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Final Report on the I-DON'T-FALL Pilot Operations

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EXECUTIVE SUMMARY

The aim of this deliverable is to provide the Final Report on the Pilot Operations.

Here will be included the evolution of the pilots, all the issues they encountered, solutions to general and particular problems from both a project and a pilot point of views.

Document Information

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GLOSSARY

ICF – Informed Consent Form

IDF – I-DONT-FALL

ENG - ENGINEERING - INGEGNERIA INFORMATICA SPA

NFE - Stichting Nationaal Ouderenfonds

FSL – Fondazione Santa Lucia

FSM – Fondazione Salvatore Maugeri

HGG - Fundacio Hospital Asil de Granollers

SERMAS - SERVICIO MADRILENO DE SALUD

FRONTIDA - APHOI KOUMANAKOU & SIA EE

SPC - SOCIAL POLICY CENTER OF THE MUNICIPALITY OF KIFISSIA

SiLO - SINGULARLOGIC ANONYMOS ETAIRIA PLIROFORIAKON SYSTIMATON & EFARMOGON PLIROFORIKIS

AUSL - AZIENDA USL DI FORLI

MOSG – Municipality of Stari Grad

UPC - UNIVERSITAT POLITECNICA DE CATALUNYA

1 INTRODUCTION

The goal of this deliverable is to provide a final and detailed history of the Pilots Operations.

Here will be described the evolution of the Pilots lists, included the withdrawal of partners, their substitution, some major and minor problems and the remedies adopted to fix them.

A project overview will be given and each pilot will have also a brief description of its own operational history.

The document is structured as follows: in Section 2 will be presented the history of the project both from the whole project side and from each Pilot point of view. There will be also described occurred problems and their remedy as well as best practices and lessons learned in relation to the operational aspects of the I-DONT-FALL pilot Operations. Finally in Section 3 conclusions will be given as an evaluation from an operational point of view.

2 HISTORY OF THE PROJECT

2.1 Project point of view

Even before to start, I-DONT-FALL encountered initial obstacles on its way. The original participants to the consortium Philips and Medic4All decided to withdraw. While Medic4All was replaced by TESAN, Philips was not replaced and its activities were shared by technical partners already present in the project.

I-DON'T-FALL Project started in 1st of April in 2012.

During the first year were completed activities regarding Requirements and Use Case Definition (WP1), Service Definition and Pilots Specifications (WP2) Platform and Service Technical Specifications (WP3). In that year also Holland partner (National Ouderenfonds) decided to withdraw from the project and was substitute by TUD (Delft University of Technology) that was in charge of all the activities of the replaced entity.

Other activities started and lasted also for second year, such as Platform Implementation, Integration and Test (WP4), Pilot Sites Preparation (WP5) and an initial part of Pilot Operations WP6) regarding user recruitment and detailed planning of the pilots (T6.1). The other activities that started and lasted until the end of the project, were Evaluation and Progress Assessment (WP7), Dissemination, Exploitation and Sustainability (WP8) and of course Project Management (WP9).

In terms of pilot operations, the first "real" obstacle founded by the project was the implementation of the Fall Detection Service as it was designed at proposal preparation time. Medic4All personnel should provide that Service that on a fall alarm should react and call patients in any country and with their specific mother tongue (i.e. Italian, Spanish, Dutch, Serbian and Greek). Unfortunately, TESAN didn't have the same languages skills to offer (to call in real time) so it was proposed to manage the alarm system with a messaging like solution. That solution was not considered sufficiently safe for the patients and the project moved to a B plan.

Fall Detection Service was offered only to Italians Pilots (FSL and AUSL) and this decision had an effect on the distribution of Fall Detection Patients among the Pilots.

Meanwhile the ethical process started at the pilots' sites but, unfortunately, the project faced with bureaucracy and another partner withdrew (i.e. AUSL). Even in this case, the strong network relationship of the project allowed having a valid substitute of AUSL. In fact, FSM entered in the project with a hard job to recover the delay but it was not enough as they could not manage patients at home for fall detection and another users reorganization was necessary. For this reason, the users involved in Detection service were completely assigned to FSL entity.

A delivery issue also affected the project; it was related to the supply of Careportal devices for which Docobo had a big problem with its supplier. It was decided to replaced them with an Android tablet with the same characteristics

(in terms of users needs) of the Careportal, this solution was fully agreed by the consortium but generated a delay which has been in any case minor than the one provoked by the Careportal production.

In the meantime, any Technical issues were fixed and test time was finished; Pilots started to Recruit, Enrol and Train patients. The Study part of the project was started. From that point to the end of the project just minor issues raised and was quickly fixed thanks to the hard work done by all the professionals involved in this big project.

Below a detailed Table that summarizes the situations that affected the partner of the project[1].

Changes in the Consortium	Main Reason for the Change	Changes in Partners Roles and Responsibilities
Philips Consumer Lifestyle (PCL) has withdrawn from the project during the negotiation stage (September 2011)	A significant change in PCL corporate strategy, which has resulted in a general withdrawal from IPTV and home management related activities	PCL's role in the consortium is undertaken by consortium partners ENG, SLG and MEDIC4ALL as follows: • ENG will undertake (lead) the integration of the home management portal of I-DONT-FALL, with the EHR portal of the project. ENG will be also in charge of providing technical support to NFE pilots in the Netherlands. • SiLO will provide the home management portal and the AAL platform to be used in the project, including the development/integration of the device drivers of the fall devices used in I-DONT-FALL. • ENG will be in charge of providing technical

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[1] Description of Work §B3.1.1 Changes to the Consortium since the proposal submission pp82-84.

support to NFE pilots in the Netherlands, thereby undertaking most of PCL's work in WP5 (NFE site preparation) and WP6 (NFE site support and pilot operation). ENG will also undertake (lead) the integration of the home management solution of I-DONT-FALL provided by SiLO, with the EHR portal of the AREAS product.

- MEDIC4ALL will provide an IP based visualization interface (such as IPTV) for the interaction of elderly and medical experts with the I-DONT-FALL management platform.

- SiLO will undertake the leadership of WP2 (originally responsibility of PCL), while also providing/integrating an IP based visualization interface (such as IPTV) to the platform based on the results of the Home.dot.old project. Furthermore, it will contribute to the development of device drivers for the I-DONT-FALL devices

DOCOBO Limited has joined the consortium as a solutions vendor on telecare solutions with emphasis on chronic diseases (October 2011)

DOCOBO has been included in the consortium given its proven expertise in the technological and scientific areas of the project and its capacity to contribute to the I-

The SiLO responsibility for providing the home management platform has been moved to DOCOBO partner:

- DOCOBO will provide the home management solution based on its

	DONT-FALL integrated programmable fall management solution.	doc@HOME product. It will integrate the doc@HOME server with I-DONT-FALL devices, while customizing the web-based remote management of the solution. DOCOBO will also undertake the exploitation/IPR/marketing and evaluation activities of PCL, with a focus on both UK and international markets (where DOCOBO is already active).
MEDIC4ALL has withdrawn from the project during the negotiation stage (October2011)	During the negotiation stage MEDIC4ALL has finalized decisions to shrink the UK branch, which has undertaken participation in I-DONT-FALL	The role of MEDIC4ALL in the consortium will be mainly undertaken by ENG and TESAN. In particular
TESAN has joined the consortium during the negotiation stage (October 2011)	TESAN will undertake the role of MEDIC4ALL (mainly in terms of the operation of telecare/teleassistance services)	• ENG will undertake all the coordination, evaluation and specification activities of MEDIC4ALL, including the leadership of WP6. • TESAN will undertake the provision and operation of call center based services (instead of MEDIC4ALL). Call Center services will be provided by TESAN during the pilot operations of the project. Furthermore, TESAN will undertake MEDIC4ALL evaluation activities. TESAN will evaluate the effectiveness of the call-center related telecare services. • DOCOBO is UK-based and hence will ensure

		the project's presence in the UK markets (role originally foreseen for MEDIC4ALL)
INTERAMERICAN has left the consortium (January 2012) FRONTIDA has joined the consortium during the final stage of the negotiation (January 2012)	Due to internal reorganization (affecting human resources and the I-DONT-FALL project team), INTERAMERICAN decided to withdraw from the project FRONTIDA will undertake the role of INTERAMERICAN in the pilot operations (involvement of 80 patients)	The role of INTERAMERICAN in the consortium, is substituted as follows: • FRONTIDA will undertake the organization and conduction of pilot operations with 80 patients (notably heart patients). Thus, FRONTIDA undertakes the role of INTERAMERICAN in pilot operations.
Stichting Nationaal Ouderenfonds decided to withdraw from the project (June 2012)	They realised that their structures were not adequate to the activities	The role was entirely taken by TUD Delft University of Technology
TUD Delft University of Technology withdraw from the project (Nov 2013)	Internal reorganization of the roles	A new patients modulation was necessary to guarantee the original number of the patients' sample. This issue was fixed by the entrance in the consortium of FSM as new partner and the last remodulation of Patients number among pilots.
AUSL withdraw from the project (Jan 2014)	Due to bureaucracy issue, ethical process was stopped and the partner was forced to give up.	
FSM has joined to the consortium (Jan 2014)		

In the following part details on evolution of Patients distribution and a summary of each Pilots history are described.

2.1.1 Evolution of Patient Distribution:

In the following table, column P is referred to Patients allocated in Prevention Study and D is referred to patients allocated in Detection Study.

Pilot	Original		I Amendment		Final	
	P	D	P	D	P	D
NFE	40	3	n.a.	n.a.	n.a.	n.a.
TUD	n.a.	n.a.	40	3	n.a.	n.a.
FSL	80	3	80	3	86	22
FSM	n.a.	n.a.	n.a.	n.a.	70	0
HGG	60	3	60	3	50	0
SERMAS	60	3	60	3	57	0
FRONTIDA	80	3	80	3	80	0
SPC	70	3	70	3	70	0
AUSL	60	3	60	3	n.a.	n.a.
MOSG	50	3	50	3	87	0

2.2 Pilots

In this section each pilot history is summarized including a description of main issues reported and some Lessons learned during pilots operations.

To give a general overview can be reported that main issue was related to technical devices, that represented the weak spots of the platform since they were the real innovative part and for the first time integrated among them. In particular, some devices were not designed to be easily integrated with others, while other devices suffered the step from prototype status to that of device for the "market" ready to use. However, the platform as a whole encountered problems, somehow expected, to face hospitals internal policies for security reasons that were in any case originally underestimated.

Another general issue faced by almost the whole pilots partner is related to Ethical committees that in absence of CE mark asked for more time to give their green light.

With regards to Lessons Learned it is important to stress the straight collaboration between clinicians and technicians that should be maintained along all project phases to have a good result.

Another confirmation of the general good reaction of the patients versus technology is given by the fact that nowadays technology is strongly present in our lives, but also due to the accurate training made by the clinician to the patients before to start the study.

2.2.1 Fondazione Santa Lucia

2.2.1.1 Main issues

- Technical problems with i-Walker
- Adapt Wi-Fi Parameter to Careportal and i-Walker connection
- Technical problems in record data detection
- Sociable platform "missed" some training sessions

2.2.1.2 Lesson Learned

- Ethical committee: complex procedures due to contemporary presence of many technical devices and clinical protocol
- Procurements of Equipment: complex bureaucracy
- Recruitment phase: good feeling between patients and clinicians
- Drop-out strategy: continuity of care
- Feedback from users: difficulties in managing devices but very positive answer for the program
- Configuration of i-Walker parameters: at the beginning we changed some configuration in the handlebar to create a good feeling between users and i-Walker

2.2.2 Fondazione Salvatore Maugeri

2.2.2.1 Main issues

- Technical problems with i-Walker
- Adapt Wi-Fi Parameter to Careportal and i-Walker connection

2.2.2.2 Lesson Learned

- Ethical committees requires more time and a specific approach when in a trial are involved technical devices as in IDF
- Procurements of Equipment: complex bureaucracy

2.2.3 Fundacio Hospital Asil de Granollers

2.2.3.1 Main issues

- WIMU: battery problems. Low incidence on project progress.
- i-Walker: charger problems. Low incidence on project progress.
- Care Portal: tethering, smartphone connection. High incidence (30 minutes for each transfer instead of 5' each patient)

2.2.3.2 *Lesson Learned*

- Importance of researcher-patient feedback: clinical adaptation of new technologies to geriatric subjects; ability of geriatric population to adapt to new technologies.

- Major importance of recruitment: fragile and pluripathological population.

- Best practices, Drop-out prevention strategy:
    - Motor impairments = physiotherapists checked the patients after clinical doctorscreenings
    - Placebo = offer of additional training once the Project is finished (to increase motivation).

2.2.4 Servicio Madrileno de Salud

2.2.4.1 *Main issues*

- Minor problem related to i-Walker

- Careportal initial problems solved along the initial trial time.

- Major issue related to Hospital network due to security settings

2.2.4.2 *Lesson Learned*

- Ethical committee process: it is important to be very proactive just in case is delayed in time committee efforts (presentation and response).

- Recruitment and Drop out strategy:
    - Accuracy in users selection.
    - Motivation
    - Continuity of care

- Feedback from users
    - We thought we were going to have many problems with placebo branch users, but it has not happened.
    - Our patients (who are very old, almost all over 80 years) have complained of the excessive length of physical training.
    - Positive feedback from the cognitive training group.

- Technical Issues:
    - Collaboration between clinical personal and technicians has been fundamental to continue with the trainings.
    - Anticipating more time for devices deployment

- o Regarding the problems with the connections between devices, we have solved the issues with alternative ways.

- o Sociable program has improved since the beginning of the project.

- o Configuration i-Walker: special parameter settings, some problems with our patients (very old and they can't handle it well).

2.2.5 FRONTIDA

2.2.5.1 *Main issues*

- · The i-walker Wi-Fi dongle stopped working. Was bought a new one and UPC installed the appropriate drivers. Problem solved.

- · Was faced a problem 2 times in the past where the i-walker could not be turned off. After performing a fuse reset problem was solved.

- · Replacement of the i-walker after problems encountered with central unit and wheels. At first a new central unit was sent from UPC, and afterwards it was decided to replace the i-walker.

2.2.5.2 *Lesson Learned*

- · i-walker users they have to wait for each of the i-walker's exercises to be stored and uploaded

- · Disconnection problems between i-walker and careportal at the beginning or during the training often disappoints the users

- · The 60' i-walker exercises in many cases tires the elderly

- · Configuration of the i-walker regarding the abilities of each user is difficult

- · Spatial constraints in the homes of the users provide difficulties not only for the i-walker exercises but also for the wimu tests

- · National holidays or other reasons (sickness, personal matters) especially for home users impede the trials and imply the continuous re-arrangement of the training schedule, especially for home users

- · Expressed unwillingness from some users to do the assessments for third time, also after 6 months situation concerning users might have changed

2.2.6 Social Policy Center of the Municipality of Kifissia

2.2.6.1 *Main issues*

- · Problems with internet connection. It was faced several problems in Municipality's Polyclinic. Sessions were often cancelled due to Internet connection issues.

- · The administration of so many neuropsychological & psychological tests lasts 90 minutes and it sometimes makes the elderly getting tired and nervous.

- Randomization: Some users were complaining because they wanted and needed cognitive training and the Randomization brought physical (or the opposite).

2.2.6.2 Lesson Learned and Best Practices

- The platform was well accepted by the patients

- User – friendly, easy to use and get acquainted with

- Most of patients found interesting training

- Most of patients felt well and their mood had improved after sessions.

- About ethical committee process, it has been showed that as sooner the concerning documents are given for the approval, the procedure is finished faster. About the SPC, it was important that in the committee of ethical approval, were included members who are involved with the program. Also their good intentions and Knowledge made the process much easier.

- About the procurement of equipment, the direct cooperation with the technical partners and especially in SPC with the technical partners in Greece (Singular Logic). The good cooperation and networking between the partners and the synchronization for the procurement of equipment were very affective for the whole procedure

- About the recruitment, we realized that briefing the target group about the program is very useful when it's done by professionals. It is important the approach and briefing of the elderly will take place in locations where they spare time, and also their briefing must be as full and complete as possible.

- Recruitment process: This procedure (application form and personal interview) before assessments, we think that is a good practice to avoid drop outs and to include in the participation of the program those who are really in need.

- If internet connection problems response on time with alternative plans we can minimize the problems.

- Configuration of i-Walker parameters, personalization capabilities of the platform will help a lot and this must be a situation in progress.

- Training of professionals from technical partners and the constant communication and cooperation between medicals and technicians helped a lot.

- The relationship between the user and the professional working therapeutically for the user and to other areas of their life.

2.2.7 Municipality of Stari Grad

2.2.7.1 Main issues

There were many technical problems with the iWalker (electronic board, battery, fuser, changing the wheels motors, power plug, etc.)

Three times colleagues from SiLO (once) and UPC (twice) visited the pilot to install the iWalker and correct the problems (electronic board, wheels)

They purchased the additional iWalker from UPC

2.2.7.2 Lesson Learned

· Procurements of Equipment - This part was much more complicated for MoSG since it is a public institution and the potential custom problems

· Recruitment – no problems although the number of patients increased (from 50 to 87). However, the internal assessment process must be improved significantly.

· Feedback from users was really very good

· Technical Training was very good.

· Configuration of i-Walker parameters – more deeper explanations and recommendations was necessary

· Technical problems (communication with technical partners) - very good communication with technical partners.

3 CONCLUSIONS

In this deliverable we have presented the pilot operations results. We have given details on evolution of pilots and we shown as the consortium faced some minor and other major issues and in both cases found solutions that allow to save (first) the number of involved patients and (second) resources allocated.

An overall picture of the issues and of the lessons learned has given as well as analytics views of each single pilot was collected to give a clear history of the project and the pilots.

All these aspects have driven the Project to the end of the activities assuring any commitments made.

4 REFERENCES

[1] IDONTFALL Annex

[2] IDF Deliverables D2.1, D2.2, D2,3, D6.1, D6.2, D6.3

[3] I-DON'T-FALL Description of Work