Project Number: **297178**
Acronym: **FATE**
Title: **Fall Detector for the Elder**
Call (part) identifier: CIP-ICT-PSP-2011-5
Start date: 01/03/2012
Duration: 36 months

D3.1 Common validation plan

Nature[1]: R
Dissemination level[2]: PU
Due date: Month 12
Date of delivery: Month 12
Partners involved (leader in bold): **TER**, UPC, MFKK, NUIG
Authors:

---

[1] R = Report, P = Prototype, D = Demonstrator, O = Other

[2] PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE= Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)

Revision history

Date	Partner	Description	Name
05/02/2013	TER	First Version	Helena Fortune, James Doyle
18/02/2013	UPC/ NUIG	Contribution from UPC and NUIG combined	J. Manuel Moreno Arostegui, Alejandro Rodríguez-Molinero
21/02/2013	MFKK	Contribution from MFKK	Zsolt Baranyai
01/03/2013	UPC	Final validation	Joan Cabestany

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

DISCLAIMER

The work associated with this report has been carried out in accordance with the highest technical standards and the FATE partners have endeavoured to achieve the degree of accuracy and reliability appropriate to the work in question. However since the partners have no control over the use to which the information contained within the report is to be put by any other party, any other such party shall be deemed to have satisfied itself as to the suitability and reliability of the information in relation to any particular use, purpose or application.

Under no circumstances will any of the partners, their servants, employees or agents accept any liability whatsoever arising out of any error or inaccuracy contained in this report (or any further consolidation, summary, publication or dissemination of the information contained within this report) and/or the connected work and disclaim all liability for any loss, damage, expenses, claims or infringement of third party rights.

Table of contents

Competitiveness and innovation Framework Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

1. Introduction

The main objective of the FATE project is to validate and demonstrate fall detection technologies in aspects of technical, socio economic and heath care sectors and the benefits it brings to its users. There is a requirement within the project to prepare a validation plan 12 months after the commencement of the project.

In order to maximise the effectiveness and benefits of the project it is essential to adopt consistent assessment and validation methods across all three sites involved. A common approach for each respective assessment and validation activity needs to be adopted so that the results from the different participant sites are comparable and can be generalised in a consistent and effective manner.

The Role of this document

This deliverable 3.1 builds upon the work completed in the earlier deliverables and effectively addresses a number of relevant areas within the FATE project. Essentially within the deliverable there are a number of strands which need to be considered to include, technical performance and safety, project management, implementation and testing to legal and ethical requirements. This document attempts to implement a structure around all of the above and provide a template which is consistent to all sites and allow them to tie back to the use cases which have been completed in D1.1.

We have structured this deliverable from adopting best practice from other similar technical deployments which have been included in Commonwell and Independent projects.

2. Overall Validation Framework

2.1. Validation Approach

Within the FATE project a common validation plan will be developed on the basis of best practice guidelines from previous EU CIP projects.

Validation has a key role in establishing the benefits which all stakeholders can gain. State-of-the-art validation ensures that the project will be able to establish the extent that FATE has met its objectives, what impacts it has generated on the site level and what its European added value is.

The results from the validation process will provide important input to the definition of the business case, exploitation and marketing plans and will, therefore, be instrumental for decisions on the direction of any future investments of the final product. Despite the fact that FATE will be implemented and applied in three different European sites, its validation process will be based on commonality. One of the major challenges within D3.1 is, therefore, to reach full agreement among the team (on the concept, common impacts and indicators, use cases, success criteria, operational methods, and other specifics of validation).

As a "milestone" in this process the present document, the Common Validation Plan, i.e. this document, has been prepared. For this activity, the following steps were undertaken to facilitate the consensus-formation process in a systematic and comprehensive manner:

Step 1: Definition of specific and detailed objectives for FATE

Input was used from the D1.3 Complete Pilot Definition to produce a list of objectives to be validated.

Step 2: Precise description of the objectives.

For each objective, descriptions are provided on:
• technologies and functions,
• related users/ stakeholders

Step 3: Impact definition

This step covered:
• Definition of expected impacts
• Practical considerations of validation

Step 4: Definition of assessment objectives

On the basis of step 3, operational objectives of the assessment process are defined.

Step 5: Outline of validation methods for each assessment objective

This step provided input to the key elements of the Common Validation Plan. For each assessment objective, it covered:
• indicators which will be used,
• success criteria which will be used, and
• methods which will be used

2.2. Common Validation Basis

For each expected impact, clear assessment objectives, a series of operational indicators, and reference cases have been identified. Throughout these exercises, an effort will be made to reach the highest degree of commonalities in defining these key elements of validation.
The verification stage will ensure the correct behaviour and acceptability of the implemented prototype through functional and usability testing in a sample of real life.

2.3 Terminology

It is important to achieve consensus on the basics of the validation process between all project sites. As a first step, a common terminology should be used throughout the project.
The purpose of this section is to explain terms and phrases essential for a good understanding of the validation process.
The proposed definitions are based on the formal evaluation guidelines from the healthcare, telecare medical and technology sectors.

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

Term Definition

Application The product of an Research and Technological Development Project, usually a system or service as installed and operating in a real-life environment.

Appraisal groups Different groups of users/ non-users affected by the impacts of an application. Benefits and drawbacks are estimated for these impacts.

Assessment The general term for describing the process of systematically analysing and reporting the performance and/ or impacts of a candidate application. Analyses are usually undertaken in comparison to a reference case, and include an experimental process based on real-life trials, involving user interaction. The term is often used synonymously with evaluation.

Assessment objective A precise statement of an individual objective of validation - it should be associated with a precise definition of the associated indicator(s) and definition of success.

Decision makers People or groups who will be influential in determining whether verification results justify proceeding to the roll-out validation stage of validation.

Definition of success Before validating an application, the expectation about the performance and impacts of the application is defined. Success or failure of validation results are tested against these criteria. So it has a vital role in the validation methodology. It is most exact when it is defined for a single indicator.

Evaluation In this project the term will be used synonymously with assessment as this reflects current usage. The narrow definition of evaluation refers to the specific process of assigning quantitative and/ or qualitative characteristics ("values") to applications during validation and comparing them with expected values in order to derive recommendations for decision makers on the future use of an application (e.g. large-scale deployment).

Impact Changes or effects brought about by an application resulting from its implementation in an experimental or real application, whether intended or unintended.

Indicator A parameter, directly measured or derived from modelling, indicating the performance or impacts of an application.

User groups Groups involved in validating the solution.

Validation Validation is the specific process of testing how an application performs with respect to the specified assessment objectives. Validation includes a verification and demonstration stage.

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

3. Methods

For the purpose of validating the FATE service data will be obtained through interviews, keeping of dairies, phone enquiries, and will be generated as a result of alerts from the service itself. Collected data will be manually scored over the duration of the pilot.

3.1 Patient Interviews

Interviews with the patient are a key method of collecting data on the validity of the FATE service. There are a number of different interviews over the duration of the pilot. These are explained in detail in the "D1.3 Complete pilot definition" document and include questionnaires about fear of falling and quality of life.

3.2 Other Stakeholders Interviews

The contact person of the patient is asked to complete a structured questionnaire a number of times during the pilot. Questions must be answered about aspects of the care required by the patient and the time devoted to this care.

3.3 Diaries

Patients will keep a diary during both the control period and the intervention period to record actual fall events. The information entered in this diary is key to proving the accuracy of FATE.

3.4 Monitoring Centre Records

The operators in the monitoring centre will keep a usability diary for the duration of the pilot. They will use it to record usability or technical problems they encounter using FATE.
A history of alarms received from the FATE service, as well as any actions taken, is held on a database in the monitoring centre. This history can be analysed and compared with the data from the falls diary.

3.5 Data from Central Computer

The computer provides logger capacity to the system, that is to say, collects useful information about the patient such as the activity level or the time the person spends in bed, which is useful information to prevent falls. During the FATE project, information sent by the different elements (fall detector, bed presence sensor, i-Walker when applicable) will be collected.

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4. Indicators

1.	**System's performance**	1.1.	System's stability.
		1.2.	System's transmission reliability.
		1.3.	System's data reliability
2.	**System's effectiveness**	2.1.	Fall detection.
		2.2.	Reduction of long-lie syndrome.
		2.3.	Increasing activity and functional capacity.
		2.4.	Improving gait and balance.
		2.5.	Improving quality of life.
		2.6.	Decreasing the number of interventions for fall risk reduction.
		2.7.	Decreasing contacts and surveillance by primary care physicians.
3.	**System's safety**	3.1.	System's safety to use.
4.	**Usability and user satisfaction**	4.1.	Usability of the whole system.
		4.2.	Usability of each subsystem
5.	**System's efficiency**	5.1.	To estimate system's cost.
		5.2.	To estimate system's cost-benefit.
		5.3.	To estimate system's cost-effectiveness.

4.1 Indicator Fact Sheets

The indicators listed above are applicable to all 3 pilot sites and are therefore considered common indicators. All indicators are thoroughly described in fact sheets which are based on the following structure.

1. Relevance

Explanation of the relevance of the indicator for reaching project goals, expectations for and direction of indicator, contribution to measuring the impact, other background info.

2. Definitions of key terms

Precise definition of any concepts and terminology the indicator is based on.

3. Stakeholders

Listing and precise description of the stakeholders in data gathering for the respective indicator.

4. Methods

Explanation of the method (tool) used to gather data.

5. Operational issues

Explanation of any other points regarding data gathering.

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

6. Success criterion

Clear identification of units of "measurement" or direction of a trend that indicates success.

7. References to other indicators

Explanation of similarities to other indicators.

8. Site-specific issues

Description of any site-specific aspects to be considered in the application of this indicator.

9. Evaluation Period

While the study will last 16 months and will take place between April 2013 and July 2014, data for individual indicators may only be gathered during parts of this period. The exact evaluation period for each indicator is listed under this point of the fact sheet.

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4.1.1 Indicator 1.1 System's Stability

Number:	1.1
Indicator:	System's stability
Relevance:	At all stages of the pilot it is of paramount importance that the FATE system is stable and runs without need for intervention.
Definition of Key Terms:	"System stability" is understood as ability if the FATE system to remain in a constant useable state unless affected by an external factor and the ability to return to the constant state when the external factor is removed.
Stakeholders:	Patients, researchers and monitoring centre operators.
Methods:	Data from patient interviews and from the monitoring centre
Operational issues:	
Success criterion:	The success criteria will be the time the FATE system continues without assistance, a low number of technical interventions and low number of times the system has to be resumed.
References to other indicators:	
Site-specific issues:	
Evaluation period:	Entire pilot

4.1.2 Indicator 1.2 System's Transmission Reliability

Number:	1.2
Indicator:	System's transmission reliability
Relevance:	FATE can only be deemed a reliable and useable system if the transmission of data is proven to be reliable.
Definition of Key Terms:	"System's transmission reliability" is understood as the number of data packets from the FATE system which correctly reach the server.
Stakeholders:	Patients, researchers and monitoring centre operators.
Methods:	Data from the falls diary matched with data from the client history file held in the monitoring centre.
Operational issues:	
Success criterion:	The success will be determined by the small number of data packet errors.
References to other indicators:	This indicator takes into account indicator 1.1 System's stability.
Site-specific issues:	None
Evaluation period:	Entire pilot

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4.1.3 Indicator 1.3 System's Data Reliability

Number:	1.3
Indicator:	System's data reliability
Relevance:	Data from all subsystems of the FATE system must be reliable.
Definition of Key Terms:	"Data reliability" is the accuracy and completeness of data given the use it is intended for.
Stakeholders:	Patients, researchers and monitoring centre operators.
Methods:	Data from the falls diary matched with data from the client history file held in the monitoring centre.
Operational issues:	
Success criterion:	The success will determined by the data being reported by FATE system matching actual events.
References to other indicators:	This indicator takes into account indicator 1.1 System's stability
Site-specific issues:	
Evaluation period:	Entire pilot

4.1.4 Indicator 2.1 Fall Detection

Number:	2.1
Indicator:	Fall detection
Relevance:	The main objective of FATE is the correct detection of the falls occurring with elderly people.
Definition of Key Terms:	"Fall detection" is defined as the ability of the FATE system to detect actual falls occurring in the elderly.
Stakeholders:	Patients, researchers and monitoring centre operators.
Methods:	Data from the falls diary matched with data from the monitoring entre
Operational issues:	
Success criterion:	The success will be determined by the number of true falls occurring (falls diary, weekly telephone interviews) which are detected and reported by the FATE system.
References to other indicators:	This indicator takes into account all 3 indicators above for "System's performance".
Site-specific issues:	
Evaluation period:	Entire pilot

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4.1.5 Indicator 2.2 Reduction of Long-lie Syndrome

Number:	2.2
Indicator:	Reduction of long-lie syndrome
Relevance:	One of FATE's complementary objectives is the prevention of long-lie syndrome.
Definition of Key Terms:	"Long-lie Syndrome" - a product of long stays on the ground after falling, and because of the lack of functionality to rise, this situation can cause death from acute renal failure
Stakeholders:	Patients and researchers
Methods:	Data from patient interviews at different stages in the pilot process
Operational issues:	
Success criterion:	The success will be determined by a reduction in the amount of time a patient spends on the floor following a fall.
References to other indicators:	This indicator takes into account indicator 2.1 Fall detection
Site-specific issues:	
Evaluation period:	Entire pilot

4.1.6 Indicator 2.3 Increasing Activity

Number:	2.3
Indicator:	Increasing activity and functional capacity
Relevance:	One of FATE's complementary objectives is the reduction of the fear of falling. Reducing this fear will lead to an increase in activity and functional capacity of the patient.
Definition of Key Terms:	
Stakeholders:	Patients, contacts and researchers
Methods:	Data from patient interviews at different stages in the pilot process
Operational issues:	
Success criterion:	The success will be determined by comparing the amount of activity undertaken by a patient before and during the FATE pilot.
References to other indicators:	This indicator takes into account indicator 2.1 Fall detection
Site-specific issues:	
Evaluation period:	Entire pilot

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4.1.7 Indicator 3.4 Improving Gait and Balance

Number:	2.4
Indicator:	Improving gait and balance
Relevance:	Increase in activity by the patient, due to reduction in the fear of falling, may lead to an improvement in their gait and balance,
Definition of Key Terms:	"Gait and Balance" , "Gait" is defined as a person's manner of walking. "Balance" is an even distribution of weight enabling someone to remain upright and steady.
Stakeholders:	Patients and researchers
Methods:	Data from patient interviews at different stages in the pilot process
Operational issues:	
Success criterion:	The success will be determined by comparing the results of the patient's Tinetti's scale before and during the pilot.
References to other indicators:	This indicator takes into account indicator 2.3 Increased activity
Site-specific issues:	
Evaluation period:	Entire pilot

4.1.8 Improving Quality of Life

Number:	2.5
Indicator:	Improving quality of life
Relevance:	Increase in activity by the patient, due to reduction in the fear of falling, may lead to an improvement in their quality of life.
Definition of Key Terms:	The World Health Organisation defines Quality of Life as individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment.
Stakeholders:	Patients, carers and researchers
Methods:	Data from patient interviews at different stages in the pilot process
Operational issues:	
Success criterion:	The success will be determined by comparing individuals' own views of their wellbeing before, during and after the pilot.
References to other indicators:	This indicator takes into account indicator 2.3 Increased activity
Site-specific issues:	
Evaluation period:	Entire pilot

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4.1.9 Indicator 2.6 Decreasing Interventions

Number:	2.6
Indicator:	Decreasing the number of interventions for fall risk reduction
Relevance:	Improved gait and balance in a patient should reduce the number of interventions needed.
Definition of Key Terms:	
Stakeholders:	Patients and researchers
Methods:	Data from patient interviews at different stages in the pilot process
Operational issues:	
Success criterion:	The success will be determined by comparing the results of the patient's quality of life questionnaire before and during the pilot.
References to other indicators:	
Site-specific issues:	
Evaluation period:	Entire pilot

4.1.10 Indicator 2.7 Decreasing Contacts

Number:	2.7
Indicator:	Decreasing contacts and surveillance by primary care
Relevance:	Improved gait and balance in a patient should reduce the need for contact with and surveillance by the primary care team.
Definition of Key Terms:	
Stakeholders:	Patients and researchers
Methods:	Data from patient interviews at different stages in the pilot process
Operational issues:	
Success criterion:	The success will be determined by comparing the results of the patient's questionnaire before and during the pilot.
References to other indicators:	
Site-specific issues:	
Evaluation period:	Entire pilot

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4.1.11 Indicator 3.1 System's Safety

Number:	3.1
Indicator:	To estimate system's safety
Relevance:	The FATE system must be safe for patients to use and not have any adverse effects.
Definition of Key Terms:	
Stakeholders:	Patients and researchers
Methods:	Data from patient interviews at different stages in the pilot process
Operational issues:	
Success criterion:	This must be determined that the use of the FATE system has no adverse effects on the participants in the pilot.
References to other indicators:	
Site-specific issues:	
Evaluation period:	Entire pilot

4.1.12 Indicator 4.1 Usability of Whole System

Number:	4.1
Indicator:	Usability of the whole system
Relevance:	The FATE system comprises a fall detector, bed presence sensor, central computer, mobile phone and ZigBee network. For the residential home pilot there is also an i-Walker included. The entire system must work together to be successful.
Definition of Key Terms:	
Stakeholders:	Patients, researchers, monitoring centre operators
Methods:	Interviews with patients and their carers, results of Quebec User Evaluation of Satisfaction with Assistive Technologies (QUEST).
Operational issues:	
Success criterion:	The success will be determined by all parts of the FATE system working correctly when operating together.
References to other indicators:	
Site-specific issues:	
Evaluation period:	Entire pilot

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4.1.13 Indicator 4.2 Usability Each Subsystem

Number:	4.2
Indicator:	Usability of each subsystem
Relevance:	The FATE system comprises a fall detector, bed presence sensor, central computer, mobile phone and ZigBee network. For the residential home pilot there is also an i-Walker included. Each component should work independently of the others.
Definition of Key Terms:	
Stakeholders:	Patients, researchers, monitoring centre operators
Methods:	
Operational issues:	
Success criterion:	The success will be determined by all parts of the FATE system working correctly independently.
References to other indicators:	
Site-specific issues:	
Evaluation period:	Entire pilot

4.1.14 Indicator 5.1 System's Cost

Number:	5.1
Indicator:	To estimate system's cost
Relevance:	It is important to document the row cost of the FATE system and services implementation in pilot settings. Also to estimate the cost the system could have in a real market scenario.
Definition of Key Terms:	
Stakeholders:	Companies which could manufacture the system or its components, companies interested in providing FATE service, clients, etc.
Methods:	
Operational issues:	
Success criterion:	Low cost comparing with competitors' solutions on the market.
References to other indicators:	This indicator is the base for calculation of cost-benefit and cost-effectiveness
Site-specific issues:	
Evaluation period:	Entire pilot

Competitiveness and innovation Framework
Programme
CIP-ICT-PSP-2011-5 297178
Fall Detector for the Elder

4.1.15 Indicator 5.2 System's Cost-Benefit

Number:	5.2
Indicator:	To estimate system's cost-benefit
Relevance:	Cost-benefit must be positive for a real market implementation
Definition of Key Terms:	Cost of the system (see indicator 6.1) should be balanced with the expected benefit in monetary terms.
Stakeholders:	Companies which could manufacture the system or its components, companies interested in providing FATE service, clients, etc.
Methods:	Benefit estimations will based on market size and market plan, also on the costs of the adverse health events that the system could avoid.
Operational issues:	
Success criterion:	Cost-benefit of the FATE system is positive.
References to other indicators:	This indicator takes into account the cost, and is related with cost-effectiveness
Site-specific issues:	
Evaluation period:	Entire pilot

4.1.16 Indicator 5.3 System's Cost-Effectiveness

Number:	5.3
Indicator:	To estimate system's cost-effectiveness
Relevance:	Cost-effectiveness does not considers only monetary benefits, but other kind if benefit which are important in health services.
Definition of Key Terms:	Cost-effectiveness compares the relative costs with the health outcomes.
Stakeholders:	Service providers, regulatory organizations and administration.
Methods:	It is calculated comparing costs with "health gain" indicators.
Operational issues:	
Success criterion:	Effectiveness outweighs costs.
References to other indicators:	It is related with cost, effectiveness and safety indicators
Site-specific issues:	
Evaluation period:	Entire pilot.