Introduction

Falls in the elderly create a major health burden for the society. It is estimated that one third of the elder population over 65 years falls each year [1]. The effects can be severe, including disability, functional decline, fear of falling again, leading to further loss of function, depression, feelings of helplessness, and social isolation [2] and reduced quality of life. Also, the "long-lies", i.e. the period of time spent on the ground or floor for more than an hour after a fall, can lead to serious complications including pressure ulcers, rhabdomyolysis, pneumonia, hypothermia, dehydration, and even death. Getting help after an immobilizing fall improves the chance of survival by 80% and increases the likelihood of a return to independent living [3].

Due to the demographic changes caused by the aging of the population registered in recent years, falls became one of the main causes for hospitalization in a geriatric unit. Besides the physical costs of falls on the seniors, treating falls injuries in the elderly can be very costly. Direct costs are what patients and insurance companies pay for treating fall-related injuries, namely fees for hospital and nursing home care, doctors and other professional services, rehabilitation, community-based services, use of medical equipment, prescription drugs, changes made to the home, and insurance processing [2].

Following this "ever-changing" world, it is noticeable the proliferation of Information and Communication Technologies (ICT) solutions targeting the healthcare sector, improving the variety and quality of methods of prognostic, therapeutic, diagnostic and health promotion. In particular, the development of new ICT-based solutions for detection and/or prevention of fall accidents among the older people has raised much attention in recent years due to the manifested potential to reduce the incidence of long-lies and enhance the independence and quality of elderly's life [4].

Additionally, ICT-based solutions for falls could significantly reduce the cost associated with elderly care, with benefits for the economy as whole, such as the mitigation of the iniquities and exclusion under the healthcare system driven by economic, social and environmental factors. In fact, much of Research and Development (R&D) spending goes on developing new products but there are also important spill-over effects which allow gains of efficiency and increase in the market profitably [5].

Traditionally, the market uptake of an ICT solution requires a careful study of the market, taking also into account the commercial and regulatory issues. One of the most important instruments to evaluate the feasibility of product development is a roadmap because it helps leveraging the power of stakeholders support. Market potential, interoperability, cost effectiveness and sustainability of solutions are some of the key drivers in the development of solutions, while putting the client in the epicenter of the design, implementation and evaluation of ICT solutions is of paramount importance [5].

However, there are still several factors that hinder the market penetration of ICT-enabled technologies for falls. The lack of standards, lack of interoperability between solutions and framework, lack of legal clarity, ineffective e-health strategies, regulatory aspects including reimbursement schemes, uncertainties about being medical devices (MD) and the awareness on the usefulness of such tools, are some of the most hardly broken barriers. Due to the lack in standards and its use, and the lack of interoperability of solutions and frameworks, market uptake is slow.

1.1 Deliverable Objectives

The main goal of task T4.3 is the construction of a roadmap for market development for market development of ICT solutions for fall prevention and management. The construction of this roadmap was carried out in two phases: a first draft phase describing the main requirements and barriers which hinder the development of the market for ICT-based fall prevention and effective intervention solutions for, in "*D4.3.1. Market development Roadmap. Preliminary*" [6]; and a second and final phase, which results are described in the current document.
The final roadmap for the market development will contain the key challenges, steps and phases (pathways) to go through while implementing a business process of ICT-based fall prevention and effective intervention solutions for elderly people. Additionally, it will be enhanced by the final version of recommendations gathered from experts, identified stakeholders with knowledge on the market uptake of ICT-based solutions for falls, and based on the experience of network partners and members.
The European Commission's recommendations for D4.3.2, namely the need to "*focus more on showcasing and publishing clear examples of cost-effectiveness of using fall detection schemes of various types in health care settings*" and the need to focus more on "*identified barriers and critical success factors such as IPR or MDD*", were taken in consideration while developing this roadmap.

1.2 Summary

In the previous deliverable four main topics, essential for the construction of a roadmap for market development of ICT solutions for fall prevention and management, were discussed [6]. These topics are: conveying legal clarity, building-up awareness, driving prescription and engaging end-users. In the current document, the challenges, steps and phases while addressing these issues will be highlighted and final recommendations are drawn based on the opinion of some experts on this field.
Thus, chapter 2 include a brief description on the current situation regarding the market development, including the main actors usually involved in this process and an overview of the main barriers that hinder the development of the market for ICT-based fall prevention and effective intervention solutions for elderly. The methodology used for stakeholder's consultation is presented in a stepwise scheme and the questionnaire used in the interview is detailed on chapter 3. Chapter 4 describes the process of success cases selection and briefly describes each one of the success cases' technologies. The results and the analysis of the interview are presents in chapter 5 and the final remarks are described on chapter 6.

2. Market Development Roadmap

Traditionally, having as final goal to address the need or the improvement of a current technology, the **market uptake** requires a careful **study** of the market, taking also into account the **commercial and regulatory issues**. One of the most important instruments to evaluate the feasibility of product development is a **roadmap** because it helps leveraging the power of stakeholders support. It becomes also imperative to estimate the potential market, select one or more target markets and develop a corporative strategy that satisfies the needs and wishes of members of the target market. At the same time, an evaluation of motivational factors of economic agents should not be forgotten to outline a business model and face its inherent challenges. Thus, a market research analysis enables:

- Identify the core segments market for the technology
- Evaluate the suitability of product characteristics given existing needs in the market
- Define the competitive edge, understanding the pros and cons of other market players
- Project sales revenues and profits
- Determine appropriate pricing

Market uptake barriers such as the lack of an adequate economic model and technical barriers have been addressed in previous deliverables, [7] and [8], respectively. Other barriers which still hinder the development of the market for ICT-based fall prevention and effective intervention solutions for elderly include lack of legal clarity, slow adoption of eHealth by healthcare professionals and societal challenges and the lack of effective/affordable fall prevention/intervention and security programs around European Union (EU).

2.1 Which are the main actors?

The main actors involved in the market uptake of ICT-enabled solutions for falls can be clustered into three main categories:

- **Health care providers** that include the actors involved in the research and development phase of the ICT-based solutions
- **Prescribers of ICT solutions** that include actors with knowledge to prescribe ICT solutions to address a specific need of the end-user
- **End-users** that are the main beneficiaries of the ICT solution, in this particular case, the seniors

Individually, the main participants in the market uptake of an ICT-enables solution for falls are:

Governments and public authorities play an important role regarding regulatory matters to address new challenges caused by the world ageing population and emerging technologies

Insurance companies are particularly important in the reimbursement squemes, as the healthcare costs are increasing year after year

Industry are the main actors involved in the design and development of an ICT-based solution

Research Centres, Start Ups and Spin Offs take part directly in the innovation processes by participating in the research and invention activities that influence innovation

Health centres are particularly valuable in the design and testing phases in order to support better health outcomes

Health professionals (e.g. general practitioners and nurses) are the main prescribers of using ICT as a tool for detecting and preventing falls

End-users are the main beneficiaries of the product and should be involved in the development from the beginning for a user-centred approach

2.2 What are the main barriers?

The major obstacles that hinder the development of the market for ICT-based fall prevention and effective intervention solutions for elderly can be classified into four main categories, previously identified in [6]:

1. Conveying Legal Clarity
2. Building up awareness of ICT solutions
3. Driving prescription of ICT solutions
4. Engaging end-users

Next, a brief description of each one of these obstacles is presented with a brief explanation on how they can hinder market uptake of ICT-based solutions for falls.

2.2.1 Conveying Legal Clarity

Technological solutions for healthcare are evolving faster than legislation. This results in legal uncertainties which hinder the development and adoption of ICT-based fall prevention and effective intervention solutions. Among the most critical barriers are the ones related to:

- Privacy, data storage and protection
- Medical devices classification
- eHealth and Electronic Health Record (EHR) specific country legislation
- IPR issues
- Regulatory aspects
- Reimbursement schemes

All these barriers were further exploited in T4.2. In particular, the classification of the device into Medical device was identified as being the most complex and unclear:

"The manufacturer has the choice to define the product as medical device or not. Both alternatives have their pros and cons. Medical devices have been placed in the market without sufficient clinical evaluation and products have been placed in the market as non-medical devices although the intended purpose pronouncedly has been diagnosis and/or treatment of human beings.", from [8]

The legal provisions on ICT-based solutions are at different stages among the EU countries and lack a homogeneous framework. Thus, the development and implementation of a global standardized and widely accessible platform including standards, specifications, use cases, workflows, subset of terminologies, interoperability agreements and guidelines would allow to close the gap caused by all these issues caused by legal clarity. Specific initiatives concerning legislation or regulations for fall prevention for elderly or related to ICT and fall prevention for elderly could be also included. As an example, it is mentioned in [6], the platform found in the European Commission site regarding the laws on EHRs in the EU Member States [9]. A global legal view of the problem is needed; public and private social care institutions, insurance companies and local and national authorities must share their view points and act together.
Besides, there hesitance in adopting the use of standards is associated with factors such as:

- Complexity
- Implementation costs
- Competition
- Interoperability problems
- Slow standard development process compared to the fast innovation process

- Slow implementation of ICT based solutions
- In the Medical sector the 'evidence base' is the paradigm to develop guidelines
- Difficulty to know which standard to use
- Not all challenges are solved in the standards

2.2.2 Building up awareness of ICT solutions

The lack of general knowledge in the existing ICT fall prevention solutions also hinders the adoption of these solutions. Currently, most people including physicians, patients and general citizens, are not aware of the possibility of using ICT solutions. More than disseminate the solution itself, is important do propagate its benefits. Dissemination can only be effective if the information provided for the addressed stakeholders is comprehensive and oriented to their specific needs and interests.

Several best practice and dissemination actions to increase awareness of ICT solutions among the different stakeholders, especially the elderly, the healthcare providers and the elderly´s family were already collected in [6], summarized in the following diagram.

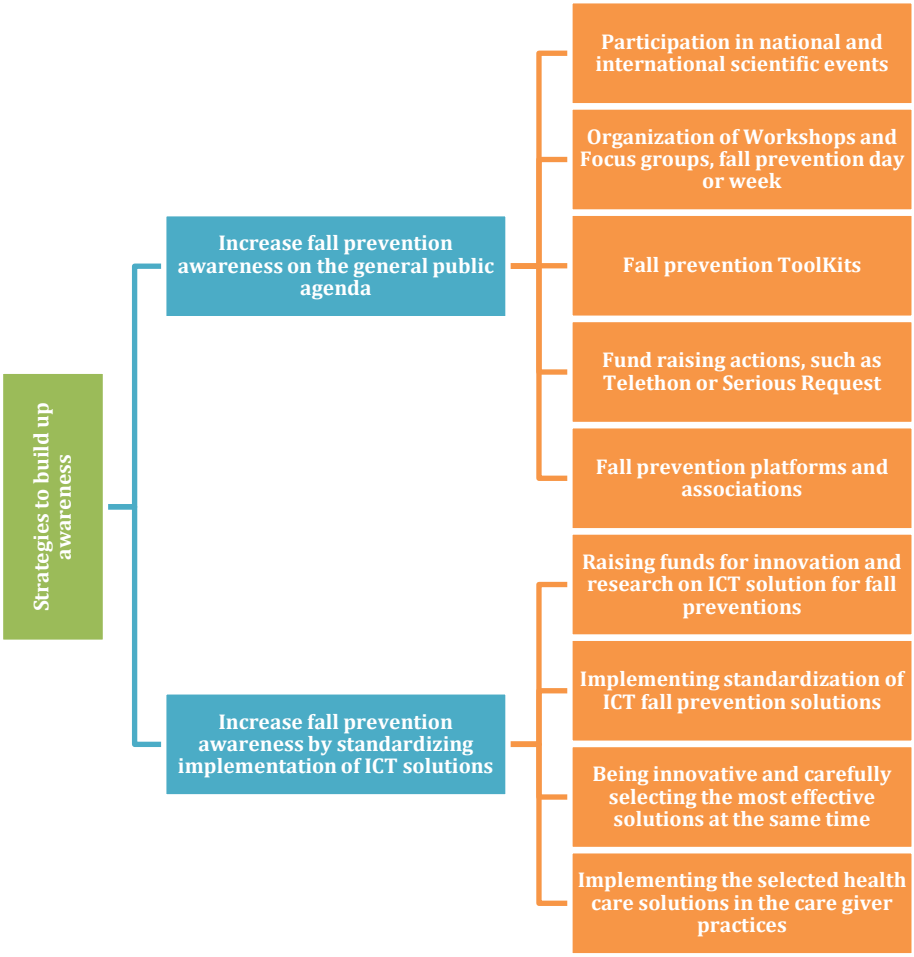

Figure 1. Awareness strategies collected in [6].

2.2.3 Driving prescription of ICT solutions

Issues regarding the prescription of ICT solutions are fully related with awareness on ICT solutions. Providing clinical stakeholders with objective information about the clinical impact and the benefits of ICT solutions for falls may contribute to drive prescription of such solutions.

How can we convince prescribers, i.e. health professionals, social care and insurance companies of the benefits of adopting ICT-based solutions for falls and the importance of prescribing fall prevention programs? As identified in [6], the press releases, social networking and workshops or focus group are important.

However, specific to driving prescription of fall prevention solutions, there are some particular actions that may help creating a more sustained base of knowledge to justify the importance of prescribing fall prevention programs:

- **Presentation of scientific results:** Presentation of scientific results and evidence-based studies validating the outcomes of the implementation of these solutions in national and international medical congresses
- **Clinical trial results dissemination:** Disseminate the main achievements of clinical trials to the research community, trial participants and the general public
- **Partnerships and alliances:** Partnership and alliances with other health professional associations, governmental and non-governmental agencies and National or International medical associations
- **Face-to-face meetings:** Face-to-face meetings with other health professionals and caregivers in order to share information, points of view and promote the knowledge transfer
- **Inviting experts** in falls-related ICT solutions to lecture in clinical training programmes

These options may potentially help reaching a broader audience, since medical literature in currently available online and most prescribers should be able to access it. They may also motivate the healthcare facilities managers or insurance companies interested in reducing the care costs and enhancing the quality of services they are providing through the use of ICT-based solutions for fall prevention and intervention.

2.2.4 Engaging end-users

Older adults face numerous barriers in adopting ICT solutions for healthcare that must be taken into account:

- **Decreased familiarity with technologies:** The acceptance of modern technologies that are electronic or digital may be more difficult for the current generation of seniors which did not grow up with these types of technologies
- **Perceived personal need for technology:** The easiest way for elderly is still asking family members for help, that can reduce the need for technology
- **Trust on technology:** The lack of trust in the veracity of the information and fear to replace people by ICT solutions
- **Privacy:** Older adults with greater privacy concerns will select human support over technology when given the choice
- **Design challenges:** Older adults face several physical (e.g. loss of vision and tactile senses) and cognitive challenges (e.g. loss of memory and poor recall) that humper the interaction with new technologies
- **Societal challenges:** Important key figures, such as professional caregivers, friends and family, can also positively or negatively influence acceptance of technology
- **Benefits expected of technology:** Older adults mention that they would use technology when they perceive it as useful

It is important to understand the end-users special needs - user-centred approach - and take specific actions to engage and convince them, their family or careers of the benefits and usability of fall prevention and management products and reduce the resistance to technological. There is handful of success factors can help with user engagement:

Design of the solution: There are specific design factors that need to be considered when the technology targets the elderly population directly

Education of caregivers: Frontline care workers in the health profession are often key influencers in the decisions made by families of older people

Costs of the product: Critical to the uptake of any ICT-based fall management system is the cost and identifying who should pay

Informing of older person: Informing the older person of the existence of falls prevention and falls management technology is key to getting them interested.

Empowering patients and boost patient-centric healthcare systems may be the key to reduce the gap between end-users and ICT-based solutions.

3. Methodology

The objective of this deliverable is to identify best practices and finally draw a roadmap on market development to help overcoming the multiple barriers that hinder the development of the market for ICT-based fall prevention and effective intervention solutions for elderly.
The main barriers that hinder the market development were already identified based on know-how and expertise of the E-NO FALLS project partners and network members, published literature and empirical information obtained from the different stakeholders. Now, the next step is to gather the opinion from experts on this field, identified stakeholders that have knowledge on market development of ICT-based solutions for falls.
The method selected to reach this goal is to interview a set of selected entities identified as success cases and understand which factors have been determinant to their success and which obstacles were found in their path to market. To gather the opinion of the identified stakeholders regarding market development of ICT solutions for falls, a questionnaire was prepared.
Finally, all the gathered information will be carefully analyzed and transferred to the roadmap on market development.

3.1 Methodological approach

The approach followed to collect information from experts and finalise the roadmap on market development can be summarized into a stepwise iterative process.
The first step was to explore and identify, based on the literature review, the main challenges associated with market development of ICT solutions for falls and understand the current situation regarding each challenge. Then, a set of well succeeded cases of ICT-based fall prevention and effective intervention solutions for elderly people that are already under commercialization, the “success cases”, have been identified. After identifying the success cases, one representative entity of each solution was also identified.
Then, a questionnaire was developed based on the key challenges faced during the market development of an ICT-based solution, found on literature review. The identified stakeholders were contacted via phone call or skype call and the questionnaire was used to guide the conversation. The answers were annotated and validated by the stakeholders.
Lastly, the roadmap was the result from the analysis of the results obtained from the questionnaire and extraction of relevant aspects mentioned by the experienced stakeholders.

Figure 2. Key drivers to consider for the deployment of an ICT solution for falls.

3.2 Questionnaire

The questionnaire used to interview the stakeholders was developed based on the main barriers that are currently hindering the market uptake of ICT-based solutions for falls. The barriers previously identified are related to legal clarity, the awareness of ICT solutions, the prescription of ICT solutions and the end-users engagement.
The questionnaire was developed by the E-No Falls partners and oriented to address several key challenges, such as reimbursement strategies, IPRs, funding schemes and interoperability issues, which were identified as important factors to consider when implementing an ICT-based solution for falls. The questions used to guide the conversation during the interview are presented in the following lines:

1. Describe technology and market situation.
2. If possible, explain briefly the business plan.
3. Is the solution certified as a Medical Device?
Why? Which were the main factors that contributed to that decision (cost, scalability, market size, target group, etc.)?
4. Is your technology stand-alone device or is integrated with other features?
If integrated, with which other solutions does it integrate with? Hardware? Software as EHR, etc.? Why? Which were the main factors that influenced your decision?
5. Does your solution offer any type of interoperability?
Why? Considering your experience in ICT solutions for falls, how important is the interoperability of your solution? If interoperability was a concern, which standards have been adopted? Which do you consider essential?
6. Reimbursement pathways? Payers?
What is your approach regarding the payment service? Are your services covered by any kind of reimbursement mechanism? If not, do you feel that it is an obstacle for market development?
7. Deployment, how to reach the buyers?
Do you have any strategy to build up awareness on your device? Do you have any specific actions to convince prescribers, i.e. health professionals, social care and insurance companies of the benefits of fall prevention and management products? Please explain.

Do you have any specific actions to engage and convince the final users, their family or careers of the benefits and usability of fall prevention and management products? Please explain.

8. Which funding scheme was adopted? How did it affect the market approach?

Did the solution have some funding? Which was the source? Which strategies did you use to get these funds? Why was that important to reach the market?

9. How did you handle the IPR issues? (if applicable)

Are the technology and intellectual property rights of your solution acquired or licensed from other companies and individuals? If so, what was the strategy to achieve an agreement?

10. Scientific or clinical validation of the solution?

Was the solution validated scientifically or clinically? How important was this validation for the deployment/dissemination of your technology?

4. Stakeholders consultation

The method used to understand what are the key challenges, steps and phases to go through while implementing a business process of ICT-based solution for falls in the elderly was **to interview a set of selected entities identified as success cases** and understand which factors have been determinant to their **success** and which obstacles were found in their path to market.

4.1 Selected Success Cases

Many different ICT solutions for fall detection and prevention management exist or are being developed in the scope of public or private projects. However, the number of marketed solutions is limited and the solutions are the most basic versions, i.e. user-activated alarms and pendants as well as automatic wearable fall detectors. More sophisticated or innovative systems for fall detection, such as video monitoring-based fall detectors, floor vibration-based fall detectors and acoustic fall detectors are still under development and not commercially available.

In a previous deliverable [7], we have developed an inventory of falls ICT management systems and discriminated the ones that are already on the market. Having in consideration the inventory of ICT-based solutions for falls and after a brainstorming with the E-No-Falls T4.3 partners, we have selected 5 representative solutions emerged from very distinct starting points and funding schemes, namely:

- European funded projects
- PPIs
- Technology licensed to R&D centers
- Partnerships with Universities
- Direct industry investment

Thus, the selected success cases are ICT-based solutions for addressing the problem of falls in the elderly with solutions already in the market, namely:

Angel4

Case that started from an European funded project "FATE", further developed and commercialized by the start-up company Sense4Care

GoLivePhone

Case of licensing a technology from an R&D institute, further commercialized by the company Gociety

V.A.C. system

Case of a direct industry investment commercialized by Creative Specific Software (C2S) which through the European Project HAPPI

iVi Intelligent Pendant

Case of a direct industry investment, developed and commercialized by Tunstall Healthcare

MoveTest

Case of a partnerships with Universities and direct industry investment, developed and commercialized by McRoberts

Figure 3. Selected success cases.

4.2 Angel4

The Sense4Care fall detector, called "Angel4" is a standalone device that works without the common telecare services charges, becoming the most innovative sensor that allows a direct communication with the user's caregiver or relatives through standard mobile phones.
Angel4 came from the FATE project [10] where it was developed an ICT-based solution that focuses on improving the elder's quality of life by an accurate detection of falls, both inside and outside home. It is an innovative, efficient and well integrated solution composed by:

- ✓ an accurate, portable and usable **fall detector** that runs a complex and specific algorithm to accurately detect falls (worn all the time by the user in the waist)
- ✓ a **smartphone** that sends the alarms generated by the detector to an emergency service
- ✓ a **bed presence sensor** that detects if the user is on bed or not
- ✓ a **central computer** that manages the FATE system at home through a wireless network and communicates with the smartphone by means of a Bluetooth link

FATE project represents a care model focused on strengthening public and private collaboration to reach a reliable service. It thus paves the way across Europe for opening new market opportunities and benefits for all stakeholders in the health and care sectors, as well as sustainable models for the future elder generations. Fruit of these collaborations it has been developed a fall detector functional prototype that is being test with 175 volunteers in different European countries.

Figure 4. Angel4 toolkit.

The start-up company **Sense4Care** [11] have further developed and commercialized a fall detector device using part of the results of CETpD research in the European project FATE based on a knowledge transfer agreement with the **Universitat Politècnica de Catalunya (UPC).**

4.3 GoLivePhone

GoLivePhone [12] is an extremely user-friendly smartphone, specially developed for and by seniors, that allows not only detecting a fall event but also helps to prevent them. It is equipped with a lot of smart extras that can make elderly life a lot more pleasant, easier and safer. The GoLivePhone includes:

- ✓ an intelligent **fall detection** algorithm, capable of detect when the user falls and immediately sending an alarm to the carer
- ✓ an intelligent **activity monitor**, to insight and feedback of the user's activity
- ✓ **fall risk assessment**
- ✓ an intelligent **navigation system**
- ✓ **agenda and medicaments management**, that generates automatic alerts (for medication, meetings, reminders, activities, etc.)
- ✓ **emergency button** and the "**I'm fine!**" button

Figure 5. GoLivePhone.

The system was developed by Fraunhofer Portugal AICOS [13], a Research Center that has dedicated efforts in the researching new ICT-based solutions to improve of the quality of life of its end-users.
After the publication of the first scientific paper, the platform caught the interest of two Dutch entrepreneurs who have decided to license the technology. As a result of the partnership between Gociety company and the R&D institute (Fraunhofer Portugal AICOS) arose the GoLivePhone that is currently being commercialized by through Gociety.

4.4 iVi Intelligent Pendant

The iVi Intelligent Pendant is a small, lightweight device and like other pendants, the iVi allows the wearer to press a **help button** to generate an alarm call when they need help from anywhere in their home, 24 hours a day. The iVi also provides an added layer of protection by automatically generating a call for assistance if a fall is detected and the wearer is unable to push the help button.

The iVi has a range of wearing options, and can be adjusted to suit individual needs. Besides, iVi is the only product of its kind to feature a **"not-worn" alert**, which will notify the monitoring centre if the iVi has not registered movement for a period of time (3, 5 or 7 days), suggesting that the user has not worn it.
The sensitivity settings can be adjusted to suit the individual user, and in addition to the help button which the user can press to manually raise an alert, the iVi also has a **cancel button** enabling activations to be cancelled in their early stages.

Figure 6. iVi Intelligent Pendant.

iVi Intelligent Pendant was developed and commercialized by Tunstall Healthcare, the world's leading connected healthcare provider, with a vast experience on commercializing ICT-based solutions dedicated to the end-users. Tunstall develops innovative products and services to help older people and those with long-term needs live life to the full for over 50 years.

4.5 V.A.C. - Visualisation et Alerte de Chute

V.A.C. (Visualisation et Alerte de Chute) is a non-invasive system to **detect falls** indoors. The potential markets are hospitals, nursing homes and private homes.

V.A.C. is composed by a simple optical sensor and an intelligent algorithm which analyzes image and detect if elderly people has fallen or not. The system also acts as an **actimetry**, monitoring human rest/activity cycles or abnormal absences. The system sends a **notification** to a Smartphone or other systems. The camera has been designed to increase acceptability of customers.
The V.A.C system respects customer privacy. The algorithm processes and analyses automatically the images and there is no need for personnel checking the cameras. The images' analysis is done in local. The alert system can be customized and the options are: a simple message or a blurred image of the fallen subject.

Figure 7. V.A.C. system.

V.A.C. system was developed, patented and commercialized by Creative Specific Software (C2S) [14], is composed by a simple optical sensor and an intelligent algorithm which analyzes image and detect if elderly people has fallen or not.

C2S was one of the winners of **Happi project** (ENT/CIP/11/C/N02C011; Healthy Ageing – Public Procurement of Innovation). The goal of Happi project is to use public procurement to stimulate demand-driven innovation in healthy ageing to address the challenge of demographic change in Europe.

4.6 MoveTest

The MoveTest [15] consists of a hardware unit, managing software, and one or more chosen modules, accessible through our web service. The system includes:

- ✓ 6 standardized tests
- ✓ Temporal and kinematic outcomes
- ✓ Remotely controlled
- ✓ Customized test protocols
- ✓ FDA and EMA approved medical device
- ✓ Conform ISO-13485
- ✓ Platform for multi-center studies
- ✓ Cloud-based analysis and storage of data
- ✓ Graphical and Database output

Figure 8. MoveTest System.

The MoveTest allows short physical performance tests using one single device attached around the waist of the subject. The system allows the integration of 6 test modules that includes tests for **Gait**, **Sway**, **Sit-to-Stand**, **Timed Up and Go**, **Short Physical Performance Battery (SPPB)** and **6-Minute Walk** test. Dedicated software will assist the user in efficiently performing a pre-defined test protocol.
MoveTest was developed and commercialized by McRoberts in collaboration with University of Amsterdam. McRoberts is an innovative and flexible organization with 25 years of experience, and one of the leaders in ambulatory monitoring of physical activity. Besides MoveTest, McRoberts has another solution under commercialization, the MoveMonitor, which aims to assess the physical activity status of the patients.

5. Results of the Interview

After identifying the success cases, one representative entity of each solution was interviewed. The responses to the questionnaires' questions are available in the Annex 1 and the analysis of the answers is presented in the next section.

5.1 Analysis of the results

1. Describe technology and market situation.

Four successful ICT-based solutions for falls were identified and interviewed. All the identified cases are already available in the market. The solutions are diverse and include:

- a vision-based solution that automatically detects falls indoors and also monitors the activity (V.A.C)
- a fall detector for elderly that works inside and outside home (Angel4)
- a pendant that detects falls automatically and is integrated with other functions such as the "help button", "not worn alert" and "cancel button" (Tunstall iVi)
- a smartphone that, among others, detects falls, monitors the activity and estimates the risk of falling (GoLivePhone)
- an instrumented physical performance test (MoveTest) and a device to measure daily life physical activity (MoveMonitor)

2. If possible, explain briefly the business plan.

Partnership:

The partnership in the several stages of the process with other entities with expertise on different matters may be beneficial. For example, partnership with providers for the stages of investigation, development, test and validation of the solution; and partnership with experts on the market and distribution partners for the market uptake phase.

"The business plan is to pass through different partners with an established market in hospitals and nursing homes to sell/distribute their product. They will join forces with insurances companies or tele assistance companies which will sell/distribute their product." – V.A.C.

"Gociety focus on developing new solutions and applications with our partners and leave the market part for the partners that are really good at that." – GoLivePhone

"Basically, we work together with providers (Fraunhofer in this case) to investigate, develop, test and validate the solution; and distribution partners (such as the "strategic" partnership with Samsung) to bring the solution to the market." – GoLivePhone

"For the clinical market you need a local partner. We operate from The Netherlands and do not have distributors so we are looking for a partner to further market our system for the clinical market. We need a partner that is already active there." - MoveTest

Set goals and deadlines:

"They have started in the French market and they aim to reach 10% of nursing houses. They also started with the Canadian market (…) In the following months, they are planning to enter into the Spanish, the German and the Italian markets. They are planning irruption to the US market in 2018." – V.A.C.

"The business model is to continue in Netherlands and to find other countries interested. England is interested because the health care system is very similar to that of Netherlands; in German is very difficult because the health care system is completely different. Canada is another country that is interested." - MoveTest

Broaden horizons:

Improve the system and broaden horizons beyond the falls in the elderly to attract more buyers is another measure that was mentioned:

"In rehabilitation, recent publications have mentioned that COPD may cause lower limb dysfunction. As we have recently developed the 6-min walking test, this can mean more opportunities for the MoveTest for instance repeated sit-to-stand." – MoveTest

3. Is the solution certified as a Medical Device?

Four of the identified solutions were not classified as MD. The reasons were very similar:

"*it is not a medical device as it does not diagnose and it does not give/send medical data*" – V.A.C.

"it is not for prevention, diagnostics. It is only used as an alarm system. " – Angel4

"it does not prevent or reduce falls" – Tunstall iVi

Regulatory issues were also mentioned as a barrier/burden when turning a solution into a MD:

"being a medical device implies lots of tight regulations, especially in the US market." – GoLivePhone

Relying in a consumer product was also mentioned as a barrier. It is not advisable to be a MD if one depends on other consumer products.

"the smartphone is a consumer product that is not perfect (battery and other hardware issues, software issues and even the network can compromises the normal operating of the smartphone). From that perspective, we would rely on the providers (network providers, etc.) and if we want to go through the Medical area, we should not do it on a consumer product." – GoLivePhone

Additionally, MD are considered less affordable and thus, not being a MD may allow more people to buy the solution:

"The choice of not being certified as a medical device was made especially to allow more people to use the solution and make it highly affordable." – GoLivePhone

Nevertheless, in one particular case, it was mentioned that there is the plan to obtain the certification of MD to facilitate the entry in other countries.

However, MoveTest and MoveMonitor are both medical devices, with FDA registration. Although the initiative to be a MD was not a choice for the owners of the technology, they are pleased with the decision:

"(…) we were chosen by the PROactive (Physical Activity as a Crucial Patient Reported Outcome in COPD), an European project (with European funding involved), and being a MD was a requirement for meeting the American regulations." – MoveTest

"Being a MD is also an advantage to enter in the American market. The choice was not ours but in the end, we think it is very good for research market because we are more professional and for the clinical market is good as well." – MoveTest

4. **Is your technology stand-alone device or is integrated with other features? and Does your solution offer any type of interoperability?**

Due to the relation between question 4 and 5, the answers are complementary. For this reason will be analysed together. The integration with other features is very important and, in general, the solutions are integrated with other components (hardware and software) and were developed according to interoperability protocols:

V.A.C.: *"the system is completely open and interoperable with other systems like ASCOM"*, and there is a plan to add another feature like *"smoke detection"* in the future.

Angel4: the FATE system *"integrates wearable fall detector sensor, a bed sensor, a gateway through smartphone and home computer, double communication systems, zigbee wall-routers and Bluetooth dongle"* and *"the commercialized solution, the fall detector, interoperates with most common smartphones of the market."*

Tunstall iVi: *"integrates with Tunstall Lifeline home units"* for either *"fixed line phone network or GSM network"* and with *"or CareAssist pagers, where alerts are dealt with locally. It cannot be used as a stand-alone device."*

GoLivePhone: the solution is integrated with other sensor unit, *"GoLiveWear, in order to have the availability of the solution in a clip that can be wearied with any clothes"* and to the *"to backend server (working as EHR), called GoLiveAssist". "The communication between the GoLivePhone and GoLiveWear is assured by standard Bluetooth Low Energy connection. The data sent from GoLivePhone to GoLiveAssist is in the JSON format and is open to be used by*

others. We consider important to share information between different elderly assistance service providers and for that each of this entities can query GoLiveAssist using a well know tool called CouchDB."

Regarding interoperability issues, most recent solutions were developed according to interoperability issues. In one case, it was also mentioned the intension to share medical information with other solutions already available on the market, and the plan to develop an ecosystem of services and applications:

"(…) making connections with professional care organization software (such as Tunstall and others) in order to share and make available all the medical information. From the GoLiveAssist data can be shared with different service providers like Tunstall or others, so its plan to develop an ecosystem of services and applications." – GoLivePhone

MoveTest: MoveTest and MoveMonitor are diagnostic devices that works offline and in stand-alone mode. Both devices collect and store the data until the *"patient goes to the hospital and the data is uploaded to the McRoberts certified cloud system and then it produces automated reports that can be downloaded"*. *"The MoveTest has Bluetooth and a wireless connection to make the data collection easier."*

5. Reimbursement pathways? Payers?

Reimbursement mechanisms regarding ICT-based fall prevention and effective intervention solutions for elderly people are quite dependent on the country. Some countries have already recognized the importance of keeping the autonomy and independence of elderly and have programs to boost and promote the adoption of innovative solutions through reimbursement mechanisms:

"(…) in France and Canada, governments try to stimulate solutions and investments for longer autonomy and independence of elderly and they have specific laws to push the adoption of innovative solutions such as V.A.C system. In France, there is a reimbursement of 50% of the cost for private customers." – V.A.C.

Countries where reimbursement mechanisms does not exists, stakeholders interested on the topic may take the initiative to convince the governments about the importance of falls on elderly and negotiate the reimbursement mechanisms.

"Currently, we have been discussing the prevention topic with health care insurance companies and government. We want to show the importance of our solution by conducting an experiment (…). We are organizing this clinical trial in US during a few years, and we expect being able to prove with this clinical trial the importance of our solution and to show that we can indeed prevent people from falling." – GoLivePhone

"We are starting negotiating with insurance companies, next week we will have a meeting and we will find out how to deal with it." – MoveTest

6. Deployment, how to reach the buyers?

The awareness strategies mentioned include the participation in exhibitions, congress and meetings to meet new partners (V.A.C. and MoveTest), the involvement in thematic networks such as COPD network (MoveTest), the development of commercial web services and

commercial distribution services (Angel4) and direct to consumer market, in the case of Tunstall.

In the case of GoLivePhone, an interesting witness reports the existence of a "strategic partnership" through the association with powerful partners with expertise on the market:

"This is very important because people don't know that this solution exists. Our strategy is to associate with organizations like Samsung that have a very powerful connection to the market. I think that the association with Samsung (and other big companies) is useful to make "noise" in the market." - GoLivePhone

7. Which funding scheme was adopted? How did it affect the market approach

The funding schemes adopted include:

- Private funding
- Public funding
- Crowd funding initiatives:

"In 2015 we had a successful crowd funding initiative in Netherlands that was very helpful for the latest developments of our product and to finally bring the product to the market." – GoLivePhone

8. How did you handle the IPR issues? (if applicable)

In case of Angel4, the respondent chose not to share the information concerning IPR issues claiming to be "protected by trade secret". Tunstall revealed no need to deal with IPR issues. In case of V.A.C., the algorithm and the analysis process was patented and in the case of GoLivePhone, Gociety has a license to use the fall detection and geo-fencing algorithms from other institution. Finally, in the case of MoveTest, McRoberts is the owner of all IPRs that is basically "know-how" shared with Amsterdam University.

9. Scientific or clinical validation of the solution?

We have gathered four responses to this question and all of them report that the solution has already passed through the solution of the validation phase:

"Clinical validation is done with the final end-user, more than 1000 beds and 100% satisfaction. It is not a requirement as the product is not a medical device." – V.A.C

"Solution validated in almost 200 houses in Italy, Ireland and Spain during the pilots of FATE project." - Angel4

"Yes, GoLivePhone have been validated by Fraunhofer Portugal showing that we have a certain level of quality of about 90%." – GoLivePhone

"Yes, the system is validated in the PROactive project" - MoveTest

In three cases, the interviews have mentioned that the validation process was particularly important:

"Due to the excellent results obtained in the 2014-2015's European pilot where the fall detection system has been tested with 200 patients, Sense4Care company has decided to exploit the commercial rights of FATE Project and put on the market a new product to cover the demand of this kind of devices." – Angel4

"We have reasons to believe that the validation of the solution is an advantage for the product itself and also to attract the attention of other partners. We have a "strategic" partnership with Samsung USA. They mentioned that have chosen our system because it is one of the few solutions that have been validated. " – GoLivePhone

"This was the first step in being acceptable for the consortium. Face validity is realized through the use in the clinical environment in the contact between patient and care taker." - MoveTest

6. Final remarks

The present report intends to suggest the key drivers for market development of ICT-based solutions for falls in elderly based the expertise of the E-No Falls partners based on the consultation of experts in this field. In order to identify the stakeholders with expertise in marketing ICT solutions for falls, we have selected some well succeeded solutions coming from distinct backgrounds that are already under commercialization. Then, the roadmap for market development of ICT solutions for falls was developed based on the experience of the experts.
There are several questions that must be carefully considered for bringing a falls prevention and intervention ICT solution to market: Is it safe to use? Is it effective? Is it user-friendly? Is a one-problem one solution system? Or is covering other areas? Which will be the cost of the system? Which standards/legislation should comply? Is it interoperable with other systems and tools? Does it comply with medical professionals' expectations? Complies with local reimbursement models?
Our respondents identify the definition of practical use cases, research into usability aspects, and validation with end users for deployment in real scenarios as key issues. Also, new funding systems such Procurement of Innovation can assist to design and develop new ICT tools for falls and burst their introduction to the market. Finally, increasing the general awareness on the prevention of falls, especially among the older adults, is essential to increase market uptake of ICT tools for fall detection, prevention and management.

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Annex 1 – Questionnaire transcriptions

1. V.A.C. system

Describe technology and market situation.

V.A.C. (Visualisation et Alerte de Chute) is a non-invasive system to detect falls indoors. The potential market are hospitals, nursing homes and private homes. Developed patented and commercialized by Creative Specific Software (C2S), V.A.C. is composed by a simple optical sensor and an intelligent algorithm which analyses image and detect if elderly people has fallen or not. The system also acts as an actimetry, monitoring human rest/activity cycles or abnormal absences. The system send a notification to a Smartphone or other systems. The camera has been designed to increase acceptability of customers.

The V.A.C system respects customer privacy. The algorithm processes and analyses automatically the images and there is no need for personnel checking the cameras. The images' analysis is done in local. The alert system can be customized and the options are: a simple message or a blurred image of the fallen subject. As far as Mr. Larbi knows, this technology is unique in Europe.

If possible, explain briefly the business plan.

C2S have raised 1.5M€ to develop the product. The business plan is to pass through different partners with an established market in hospitals and nursing homes to sell/distribute their product. They will join forces with insurances companies or tele assistance companies which will sell/distribute their product. Example: **Arkéa Assistance**, the telecare subsidiary of Crédit Mutuel Arkéa will distribute VAC system extending its services for the elderly.

(https://www.arkeaassistance.fr/arkeaassistance/teleassistance/web/c_22731/vac-by-c2s-detecteur-chutes-et-malaises)

They have started in the French market and they aim to reach 10% of nursing houses. They also started with the Canadian market starting a collaboration with a company which offer quality care to diverse customer in the sectors of: accommodation and care for seniors, rehabilitation and specialist care services and nursing and assistance (Groupe Santé Sedna). In the following months, they are planning to enter into the Spanish, the German and the Italian markets. They are planning irruption to the US market in 2018.

Is the solution certified as a Medical Device?

No, because V.A.C is not a medical device as it does not diagnose and it does not give/send medical data. Nevertheless, they are planning to obtain this certification to enter in other countries.

Is your technology stand-alone device or is integrated with other features?

Currently, V.A.C system allows fall detection at home and actimetry monitoring. They are planning to add other features in the system in the future (smoke detection…etc).

Does your solution offer any type of interoperability?

The system is completely open and interoperable with other systems like ASCOM

Reimbursement pathways? Payers?

They have different markets and this changes depending on it.

For example: In terms of nursing house, with the V.A.C system the quality of the service for seniors is increased/improved so this might be reflected in the price of the nursing house service. They sell to the directors of nursing houses.

For private customers, depends of the country. For example, in France and Canada, governments try to stimulate solutions and investments for longer autonomy and independence of elderly and they have specific laws to push the adoption of innovative solutions such as V.A.C system. In France, there is a reimbursement of 50% of the cost for private customers.

Deployment, how to reach the buyers?

At the moment, exhibitions in France (Hopital Expo) to meet new partners and C2S strategy is these partner advertises V.A.C. product.

Which funding scheme was adopted? How did it affect the market approach

Mr. Larbi created C2S with a capital of 10.000€. C2S managed to raise 1.5M€ for developing the product with business angels. (I might not understood correctly this question).

How did you handle the IPR issues? (if applicable)

Patent in the algorithm and the analysis process over the world. France, Europe, USA, Canada, Australia. (US20150023551- Method and device for detecting falls by image analysis)

Scientific or clinical validation of the solution?

Clinical validation is done with the final end-user, more than 1000 beds and 100% satisfaction. It is not a requirement as the product is not a medical device.

2. Angel4

Describe technology and market situation.

An evolution of FATE system is already commercialized by start-up company SENSE4CARE.

If possible, explain briefly the business plan.

Direct commercialization of the device without any compromise in any service.

Is the solution certified as a Medical Device?

No. It is not a medical device due to it is not for prevention, diagnostics. It is used only as an alarm system

Is your technology stand-alone device or is integrated with other features?

FATE is a system that integrates wearable fall detector sensor, a bed sensor, a gateway through smartphone and home computer, double communication systems, zigbee wall-routers and Bluetooth dongle.
A complex service covering fall detection at home and outside needs a complex system

Does your solution offer any type of interoperability?

The commercialized solution, the fall detector, interoperates with most common smartphones of the market.

Deployment, how to reach the buyers?

SENSE4CARE has developed a commercial web and also contacted commercial distribution

Which funding scheme was adopted? How did it affect the market approach

Private funding

How did you handle the IPR issues? (if applicable)

The fall detector system is protected by trade secret

Scientific or clinical validation of the solution?

Solution validated in almost 200 houses in Italy, Ireland and Spain during the pilots of FATE project.

Due to the excellent results obtained in the 2014-2015's European pilot where the fall detection system has been tested with 200 patients, **Sense4Care** company has decided to exploit the commercial rights of FATE Project and put on the market a new product to cover the demand of this kind of devices. The **Sense4Care** fall detector, called "**Angel4**" is a standalone device that works without the common telecare services charges, becoming the most innovative sensor that allows a direct communication with the user's caregiver or relatives through standard mobile phones.

3. Tunstall iVi

Describe technology and market situation.

THE iVi INTELLIGENT PENDANT is a small, lightweight device which automatically detects falls, and like other pendants, the iVi allows the wearer to press a help button to generate an alarm call when they need help from anywhere in their home, 24 hours a day. The iVi is the only product of its kind to feature a 'not-worn' alert, which will notify the monitoring centre if the iVi has not registered movement for a defined time period, suggesting that the user has not worn it. The pendant has several wearing options and can be adjusted to suit individual needs.

The sensitivity settings can be adjusted to suit the individual user, and in addition to the help button which the user can press to manually raise an alert, the iVi also has a cancel button enabling activations to be cancelled in their early stages.

- Go-to-market or license. Why?

The iVI Fall Detector is currently available on the market.

Is the solution certified as a Medical Device?

This is not considered a medical device as it does not prevent or reduce falls.

Is your technology stand-alone device or is integrated with other features?

The iVi Fall Detector is integrated with the Tunstall Lifeline home units, where alerts are handled in a call centre, or CareAssist pagers, where alerts are dealt with locally. It cannot be used as a stand-alone device.

Does your solution offer any type of interoperability?

The iVI Fall Detector works with Tunstall's range of Lifeline home units, for either the fixed line phone network or GSM network, and with the CareAssist Pager.

Reimbursement pathways? Payers?

This device is sold as part of an integrated solution with the Lifeline Unit or Care Assist pager. The solution is personalised to the user's needs and may also include other devices such as bed/chair occupancy sensors. The solutions are sold on the private pay market directly to the users, and are also purchased and distributed by health services providers.

Deployment, how to reach the buyers?

The main target market for Tunstall Emergency Response is the Health Service Executive where falls are a significant driver of cost but alternatively through our direct to consumer market where families may purchase the equipment to allow their dependent remain at home.

Which funding scheme was adopted? How did it affect the market approach

In the Republic of Ireland, there are currently more than 100,000 social alarms in the telecare market. Of the current market 85% of users are publicly funded and 15% are privately purchased. The current take up is approximately 25% of people over 65. There has been limited take-up of more advanced telecare in Ireland to date, although some social alarm providers and social care providers now offer second generation telecare as part of their services.

How did you handle the IPR issues? (if applicable)

No IPR issues

4. GoLivePhone

Describe technology and market situation.

GoLivePhone is an extremely user-friendly smartphone, specially developed for and by seniors, that allows not only detecting a fall event but also to prevent or assess the risk of a fall event occurs.

Due to the aging of the population, the detection and prevention of a fall is very important. Falls have a huge impact on the senior's independence and quality of live. Besides, the financial situation of the senior is compromised and the situation becomes a burden also for insurance companies, health care organizations and governments. For this reason, this kind solution has raising much attention particularly because of the fall detection and fall prevention.

If possible, explain briefly the business plan.

We have a very simple business model is based on a license model. Gociety focus on developing new solutions and applications with our partners and leave the market part for the partners that are really good at that. Basically, we work together with providers (Fraunhofer in this case) to investigate, develop, test and validate the solution; and distribution partners (such as the “strategic” partnership with Samsung) to bring the solution to the market.

Is the solution certified as a Medical Device?

No, being a medical device implies lots of tight regulations, especially in the US market. Besides, the smartphone is a consumer product that is not perfect (battery and other hardware issues, software issues and even the network can compromises the normal operating of the smartphone). From that perspective, we would rely on the providers (network providers, etc.) and if we want to go through the Medical area, we should not do it on a consumer product.
The choice of not being certified as a medical device was made especially to allow more people to use the solution and make it highly affordable.

Is your technology stand-alone device or is integrated with other features?

Initially, the solution was based on a smartphone that the senior wears on the pocket or on the belt. Recently, a new component is being developed, the GoLiveWear, in order to have the availability of the solution in a clip that can be wearied with any clothes. This solution is already on the way to the market. GoLivePhone sends data to backend server (working as EHR), called GoLiveAssist that is used by the caregivers to follow-up the seniors and to assist them in case of emergency or request.

We are providing what we call “the next generation of mobile personal emergency response solutions”, making connections with professional care organization software (such as Tunstall and others) in order to share and make available all the medical information. From the GoLiveAssist data can be shared with different service providers like Tunstall or others, so its plan to develop an ecosystem of services and applications.

Does your solution offer any type of interoperability?

The communication between the GoLivePhone and GoLiveWear is assured by standard Bluetooth Low Energy connection. The data sent from GoLivePhone to GoLiveAssist is in the JSON format and is open to be used by others. We consider important to share information between different elderly assistance service providers and for that each of this entities can query GoLiveAssist using a well know tool called CouchDB.

Reimbursement pathways? Payers?

For the moment, 99% of the costs are paid by the final users, the seniors and it is not reimbursed.
Currently, we have been discussing the prevention topic with health care insurance companies and government. We want to show the importance of our solution by conducting an experiment with two groups: one with the fall detection and another without. We are organizing this “clinical trial” in US during a few years, and we expect being able to prove with this clinical trial the importance of our solution and to show that we can indeed prevent people from falling.

Deployment, how to reach the buyers?

This is very important because people don't know that this solution exists.
Our strategy is to associate with organizations like Samsung that have a very powerful connection to the market. I think that the association with Samsung (and other big companies) is useful to make “noise” in the market.

Which funding scheme was adopted? How did it affect the market approach

Private Funding.
In 2015 we had a successful crowd funding initiative in Netherlands that was very helpful for the latest developments of our product and to finally bring the product to the market.

How did you handle the IPR issues? (if applicable)

In this case, the technology is licensed from other institution (Fraunhofer Portugal AICOS).
After an investigation regarding the specific needs of the seniors, we became interested on fall detection applications. Then, we found Fraunhofer Portugal working on fall detection and we establish the contact. That's how it all began. Currently Gociety has a license to use the fall detection and geo-fencing algorithms.

Scientific or clinical validation of the solution?

Yes, GoLivePhone have been validated by Fraunhofer Portugal showing that we have a certain level of quality of about 90%.

We have reasons to believe that the validation of the solution is an advantage for the product itself and also to attract the attention of other partners. We have a “strategic” partnership with Samsung USA. They mentioned that have chosen our system because it is one of the few solutions that have been validated.

5. MoveTest

Describe technology and market situation.

The MoveTest is an instrumented physical performance test, it is a device that includes Sit-to-Stand test, TUG test and Gait test. MoveMonitor is used to measure daily life physical activity.

We have 3 markets: Research, Clinical Trials and Clinical Care. The most interesting market for E-NO-FALLS is the Clinical market. McRoberts is in particular successful in the respiratory field, especially COPD (Chronic Obstructive Pulmonary Disease). For the moment, we have 10 hospitals working with the MoveMonitor. The patients that enter in the diagnostic process are coming twice to the hospital: the first time they look at the lungs and second time they look at the physical activity. Then, they receive an advice that is part of the protocol. All the Netherlands's patients have to receive a physical activity advice. The second market is geriatrics, that is starting in a University Hospital in Amsterdam. There are some raising interests in this field. I had a presentation on the yearly geriatrics days where I have presented the MoveMonitor and the way we use in clinical practice.

In a user meeting, we have interviewed the people that are working with it and they were very open to tell their experience and they are very positive because the MoveMonitor gives more information regarding the people's life through the 7 days report.

We are an integrated part of the COPDnet, and we have more and more hospitals interested. The hospitals pay for this service so there is no insurance companies involved.

If possible, explain briefly the business plan.

Regarding the Clinical Market, the business model is to continue in Netherlands and to find other countries interested. England is interested because the health care system is very similar to that of Netherlands; in German is very difficult because the health care system is completely different. Canada is another country that is interested.

For the clinical market you need a local partner. We operate from The Netherlands and do not have distributors so we are looking for a partner to further market our system for the clinical market. We need a partner that is already active there.

The MoveTest is very interesting also for geriatric market and in particular for fall prevention in elderly. In rehabilitation, recent publications have mentioned that COPD may cause lower limb dysfunction. As we have recently developed the 6-min walking test, this can mean more opportunities for the MoveTest for instance repeated sit-to-stand.

Regarding fall risk as a measure, we are working together with University of Amsterdam in in order to improve the fall risk methods. For the moment, we don't have the fall risk in the MoveMonitor but we are planning to add it soon. So, we are acquiring clinical experience and working on turns, sit-to-stand, stairs climbing and cycling in order to have a diagnosis as accurate as possible.

Is the solution certified as a Medical Device?

MoveTest and MoveMonitor are both medical devices, with FDA registration. The decision was made because we were chosen by the PROactive (Physical Activity as a Crucial Patient Reported Outcome in COPD), an European project (with European funding involved), and being a MD was a requirement for meeting the American regulations. This was a huge decision that has changed the way of the company works. Being a MD is also an advantage to enter in the American market. The choice was not ours but in the end, we think it is very good for research market because we are more professional and for the clinical market is good as well.

Is your technology stand-alone device or is integrated with other features?

MoveTest and MoveMonitor are diagnostic devices that works offline. The device has 11 sensors included but they do not communicate directly with the patient. We only collect data because we don't want to influence the patient during the research, and also in clinics, it is not used for intervention.

Does your solution offer any type of interoperability?

The MoveMonitor collects and stores the data for one week. Then, when the patient goes to the hospital and the data is uploaded to the McRoberts certified cloud system and then it produces automated reports that can be downloaded. The MoveTest works similar, the patient wears the device, performs the tests, the data is stored and then synchronized with the cloud and finally the report comes out. MoveTest has Bluetooth and a wireless connection to make the data collection easier. The outcomes are stored in a database to make data handling as easy and efficient as possible. Raw data are stored in the cloud to make reanalyze of existing data easy.

Reimbursement pathways? Payers?

In research, they buy and work with it for many years. In hospitals it is different, the hospital buys as many devices as necessary for the clinical pathway and provides the devices to their patients. The usability is very important.
We are starting negotiating with insurance companies, next week we will have a meeting and we will find out how to deal with it.
We think that the device is beneficial for patients, cheap and does not give any negative side effects like, for example, medication. Besides, people see the benefits of using it.

Deployment, how to reach the buyers?

At the moment, the buyers are the hospitals and may be in the future also physiotherapists. For the moment, we try to reach them talking in congresses and meetings where we meet researchers and physiotherapists. Also COPD network helps spreading the device.

Which funding scheme was adopted? How did it affect the market approach

Only private funding.

How did you handle the IPR issues? (if applicable)

Intellectual property rights are totally ours, and it is "know-how". We share some knowledge with Amsterdam University.

Scientific or clinical validation of the solution?

Yes, the system is validated in the PROactive project. The results of this comparative validation have been published. This was the first step in being acceptable for the consortium. Face validity is realized through the use in the clinical environment in the contact between patient and care taker.

Thematic Network
CIP-ICT-PSP 2012 Call 6 | Ref.: 325137
European Network for FALL Prevention, Intervention & Security

E - NO FALLS

D4.3.2
Market development Roadmap. Final

E-NOFALLS

Innovation Procurement to develop ICT solutions for fall prevention and intervention

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1 Introduction

Foreword

This document aims to provide a roadmap that addresses the key challenges, steps and phases to go through while implementing a **business process** of **ICT-based fall prevention and effective intervention solutions** for elderly people.

Falls

Falls constitute a problem in elderly and determine the growing of morbidity and mortality by being one of the main causes for hospitalization in a geriatric unit. Estimated 80% of all accidents which lead to injuries with serious consequences are caused by falls in elderly people. Falls still constitute a major threat to the health and well-being of elderly people.

ICT for Fall Prevention and Intervention

Technological developments has boosted the development of new ICT solutions for detection and/or prevention of fall accidents that may prolong the independence and enhance the quality of the elderly's life. With an appropriate knowledge of the risk of falls, ICT tools enable better implementation of activities in both prevention and detection of falls.

2 Methodology

The objective of this deliverable is to identify best practices and draw a roadmap on market development of ICT-based fall prevention and effective intervention solutions for elderly. The methodology followed to reach this goal can be summarized into 7 steps:

1. **Literature review:** Explore and identify, based on the literature review, the main challenges associated with market development of ICT solutions for falls, and understand the current situation regarding each challenge
2. **Identification of the success cases:** Identify well succeeded cases of ICT-based fall prevention and effective intervention solutions for elderly people that are already under commercialization, the "success cases"
3. **Stakeholders' identification:** For each success case, identify one representative entity of each solution
4. **Questionnaire development:** The questionnaire is based on the key challenges faced during the market development of an ICT-based solution, found Step 1
5. **Interview process:** The identified stakeholders were contacted via phone call or skype call and the questionnaire was used to guide the conversation. The answers were annotated and validated by the stakeholders
6. **Questionnaire analysis:** Analysis of the results obtained from the questionnaire and extraction of relevant aspects mentioned by the experienced stakeholders
7. **Conclusions and recommendations:** Draw recommendations based on the conclusions of the questionnaires

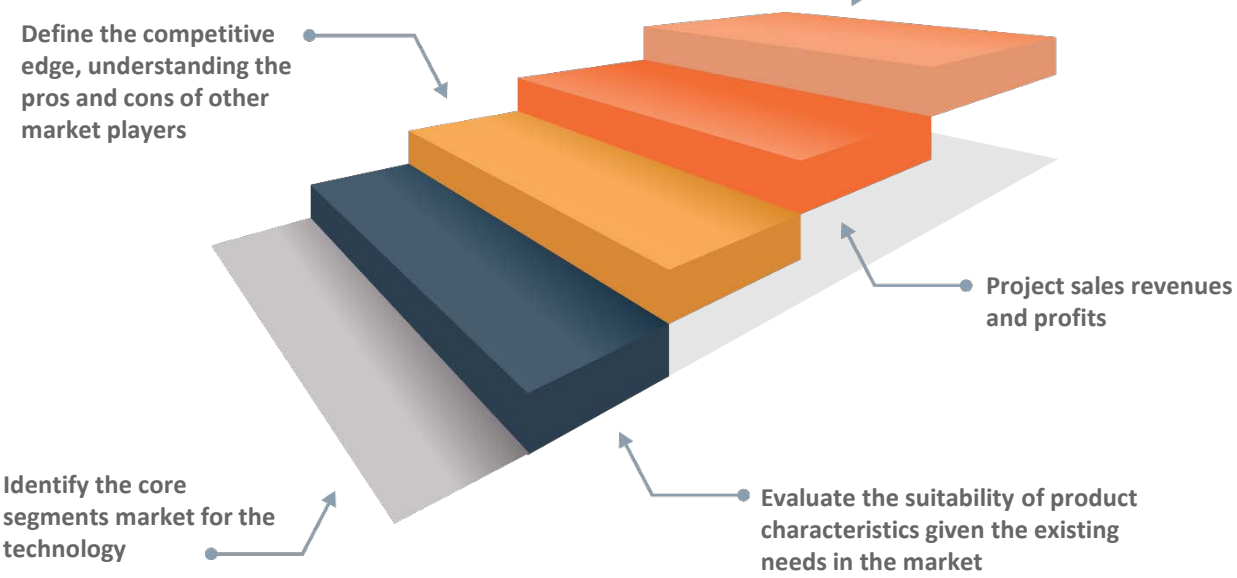
3 Market Development Roadmap

Traditionally, having as final goal to address the need or the improvement of a current technology, the **market uptake** requires a careful **study** of the market, taking also into account the **commercial and regulatory issues**.

One of the most important instruments to evaluate the feasibility of product development is a **roadmap** because it helps leveraging the power of stakeholders support. It becomes also imperative to estimate the potential market, select one or more target markets and develop a corporative strategy that satisfies the needs and wishes of members of the target market. At the same time, an evaluation of motivational factors of economic agents should not be forgotten to outline a business model and face its inherent challenges.

Market Research

A market research analysis includes:



4 Which are the main actors?

Governments and public authorities play an important role regarding regulatory matters to address new challenges caused by the world ageing population and emerging technologies

Insurance companies are particularly important in the reimbursement squemes, as the healthcare costs are increasing year after year

Industry are the main actors involved in the design and development of an ICT-based solution

Research Centres, Start Ups and Spin Offs take part directly in the innovation processes by participating in the research and invention activities that influence innovation

Health centres are particularly valuable in the design and testing phases in order to support better health outcomes

Health professionals (e.g. general practitioners and nurses) are the main prescribers of using ICT as a tool for detecting and preventing falls

End-users are the main beneficiaries of the product and should be involved in the development from the beginning for a user-centred approach

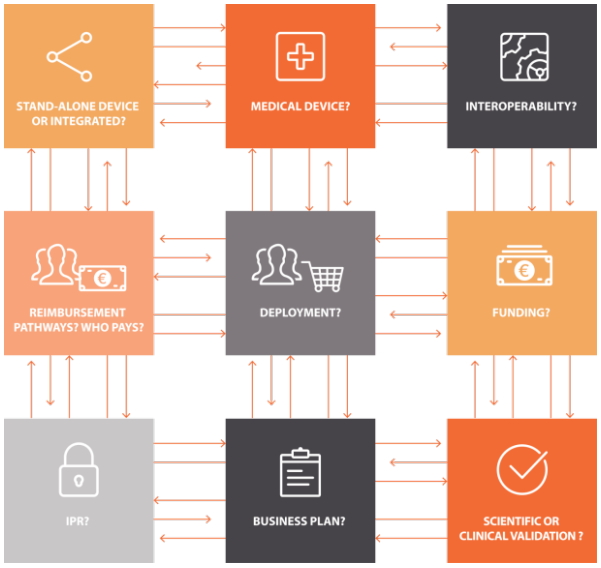
5 What are the main barriers?

The major obstacles that hinder the development of the market for ICT-based fall prevention and effective intervention solutions for elderly can be grouped into four main categories:

1. **Conveying Legal Clarity:** The legal provisions on ICT-based solutions are at different stages in the different countries of EU and lacks a homogeneous framework;
2. **Building up awareness of ICT solutions:** The lack of general knowledge in the existing ICT fall prevention solutions, also hinders the adoption of these solutions;
3. **Driving prescription of ICT solutions:** Specific actions to convince healthcare providers to effectively adopt those solutions and to justify the importance of prescribing fall prevention programs;
4. **Engaging end-users:** Specific actions to engage and convince the final users, their family or careers of the benefits and usability of fall prevention and management products and reduce the resistance to technological solutions is crucial.

Key drivers to market deployment

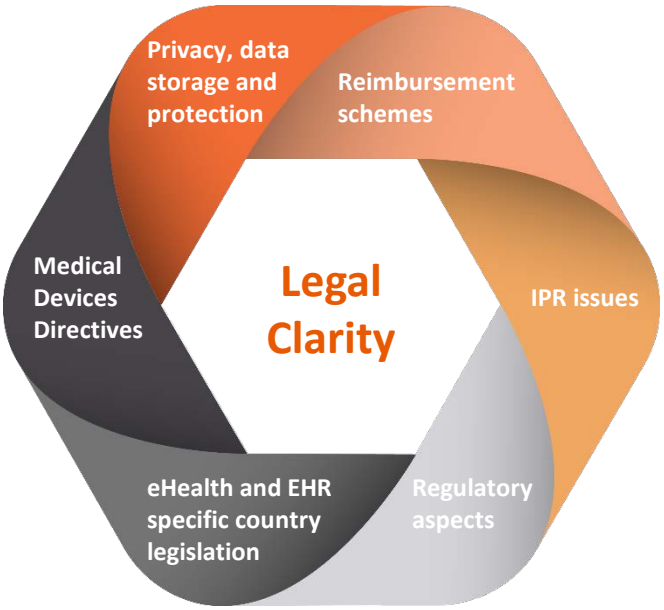
Besides the barriers, there is a set of **key drivers** that must be considered when implementing an ICT-based solution for falls.



6 How to overcome the barriers?

1. Conveying Legal Clarity

Development of a standardized and widely accessible platform including standards, specifications, use cases, workflows, subset of terminologies, interoperability agreements and guidelines to close the gap caused by legal clarity.



2. Building up awareness of ICT solutions

Increase fall prevention awareness on the general public agenda, namely, governments

- ✓ Participation in national and international scientific events
- ✓ Organization of Workshops and Focus groups, fall prevention day or week
- ✓ Fall prevention ToolKits
- ✓ Fund raising actions, such as Telethon or Serious Request
- ✓ Fall prevention platforms and associations

Increase fall prevention awareness by standardizing implementation of ICT solutions

- ✓ Raising funds for innovation and research on ICT solution for fall preventions
- ✓ Implementing standardization of ICT fall prevention solutions
- ✓ Being innovative and carefully selecting the most effective solutions at the same time
- ✓ Implementing the selected health care solutions in the care giver practices

6 How to overcome the barriers?

3. Driving prescription of ICT solutions

Providing clinical stakeholders with objective information about the clinical impact and results of ICT solutions for falls prevention and management. How?

- Scientific publications and clinical trial results dissemination
- Partnership with National or International medical associations
- Face-to-face meetings
- Inviting experts in falls-related ICT solutions to lecture in clinical training programmes

4. Engaging end-users

Specific actions to engage and convince the final users, their family or careers of the benefits and usability of fall prevention and management products and reduce the resistance to technological solutions is crucial. There is handful of success factors can help with user engagement:

- Design of the solution
- Education of caregivers
- Costs of the product
- Informing of older person

7 Stakeholders consultation

A set of **success cases** was selected in order to understand which factors have been determinant to their **success** and which obstacles were found in their path to market.

Selected Success Cases

Having in consideration the inventory of ICT-based solutions for falls, we have selected one representative solution emerged from very distinct starting points and funding schemes.

Angel4

Case that started from an European funded project "FATE", further developed and commercialized by the start-up company Sense4Care

GoLivePhone

Case of licensing a technology from an R&D institute, further commercialized by the company Gociety

iVi Intelligent Pendant

Case of a direct industry investment, developed and commercialized by Tunstall Healthcare

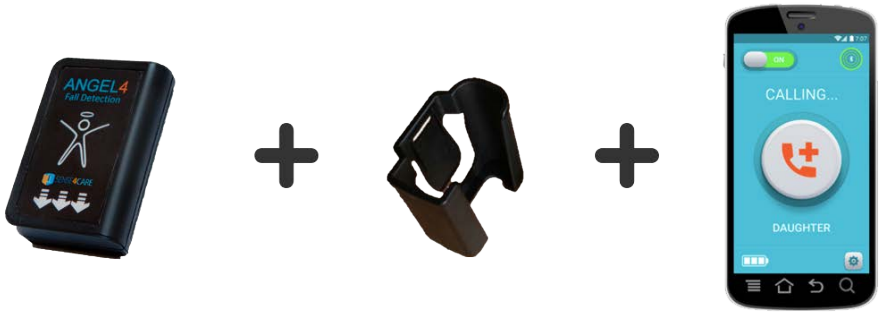
V.A.C. System

Case of a direct industry investment commercialized by Creative Specific Software (C2S) which through the European Project HAPPI

MoveTest

Case of a partnerships with Universities and direct industry investment, developed and commercialized by McRoberts

7 Stakeholders consultation



Angel4

The Sense4Care fall detector, called "**Angel4**" is a standalone device that works without the common telecare services charges, becoming the most innovative sensor that allows a direct communication with the user's caregiver or relatives through standard mobile phones.

Angel4 came from the FATE project where it was developed an ICT-based solution that focuses on improving the elder's quality of life by an accurate detection of falls, both inside and outside home. It is an innovative, efficient and well integrated solution composed by:

- ✓ an accurate, portable and usable **fall detector** that runs a complex and specific algorithm to accurately detect falls (worn all the time by the user in the waist)
- ✓ a **smartphone** that sends the alarms generated by the detector to an emergency service
- ✓ a **bed presence sensor** that detects if the user is on bed or not
- ✓ a **central computer** that manages the FATE system at home through a wireless network and communicates with the smartphone by means of a Bluetooth link.

The start-up company **Sense4Care** have further developed and commercialized a fall detector device using part of the results of CETpD research in the European project FATE based on a knowledge transfer agreement with the **Universitat Politècnica de Catalunya (UPC).**

Angel4 website: http://www.sense4care.com/en/products/angel4-whiteblack

7 Stakeholders consultation

GoLivePhone

GoLivePhone is an extremely user-friendly smartphone, specially developed for and by seniors, that allows not only detecting a fall event but also helps to prevent them. It is equipped with a lot of smart extras that can make elderly life a lot more pleasant, easier and safer. The GoLivePhone includes:

- ✓ an intelligent **fall detection** algorithm, capable of detect when the user falls and immediately sending an alarm to the carer
- ✓ an intelligent **activity monitor**, to insight and feedback of the user's activity
- ✓ **fall risk assessment**
- ✓ an intelligent **navigation system**
- ✓ **agenda and Medicaments Management**, that generates automatic alerts (for medication, meetings, reminders, activities, etc.)
- ✓ **emergency button** and the "**I'm fine!**" button

The system was developed by Fraunhofer Portugal AICOS, a Research Center that has dedicated efforts in the researching new ICT-based solutions to improve of the quality of life of its end-users.

After the publication of the first scientific paper, the platform caught the interest of two Dutch entrepreneurs who have decided to license the technology. As a result of the partnership between Gociety company and the R&D institute (Fraunhofer Portugal AICOS) arose the GoLivePhone that is currently being commercialized by through Gociety.

GoLivePhone website: https://www.gociety.eu/en/golivephone/

7 Stakeholders consultation

iVi Intelligent Pendant

The iVi Intelligent Pendant is a small, lightweight device and like other pendants, the iVi allows the wearer to press a **help button** to generate an alarm call when they need help from anywhere in their home, 24 hours a day. The iVi also provides an added layer of protection by automatically generating a call for assistance if a fall is detected and the wearer is unable to push the help button.

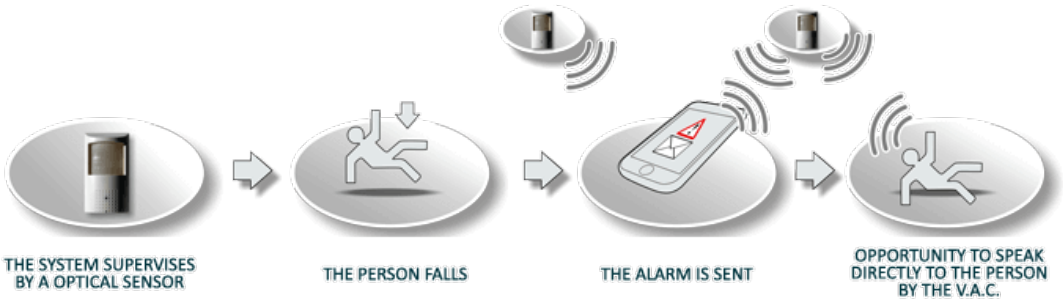
The iVi has a range of wearing options, and can be adjusted to suit individual needs. Besides, iVi is the only product of its kind to feature a **"not-worn" alert**, which will notify the monitoring centre if the iVi has not registered movement for a period of time (3, 5 or 7 days), suggesting that the user has not worn it.

The sensitivity settings can be adjusted to suit the individual user, and in addition to the help button which the user can press to manually raise an alert, the iVi also has a **cancel button** enabling activations to be cancelled in their early stages.

iVi Intelligent Pendant was developed and commercialized by Tunstall Healthcare, the world's leading connected healthcare provider, with a vast experience on commercializing ICT-based solutions dedicated to the end-users. Tunstall develops innovative products and services to help older people and those with long-term needs live life to the full for over 50 years.

iVi Intelligent Pendant website: http://www.tunstall.co.uk/solutions/ivi

7 Stakeholders consultation



V.A.C. - Visualisation et Alerte de Chute

V.A.C. (Visualisation et Alerte de Chute) is a non-invasive system to **detect falls** indoors. The potential markets are hospitals, nursing homes and private homes.

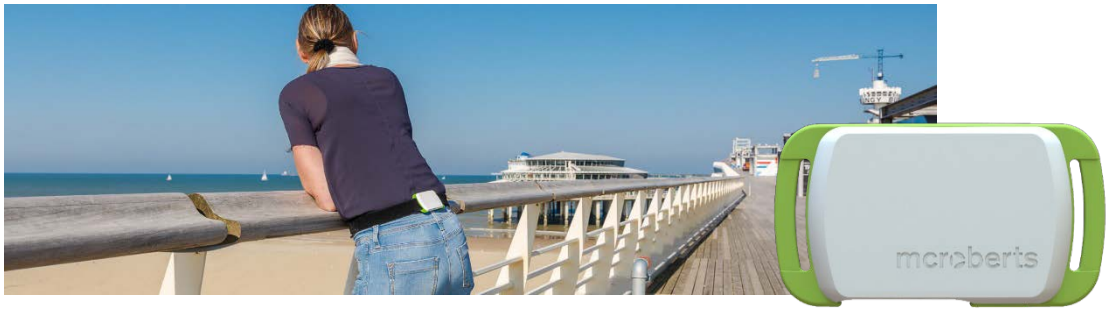
Developed patented and commercialized by Creative Specific Software (C2S), V.A.C. is composed by a simple optical sensor and an intelligent algorithm which analyzes image and detect if elderly people has fallen or not. The system also acts as an **actimetry**, monitoring human rest/activity cycles or abnormal absences. The system sends a **notification** to a Smartphone or other systems. The camera has been designed to increase acceptability of customers.

The V.A.C system respects customer privacy. The algorithm processes and analyses automatically the images and there is no need for personnel checking the cameras. The images' analysis is done in local. The alert system can be customized and the options are: a simple message or a blurred image of the fallen subject.

C2S was one of the winers of **HAPPI project** (ENT/CIP/11/C/N02C011; Healthy Ageing – Public Procurement of Innovation) that aims to use public procurement to stimulate demand-driven innovation in healthy ageing to address the challenge of demographic change in Europe. Thus, it is a case of a direct industry investment commercialized by C2S which through the **European Project HAPPI** has accessed to procurement contracts of European healthcare organizations expanding quickly its market.

V.A.C. system website: http://www.creative2s.fr/

7 Stakeholders consultation



MoveTest

The MoveTest consists of a hardware unit, managing software, and one or more chosen modules, accessible through our web service. The MoveTest includes:

- ✓ 6 standardized tests
- ✓ Temporal and kinematic outcomes
- ✓ Remotely controlled
- ✓ Customized test protocols
- ✓ FDA and EMA approved medical device
- ✓ Conform ISO-13485
- ✓ Platform for multi-center studies
- ✓ Cloud-based analysis and storage of data
- ✓ Graphical and Database output

The MoveTest allows short physical performance tests using one single device attached around the waist of the subject. The system allows the integration of 6 test modules that includes tests for **Gait**, **Sway**, **Sit-to-Stand**, **Timed Up and Go**, **Short Physical Performance Battery (SPPB)** and **6-Minute Walk** test. Dedicated software will assist the user in efficiently performing a pre-defined test protocol.

MoveTest was developed and commercialized by McRoberts in collaboration with University of Amsterdam. McRoberts is an innovative and flexible organization with 25 years of experience, and one of the leaders in ambulatory monitoring of physical activity. Besides MoveTest, McRoberts has another solution under commercialization, the MoveMonitor, which aims to assess the physical activity status of the patients.

MoveTest website: http://www.mcroberts.nl/products/mt/

8 Results of the questionnaire

Angel4

Interoperability? « Yes, the solution interoperates with most common smartphones on the market. »
Funding source? « The solution reached the market with using private funding»
Validated? « Yes, due to the excellent results obtained in the 2014-2015's European pilot, Sense4Care company has decided to exploit the commercial rights of FATE Project and put on the market a new product. »

GoLivePhone

Medical Device? « No, Medical Device implies lots of tight regulations»
Who pays? « Currently, 99% of the costs are paid by the final users, the seniors and it is not reimbursed. We have been discussing the prevention topic with health care insurance companies and governments. »
Validated? « Yes, the validation of the solution is an advantage for the product itself and also to attract the attention of other partners: Samsung USA chose our system because it is one of the few validated solutions. »

V.A.C. system

Medical device? « No, V.A.C is not a medical device as it does not diagnose, give/send medical data. »
Interoperability? « Yes, the system is completely open and interoperable with other systems like ASCOM. »
Validated? « Clinical validation is done with the final end-user, more than 1000 beds and 100% satisfaction. »

iVi Intelligent Pendant

Interoperability? « Yes, it works with Tunstall's range of Lifeline home units, for either the fixed line phone network or GSM network, and with the CareAssist Pager. »
Reimbursement pathways? « Of the current market 85% of users are publicly funded and 15% are privately purchased. There has been limited take-up of more advanced telecare in Ireland to date, although some social alarm providers and social care providers now offer second generation telecare as part of their services. »

MoveTest

Medical device? « Yes, MoveTest and MoveMonitor are both medical devices, with FDA registration. Being a MD is an advantage to enter in the American market. »
Reimbursement pathways? « No, for research, they buy and work with it for many years; in hospitals, they buys as many devices as necessary for the clinical pathway and provides the devices to their patients. »
IPR? « The IPRs are totally ours, and it is "know-how". We share some knowledge with Amsterdam University. »

9 Final remarks

Is it safe to use? Is it effective? Is it user-friendly? Is a one-problem one solution system? Or is covering other areas? Which will be the cost of the system? Which standards/legislation should comply? Is it interoperable with other systems and tools? Does it comply with medical professionals' expectations? Complies with local reimbursement models?

When considering bringing a falls prevention and intervention ICT solution to market a wide range of parameters need to be considered:

Our respondents identify the definition of practical use cases, research into usability aspects, and validation with end users for deployment in real scenarios as **key issues**.

Also, new funding systems such Procurement of Innovation can assist to design and develop new ICT tools for falls and burst their introduction to the market.

Finally, **increasing** the **general awareness on the prevention of falls**, specially among the older adults, is essential to **increase market uptake of ICT tools for fall detection, prevention and management**.