OLA – Organizational Life Assistant

FOR FUTURE ACTIVE AGEING

D3.4 Pilot Trials and Evaluation

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1 Executive Summary

The main objective of this task is to develop a trial execution plan for evaluation of the OLA system in real daily life setting and conditions.

First it will be represented the Pilots Methodology which will contain a cycle and its description of the activities which will are going to be performed during the 12 month.

The modules from the group of developments in the Work Package 2 are selected to be integrated and the technical options of the systems are also explained here in the chapter Functionalities.

This deliverable includes the Phases and Activities are divided on the following section, including the list of equipment which are going to be used in the pilot activities, including the measurements metrics which are going to be used for evaluating the health data collected from the seniors.

The methodology for the pilot evaluation is fully described, containing the objectives, the evaluation metrics to perform the evaluation and other important factors.

The Consent Form to be given to the end users was elaborated, presenting an introduction to the project, how the measurements of health data will be processed and listing what will be expected from the participants by the pilot activities coordinators.

At the end of this document is included the surveys for the seniors to evaluate their conditions and needs for a better assessment and after three surveys to evaluate the usability of the seniors, informal and formal caregivers which will be distributed after the performance activities.

2 Document Context

2.1 Role of the Deliverable

This deliverable will be the plan for the Pilot Trials, representing a guide for those activities.

2.2 Relationship to other Project Deliverables

Deliv.	**Relation**
D1.5	Title: Usability evaluation of field Trials The pre trials activities will make an impact on how should the Pilot trials should be conducted, conceding the necessary amendments on the solution and also the definition of the end-users for the trials.
D3.1	Title: Design specification and integrated architecture From the connection between this deliverable and the Work Package 2, addressing the technical issues to integrate OLA architecture to be tested in Pilot trials.
D3.2	Title: Integrated system The validation of the OLA prototype will impact the start of the activities and the respective performance.
D4.1	Title: Pilot Operations This D4.1 will make an analysis of the pilot operations, based on the specifications and metrics identified in this present deliverable.

2.3 Target Audience of the Deliverable

This document is a public deliverable. Still, it is mainly intended for the project partners and the European Commission services thus the document will be made public, but not specifically disseminated on a wider scale.

3 Project Description

3.1 General Description

This project aims to offer an answer to the societal challenges by providing an innovative Organizational Life Assistant (OLA), a virtual presence that supports instrumental activities relating to daily living needs of older adults allowing them to be more independent, self-assured and to have a healthier, safer and organized life, while easing caregivers work.

OLA will mediate and facilitate interaction (communication and collaboration) between senior citizens and their informal caregivers or other services or professionals, through technological devices such as standard computers, mobile devices (tablets) and home automation modules. These ICT (Information and Communications Technology) devices will be based on an innovative multimodal model, embracing various physical/healthy and cognitive characteristics of the older adults and will be specifically oriented to increase the level of independence of the elderly, by supporting the possibility of carers' assistance remotely and by improving the accessibility to existing services on the Web, such as on-line shopping services.

Moreover, the OLA will also provide personalized well-being and safety advices to older users in order to avoid unwanted age related health and safety situations in their own home. Such a well-being and safety advisor makes uses of a combination of user information that is collected (personal physical/health and cognitive characteristics) and extracted through emotion recognition and various sensors.

OLA also addresses a major issue that elderly face related to memory degradation and gradual decreasing of their cognitive capabilities, enabling them to remember primary health care and fiscal obligations (e.g. personal hygiene, medical and tax compliance) or helping them to find everyday items such as eyeglasses, wallet or keys. It is based on speech dialogue interfaces and space and object reconstruction and classification to capture and store daily routines and their related contexts.

The primary end-users are the big group of 65+ adults living alone with or without light physical or cognitive age related limitations, who need support from care systems. Secondary end-users are both formal and informal caregivers from public or private sectors, supporting them to cope with the increased demand for care.

3.2 System Description

OLA addresses specifically the following main issues:

- **Well-being advisor**: based on the combination of the collected user information (personal, healthy characteristics) and user interaction information (extracted through emotion recognition, sensors settings and contextual recorder capturing the routines as done by the older adult), the system will propose to the older adults personal advice adapted to their situation contributing to their preservation and well-being status in home environment. In case of risk (e.g. irregular heart rate, extreme fatigue) the system may ensure an alert to a local medical emergency service.
- **Collaborative care organizer**: based on the ISCTE-IUL and LM's knowledge of developing human-computer interaction platforms (HCI), OLA will provide online care collaboration between family and professional caregivers, by enabling a local care network to communicate, access sensor data, and coordinate care tasks. With the OLA assistant, seniors will be able to actively participate in the care organization through voice, even when they are unwilling or unable to use traditional web applications.
- **Safety advisor**: based on the combination of collected user environment information through real-time analysis and augmented reality settings, the system will propose suggestions of environment changes that interfere with accessible paths and provide alerts for intruders or other situations that can create hazard situations. In case of risk (e.g. checking intruders or fire), the system may contact local emergency services.
- **Every day instrumental daily living activities memory support**: the system will anticipate medical and fiscal compliances, remember primary health care and food requirements and could help elderly to find displaced everyday items.
- **Environment analysis**: algorithms for real-time object recognition and scene understanding will be developed based on a number of inputs (i.e. 3D object and space reconstruction by using time-of-flight and augmented reality technology) in order to analyze and decide which action to be taken in order support the elderly by suggesting environment changes and providing hints/advices for safety and accessible environments.
- **Multimodal interaction for elderly**: An adaptive organizational life assistant, a virtual presence will be developed in order to facilitating communication and collaboration between older-adults and informal caregivers or other services or professionals. This will be a user-friendly system that uses multimodal approaches based on non-invasive

and minimally obtrusive technologies (i.e. speech, silent speech, touch, gestures, RGB-D sensors).

The overall OLA system will be an easy to download and install software making use of multimodal integrated settings. OLA is in essence a service that enables the elderly user to reduce the demand of care through prevention and self-management, while at the same time also facilitating the supply of formal and informal care assistance.

A series of well-selected use cases where older adults have been supported by caregivers and care professional services will be developed, as well as pilots representing different use cases. Care units will use the system over a one year period. A new evaluation approach will be used during the pilots, investigating up to which point the OLA services alleviate caregivers support and maintain, or even improve the self-management, health and safe lifestyle of the older adult at home.

3.3 Status and Future Developments

This is the second and final version of the document, containing the Pilots Methodology and the Modules and Functionalities (with Measurement stages) which will be presented in the Field Trials. Performance metrics were defined to evaluate the pilot activities on D4.1.

4 Pilot Trials

4.1 Introduction

The Pilot Trials chapter will describe the methodology for pre trials, listing the different stages of the pilot trials in the methodology, the different modules available in the application along with the integrated devices.

4.2 Pilots Methodology

The cycle for conduction and evaluation of the pre trials is represented below:

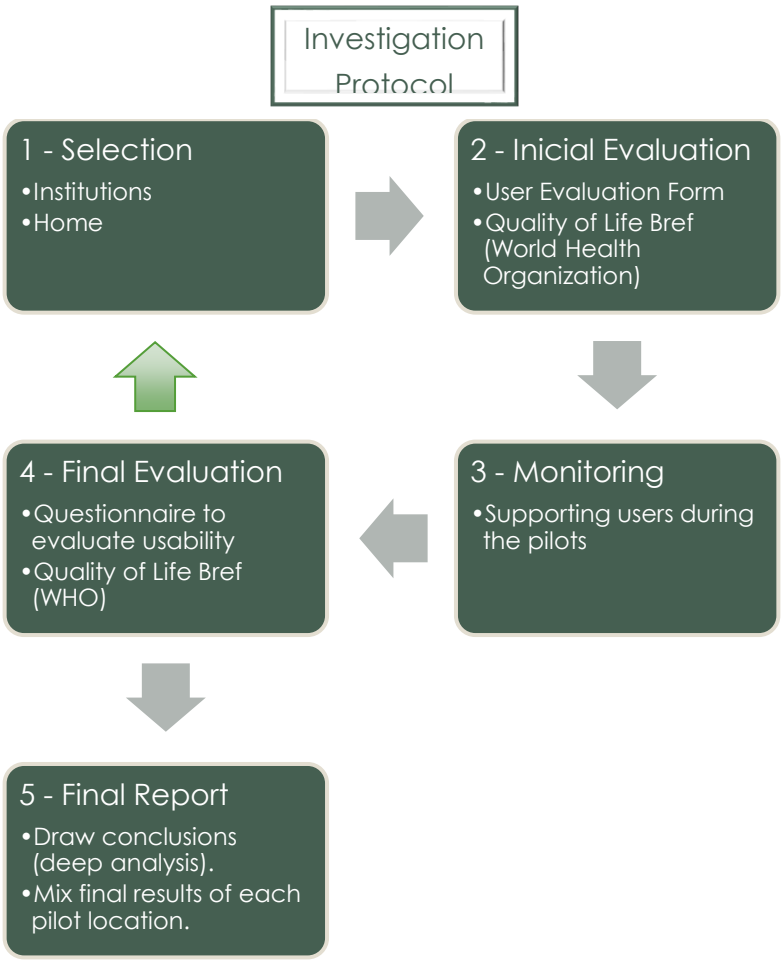


FIGURE 1 – PILOT METHODOLOGY

4.2.1 Pilots Methodology stages

Before the pilot activities can start onsite, the partners should elaborate and apply for the right to have an Investigation trial for OLA – Investigation Protocol is in the Annex 1 of this deliverable.

1. Selection – The participants must have persons from both sex, some with diabetes, others with hypertension, with support dependency and others with total independence, which will be taking in two different real environments:
    a. Institutions
    b. Home of participants
2. Initial Evaluation – The initial evaluation of the users is composed by two methods:
    a. Evaluation survey through the collection of personal information and the health status of the participants;
    b. Implement the Quality of Life Bref which will provide the quality life level of the participants, using a standard metrics of World Health Organization.
3. Monitoring – During the operations there will be given the necessary support to the participants, helping them to feel comfortable by using each device provided for the pilots. This support consists on the following group of activities:
    a. Preparing the equipment, sensors and registers necessary for the efficient use of the modules that are in the pilot;
    b. Designing a practice guideline report as a tutorial on how users should use the modules, as well as the actual monitoring parameters that must be demonstrated by the OLA personnel. This manual should also indicate the limitations of use that the modules may have;
    c. Presenting of the Modules (Health, Messages, Contacts, Agenda & Surveys) in the platform which will be the interface with the different users will be presented to them and the respective use will be evaluated by OLA staff, securing that they are performing their activities in the right manner and avoid any possible issues.
    d. Training the participants for the pilot operations.
    e. Analyzing the problems that arise on the participants on interaction with OLA Modules;
    f. Evaluating proposals for improvements on the platform, addressing problems found and to make the platform more user-friendly;

g. Bridging technical partners and the participants, the OLA staff will be solving technical issues on which stops or somehow affects the daily use of the OLA Modules and devices.

This process is made for both Selections, i.e. for the participants which will be testing in the Institutions and for those which will be using at Home.

4. Final Evaluation – This last stage it will be made and evaluation of all the participants from Portuguese, Swedish and Hungarian operations. To better evaluate the quality of the platform as a whole and the participants' satisfaction with their usability, an usability evaluation survey will be given at the end of their participation: a questionnaire created regarding usability tests, taking into consideration the links with previous questionnaires' results already used, which will give us the degree of satisfaction of the participants in this project; The completion of these questionnaires should be performed by the users and caregivers, with the support and supervision needed by the OLA people;

4.2.2 Objective

This stage of the OLA project aims to evaluate, with real users, the product and services developed under the integrated framework (that we created according to requirements harvested from the users in the first place); in order to achieve this, our most explicit data will come from the users actually using the application in all of its expected scenarios (and also unexpected). This evaluation will be done in 2 main steps:

1. Pre-pilots: designed to gather feedback on specific features / functions before the final deployment is made;
2. Pilots: designed to evaluate the usability and satisfaction of the OLA user in a comprehensive and encompassing fashion. This experimental procedure will be implemented in real contexts of use: at home and institutions.

The secondary objectives are:

- Identify improvements to be implemented in the products (services evaluation) before market introduction;
- Validate the platform-oriented architecture of OLA services, in order to study future product bundling and marketing strategies.

All encountered problems will be dealt with by the technical team and possible system's refinements or scenarios adaptation will be carried out (especially during the pre-pilots). All end-user's representatives or formal caregivers will work closely with technical developers, using a task manager software, in order to deliver error reports as soon as possible. We will extract relevant conclusions that will enable the consortium to iteratively improve the technologies developed for the project. The conclusions will ultimately demonstrate that the proposed OLA services will provide the elderly people with improved communication capabilities, more autonomy, better sense of control and self-esteem, thus increasing their quality of life and sense of well-being.

The prototypes will be tested first by a small number of elderly persons and caregivers, to allow early-stage adjustments (pre-pilots) in light of the actual pilots to be run at a later time. A series of pre-pilots will be made in controlled but realistic user environments (living labs) ensuring the validation and assessment of the system's functionalities and taking into account user satisfaction and technical viability and usability of the OLA solution. Both the elderly and caregivers (informal and professional caregivers) will evaluate the functionalities and usability of OLA services.

Subsequently, three pilot applications will be deployed to primary end-users in real-field conditions in - Sweden, Hungary and Portugal - over eleven months with at least 20 users per country. Each pilot will include the two OLA's services, dealing with the areas of well-being and health. Pilot deployment aims at demonstrating the success of the idea and the usability and acceptability of the overall OLA system.

4.2.3 Sample

These target users will be selected based on the consortium's end-user partners' wide network of partnerships with local institutions such as associations, health centers and nursing homes, or will exploit their existing connections to care institutions. Up to 60 care units, considering end-users and both informal and formal caregivers will be participating on pilots operations. Before pilot tests, target care units will be trained in order to get familiar with the OLA system. The participants are three independent groups of users of OLA products / services: seniors, formal caregivers and informal caregivers. Figures now presented are for the first type of users (seniors), and at least one formal or informal caregiver will be assigned to each senior (these caregivers can accumulate the monitoring of multiple patients, if applicable).

When seeking for senior participants, the OLA consortium will look for such people in the specified age group (mainly 65+) who are interested in IT technologies and have some experience with devices such as mobile phones, computers, household electronic equipment and gadgets. Regarding the informal and formal caregivers, the OLA consortium will look for people that already have some experience in working with seniors, have interest in IT technologies and have some experience with such devices as well. It's also expected that most (if not all) of the participants of the pre-pilots stage are also the ones participating on the effective pilots.

All participants will be informed in advance of the study's objectives and will also be asked to sign a consent form. This consent form is a written document which both the participant and the research institution contact person sign – in two original copies, one

for each party. The informed consent ensures that participants can reach a truly informed decision about whether or not to participate in the research, based on a clear understanding of what their participation involves. Once the consent document is read and the questions answered, it is signed and dated. Thus, participants give their informed consent freely, without coercion, and can quit at any moment, without any consequences.

4.2.4 Location and Date for the data collection

The pilots will take place in Portugal, Sweden and Hungary and the field operations will be for eleven (11) months, more precisely from February 2017 until January 2018 (with the possibility to extend the pilot duration, considering the future availability and interest of). With the objective of attaining a high quality feedback indicator and a greater acceptance from the users, in all trial sites, pre-pilots operations will take place earlier in the project. Those will be carried out in a supervised environment setting with a small number of selected users (5-7 by the user representative) and they will last for four months.

4.2.5 Ethics

The participants of this project's stage (pre-pilots and pilots) will be exclusively volunteers capable of deciding for themselves and able to give informed consent. Before any data collection is conducted a prior consent form will be signed. This consent form (see Annexes section 5) will accord to the rules and suggestions promoted by the EC (http://ec.europa.eu/research/participants/data/ref/fp7/89807/informed-consent_en.pdf) and will accurately describe the experiment and its duration, what kind of data will be collected and for what purposes will be used (being that only relevant data for those purposes will be used). The participant will be able to abort the user tests at any time. Prior to the filling of this informed consent, end-users will be invited to answer / use an evaluation tool in order to assess their health conditions and also an evaluation of the knowledge on the OLA devices and also to respond a Quality of Life assessment developed by the World Health Organization Quality Of Life (WHOQOL); at the end of pilots, participants will be asked to fill their usability survey, specifically designed for each type of OLA user (senior, formal and informal caregiver), testifying their opinions about their experience with OLA. This very protocol and the informed consent shall be submitted to an appropriate Ethics Committee according to the regulations for the evaluation and approval before the start of the study. Please find the questionnaires on the chapter Annexes.

Each participant invited to participate in the pre-pilots and pilots will give its consent in writing before the start of the study, while whoever users decide not to participate in the study will not do so. Nevertheless, the users can also abort their participation without any opposition at by any time, if this is their will. The study will also comply with the ethical principles underlying the Helsinki Declaration and the Good Epidemiological Practice (Good Epidemiological Practice Guidelines - IEA 2007), and all laws and regulations applicable.

All necessary measures to protect participant privacy will be taken, that will conform to all relevant guidelines on data privacy. Information that may allow identification of the participants will not be stored in any of the study's databases. Participants in the study will be identified in all study documents through a unique identification number (meaningless when out of the project).

Confidentiality is mandatory for all researchers involved in conducting the study and preparation of reports. Investigators should not disclose personal information obtained by having access to research data to anyone outside the research team. In accordance with Good Epidemiological Practices, all researchers of the study have signed a statement of professional secrecy and shall agree in writing to strictly abide by the laws and regulations applicable to the processing resulting from research on human data. The main investigator is responsible for ensuring that all team members are aware of these rules.

4.2.6 Procedure

Specific tasks which are expected to undergone during pre-pilots, including:

- Elderly biometric monitoring;
- Testing the creation and management of events, reminders and alerts (medication intake, agenda appointments, irregular physiological values, etc.);
- Development of Tutorials (and demonstrations) on using the near-finished app (for all roles separately);
- Communicating (sending and reading messages and emails, calling and requesting help);
- Collecting preliminary refinement feedback, through informal interviews and questionnaires.

During the pilots, the following added procedures are also envisaged (on top of the ones just described):

- Appointment of formal and informal caregivers;
- Briefing on any app changes and improvements since pre-pilots (updated tutorials if necessary);
- Demonstrations of multi-role features;
- Setup of 24-hours assistance;
- Filling out an existing questionnaire.

For both stages will be used the following devices:

- Tablets:
    - Tablets running Microsoft operating system with 9 inches or more.
- Bands and Wearables:
    - Microsoft Band 1 and 2
    - Safer Alarm Button
    - Other Similar devices
- Well-Being Devices:
    - Blood Pressure Meter
        - Beurer BM57 Bluetooth
        - Beurer BM85 Bluetooth
        - Fora Blood Pressure P20
        - Other Similar devices
    - Glycose Meter
        - OneTouch Select Plus Flex
        - OneTouch Verio Flex
        - Other Similar devices
    - Weight and Variance Meter:

- Fora W310
- Other Similar devices

After the actual pilots, users will be invited to answer an "exiting questionnaire" (seen above), that will register their experience using the platform for a larger period of time (contrary to the pre-pilots), using a form that is somewhat similar to the one done in the beginning of the project (here relating to OLA obviously). Even though that process is in line with the methodology framework that was already validated by the Ethics Committee of ISCTE and there isn't any special type of personal data envisaged to be requested (just general user feedback), this was considered as the sixth type of data retrieved from users.

4.2.7 Data

In this experiment we will collect the following data types:

- Health-related data that includes doctor appointments (date and specialty) and surgery dates (date and subject / specialty); medication scheduling (prescriptions, dosages, entire inventory, side effects, active substances and purpose / related medical issue) and diseases / conditions and allergies (only detection date and level of gravity, the rest can be extrapolated from the literature itself); the majority of this information is given at the start of the pilots alone.
- Physiological data that includes heart rate, blood pressure, myoelectric signals, electro-dermal activity (EDA), blood oxygen level (SPO2), body and weight. This information may be retrieved automatically by sensors or entered manually by the user (using speech or touch) in case of device malfunction or lack of communication capabilities (such as offline weight scales);
- Physical activity data that includes number of steps taken, distance run, speed and (the rest can be inferred, such as calories burned); this information is exclusively retrieved by sensors present in wearable devices;
- Circle of trust that include close relatives and friends (simple name, phone number, email and photo); formal and informal caregivers may also be part of the same contact list, but they'll have their own briefing about the project;
- Interaction data that includes any type of information needed only for assessing what the user wants (commanding), such as speech and touch. This data is discarded as soon as the outcome is achieved and is not used afterwards

(contrary to the first stage of the project, in which that data was used to create anonymized data models);

- User feedback that includes the formal and informal information disclosed by the users after they have participated in the core pilot activities about their experience using the OLA solution. This data is obtained through both written pre-templated questionnaires (quantitative), as well as both written and oral informal interviews (quantitative) and they serve the important means of evaluating the pilot stage and the overall project.

4.2.8 Milestones

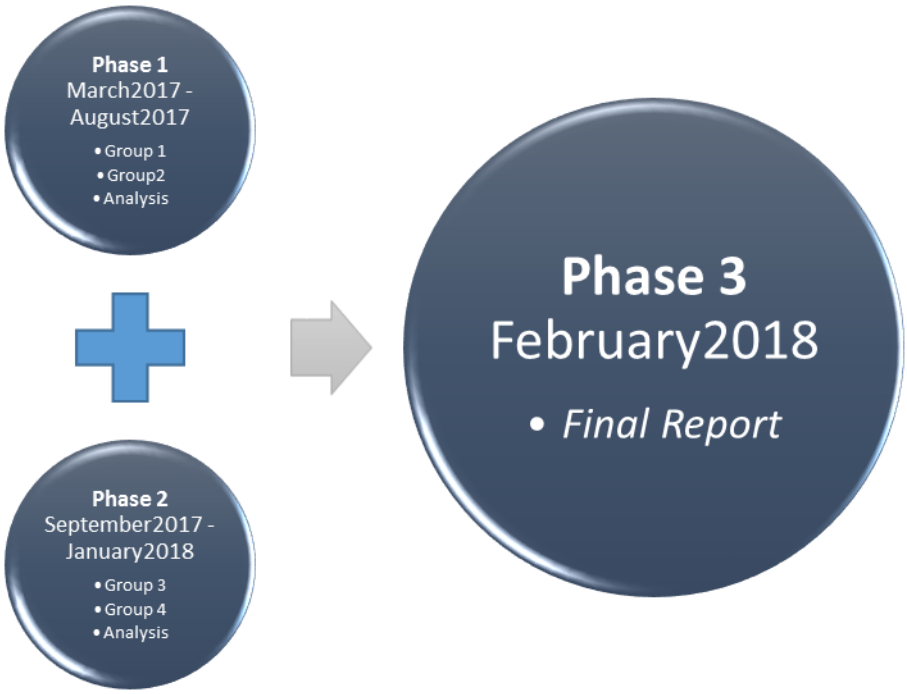


FIGURE 2 - PILOT MILESTONES

The Pilots operations will have one-year period, divided by three major phases:

- On the First Phase 2 groups of users, from charities (institutions) and at home, will be tested and ending with an analysis of the groups.

- While the Second Phase will be composed by 2 groups of seniors without need of daily support and also formal caregivers.
- On both phases it will be made an analysis of seniors and caregivers' evaluation of OLA.
- The Pilot Operations will end with the Third and Final Phase, consisting on an elaboration of a Final Report combining all the results and informal feedback from the pilots' participants.

The aim of this stage of the project (pre-pilots and pilots) is to allow the consortium to better understand the acceptability and usefulness of the OLA platform. To gather this information, different test phases were designed and will be implemented (as described before). The conclusions will ultimately demonstrate that the proposed OLA services will provide the elderly people with improved communication capabilities, more autonomy, better sense of control, and self-esteem thus increasing their quality of life and well-being.

4.2.9 Evaluation Metrics

The evaluation of the pilot activities, which will be described in the Deliverable 4.1, it will use the following structure as an initial guide to evaluate the different steps taken during the pilots in each location, including:

1 **Recruitment**: analyses on the level of acceptance from the pilot participants and present the barriers found on setting the OLA system in the pilot activities, either on seniors home and institutions. It will be compared the different realities (each pilot location will be analysed individually considering their unique reality and necessary approaches made during the recruitment phase). From the perspective of the pilot participants, in here it will be also mentioned the different interests during and after the measurements, analysing the level of acceptance on piloting OLA and the shared experience on participating in this project.

2 **Training**: mentioning the necessary training activities performed on the evaluation of the acceptance of the seniors, informal caregivers and formal caregivers. For the training section, besides the initial contact of the pilot

participants and the OLA system, it will also be described how the pilot monitoring was being conducted through the whole durations of these activities.

3 **Evaluation of data**: match the data on the system with a date taken on writing from the caretaker and also perform an evaluation on the possible error messages from the cloud.

4 **Surveys evaluation:** the pilot participants will fill a respective survey at the end of their participation on the pilot trail, sharing their perception and experience from the use of the devices, the application and in the overall system.

5 **Market introduction:** the results collected on the previous section will support on the analysis of the OLA system for its market introduction, with the identification of business opportunities and priorities established from the seniors and caregivers' perspectives (this section will establish a bridge on the relationship with D4.5 considering the results obtained on the pilot activities).

6 **Conclusions:** The last section will present the final considerations on the overall OLA system, including the visit made to the Home of the elderly in Hungary, describing the experience which the consortium had to meet them and discuss the OLA system with the pilot participants.

4.3 Modules

An important part of the usability tests carried out at this stage is the evaluation of the current modules of the OLA platform that can already be tested and the feelings they have caused in the users;

Modules that can be part of this pilot:

1. Irina Application: Main module of access to all the functionalities that we want to test and configuration of modules' functionalities. In the main screen we can access the following features: calendar, contacts, email, news, health, user settings, menus, buttons, etc.).

2. Speech synthesis: Since some users may evidence some hearing-related problems, it is an important test to assess whether speech technology already available and produced by technical partners is appropriate for a normal user case scenario; The voice attributes to be measured are: rhythm, volume, clarity, tone used, etc.;

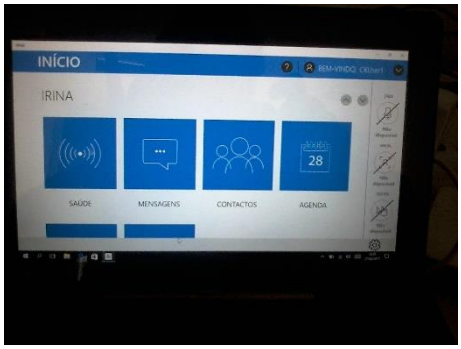
3. Speech Recognition: Users should get familiarized of having to dictate commands and phrases in the application, check the speed on which the commands are translated into actions, the frequency of a correct understanding of their voices and the difficulties felt;

4. Use of Sensors: Although at this stage the application does not support the complete list of predicted sensors, it is already possible to test it with a very broad subset approaching an almost complete scenario;
   Even if not fully automatic, such tests will serve to assess the usability of these processes.

4.4 Functionalities

This chapter will describe the functionalities which are presented on the OLA application at the initial menu and, as mentioned before on the cycle of the pilots methodology, it will be explained what is the functionality of each and how should be the procedure of the participant to use them. Once the participant makes the authentication on the app, the interface display five different options:

Health / Messages / Contacts / Agenda / Surveys



4.4.1 Health

The Health functionality includes the following health and well-being measurements:

1. Glucose;
2. Blood pressure;
3. Activity level;
4. Weight and Variance;
5. Alarming.

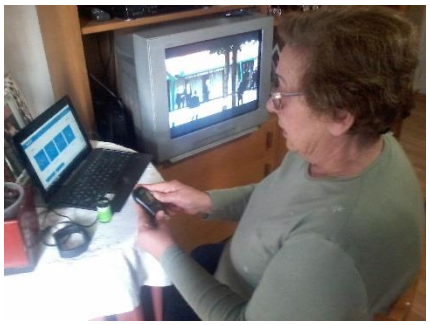
1. Glucose meter

The selected equipment for the Blood glucose measure is the *OneTouch Verio Flex* from Johnson & Johnson® (NOTE: it can also be used in the pilots and in the future by the users, the *OneTouch Select Plus Flex* model or other similar devices). The use of this equipment will be monitoring the data of user, through synchronization with the software (reference to the Deliverable 1.3 Technical Specification) resulting on the exposure of graphics on the app and also collection of quantitative data for the blood glucose measures.

The glucose level is measured from a small drop of blood collected by a lancet, which is placed on a disposable test strip to be read by the device. The result of this reading is sent to the application by Bluetooth.

Blood Glucose Monitoring is intended for self-testing (in-vitro diagnostics) by people with diabetes at home, alone or with their caregivers from their health care provider, to help them monitor the diabetes control effectiveness.

The necessary number of measurements a day to do depends on the user profile. If you do not have a history of diabetes you should do it once a day, preferably in the morning when you wake up. If you are a "pre-diabetic" because of age or type of living, you should do it twice a day, in the morning when you wake up and in the evening before dinner. In the case of diabetics, it is recommended to take it always before meals and whenever the symptoms indicate Glucose-hypoglycemic breakdowns (due to dizziness, apathy or indisposition) or in the opposite, a high blood Glucose-hyperglycemia peak.



2. Blood Pressure meter

The Blood Pressure will be measured by the *Beurer*®'s Bluetooth equipment *BM57* and *BM85*, Fora® *Blood Pressure P20* (or other similar devices) – this is a fully automatic blood pressure measurement, securing a quick and comfortable pulse or arm measurement, and the results are sent for monitoring by Bluetooth. This equipment also has a detector of possible heart rhythm disturbances during measurement - arrhythmia (irregular heart rhythm) built-in. It will be settled two daily measurements, one in the morning at bedtime and whenever you deem necessary due to any indisposition or changes in your heart rate.

3. Activity level meter

Nowadays, the smart bands and smartwatches had become very popular in society, from people with from all ages. The equipment to be used to collect activity levels will be the Microsoft® *Band 2* (could also be used Xiaomi® *My Band 2* or similar), which will be used to track heart rate and daily activities as exercise, steps, burned calories and sleep quality without keep losing track from important tasks or duties by receiving notifications. The choice of using a band for collecting this type data holds with using a device that is user-friendly – the user will not feel any discomfort on using as it is not weighty and can even be used as a stylish watch; sending the collected information by the same technology as the other devices, i.e. by Bluetooth.

4. Weight and Variance meters

The devices which will be used for the pilot trials are from two different types. It will be used a common balance in which the weight will be collected, sending the data results for monitoring, to the platform by Bluetooth.

The other type of balance scale keeps the same characteristics as the previous one with the addiction of having the ability to collect and send (by Bluetooth) data to improve balance, strength and coordination.

5. Alarming

The last item to be tested is a panic button, *SAFER Smart Pendant* by Leaf®, which is also connected with the application. In situations of any accident, strong indisposition or situations that needs an urgent assistance, the users can pressure the panic button by sending via Bluetooth a SOS alert to OLA and passed to their respective caregivers. The use of this equipment should make the seniors feel more comfortable at home by knowing that medical support will be given to him in extreme cases.

4.4.2 Messages

The Messages Functionality allows establishing the contact via email, send and receive email (use of speech).

On the Pilot Trials it will be evaluated the easiness of the user on communicating with its contacts by email (sending and reading) using voice commands. The Participant should be and feel autonomous on using any of the possible actions presented in this module (actions described in Technical Specification).

The OLA Staff will be monitoring the use of the Messages, understanding any possible problem the users might be having, so they can take the most of this functionality during the trials, with the integration of their email on the app (Microsoft® email account).

4.4.3 Contacts

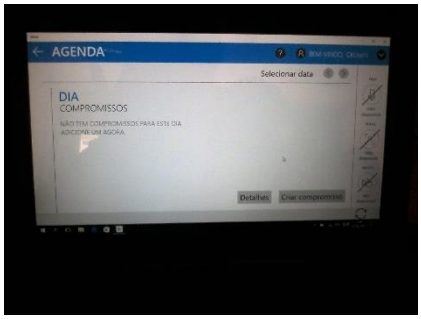
The Contacts Functionality is an interface that allows saving data about another person or entity to enable later contact, through e-mail, text message, telephone or videoconference.

On the Pilot Trials it will be evaluated the easiness of the users to manage their contacts. An autonomous used should add, edit and delete a contact without any considering issues.

The participants should be able to use is favourite method to drive through the functionality, i.e. touch, write and/or speech as it will be initial step the users need to make for keeping communication with their contacts.

4.4.4 Agenda

The Agenda Functionality is an electronic calendar that allows quick and effective management of important dates and events for the users, allowing alert warnings to remind them.



The use of the agenda by the user and the possibility of sharing their events (e.g. time to check heart rate) empowers the product and allows to plan his/her activities in an interactive way. The Caregivers will have the functionality to monitor the agenda of the seniors which is responsible for – this action improves and complements the assessment of the health conditions of his patients by using only OLA.

When the senior user creates an event, the agenda will set off an alarm of the event, establishing a great advantage of the OLA. With this functionality, the user can trust his events (or any other reminders) on OLA without be dependent of any other software, using memos – making the seniors life easier and also to his/her relatives by knowing that this user will not only have an application to keep monitor the health data of the individual but also will have someone (i.e. OLA) notifying about important actions.

In order to have an easy and effective monitoring of the user activities, OLA embraces:

- A continuous monitoring – by giving the possibility of classify a status for each action, signing if the task was performed or not.
- An interactive monitoring by the Caregivers on his/her patients – through a dynamic share of the events and its status.

Classification of Events

The events can be classified in different groups, considering its type, which will result in a different actions to be given by the user after the respective alarm is set off. On the table below there is an example of 3 events (classified with 3 different modes):

ID: 000001 **Type**: (Private/Public Public2) **Date**: 2016/08/21 **Time**: 15:00 **Description**: Cardiology Consultation **Status [to be confirmed]**: Past [occurred and not occurred] / Future event **(1)**	**ID**: 000002 **Type**: (Private/Public1 Public2) **Date**: 2016/08/21 **Time**: 08:00 **Description**: Check Glycemia **Status [to be confirmed]**: Past [occurred and not occurred] / Future event **(2)**	**ID**: 000003 **Type**: (Private/Public1 Public2) **Date**: 2016/08/21 **Time**: 18:00 **Description**: Go to the Cinema **Status [to be confirmed]**: Past [occurred and not occurred] / Future event **(3)**

FIGURE 3 - CLASSIFICATION OF EVENTS

The event is so classified in six fields:

- ID of the event;

- Type of Event:
  - Private – Only the owner of the event will have access to the event;
  - Public1 – Allows access to his formal caregiver;
  - Public2 – Allows access both to formal and informal caregiver.

- Time – determines the time when the event occurs;

- Description – A text describing the event – this field must contain perceptive; this information must be comprehensive enough so the Caregivers understand exactly what action will be performed by his/her patient.

- Status – This determines rather a past event was made or not, or simply to presume that it will be a future event (Suggestion: Marking note with the number of missing actions in the current week/month, if the suggestion of adding templates is accepted. **Example**: There was 2 [*number*] missing Health Check(s) [*Action*] this week [period].

The Status of the Event must be changed after the scheduled time for it occurrence. Confirmation – In his field the user confirms (Yes) or instead he/she made or missed the action (No).
The 3 examples refer to a different modes of events.

1. For the Events of the 1st example: The option to confirm the occurrence of the event must be available manually by the user.

2. For the Events of the 2nd example: The option to confirm that the user made the Health Check must be showed as an alarm message (approximately 10 minutes after the event settled time) and the answer has to be given by the user for him to continue use OLA. There should be an option to delay for some minutes the answer to be given.

3. For the Events of the 3rd Example: Has it is an example of a public event, this type of events, the user does not need to confirm either the user performed or not the planned action.

Note: For each mode, the alarm message must contain the description, date and time of the event.

4.5 Phases and Activities

The Pilot trials for OLA, which will occur during one year period, will be divided through different phases, separated by evaluations to enable a continuous evaluation of the activities and it will ease the objectives laid for the final report of the Evaluation of pilot trials.

Year	2017						2018	
Months	Mar + Apr	May	Jun + Jul	Aug	Sep + Oct	Nov + Dec	Jan	Feb
Phases	1st Phase				2nd Phase			3rd Phase
Activities	Group1	Analysis and preparation for May 26th Review Meeting. Note: 1 senior from Portugal will demonstrate OLA in Review Meeting	Group2	Analysis of Groups 1 and 2	Group3	Group4	Analysis of Groups 3 and 4	**Final Report**

FIGURE 4 - PLAN OF PILOT PHASES AND ACTIVITIES

The users from the first phase will have senior users without need of daily support, and user with need of daily support and also formal caregivers (homecare), while the users from second phase will be from charities (institutions).

Definition of the Users	Number to test in Phase 1	Number to test in Phase 2
Persons with diabetes/pre diabetes, hypertension or both	8	6
Dependent users	2	4
Total	10*	10*

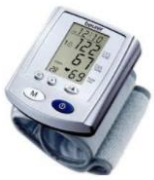
- NOTE: for the Number of Users (Table *) CKPT and LM should put their effort to balance this inconvenience so we can reach our minimum proposed of 60 users. (*Hungary* – As the request for additional Hungarian co-funding for the Hungarian pilots has been rejected by BZN's NCP – meaning that in Hungary BZN does not have the financial conditions to secure a total of 5 kits and the 20 users).

4.5.1 Equipment

At the beginning of Pilots Operations, i.e. in the beginning of March 2017, each partner will be using in each group some kits of equipment. Each kit will contain:

- **Glucose meters** plus **boxes of consumables** (each diabetic is estimated to spend between 1 to 3 consumables).

- **Raspberry PI;**
- **Heart Rate Meter (Beurer Bluetooth)**;



- **Tablet**
- **Band**

- **Panic buttons**

- **Buzzers**
- **Balance Scales**
- **Beacons**
- **Router + SIM Card**:

4.5.2 Measurement Stages

There will be a Health Measurement Check for the Equipment available in OLA, classified in the unit Millimetre of Mercury (mmHg):

1. Heart Rate Measurement

The results for the Heart Rate measurements will be classified on different levels:

1) REGULAR BLOOD PRESSURE – Patients with Systolic pressure levels lower than 120mmHg and with Diastolic pressure levels lower than 80mmHg.

2) PREHYPERTENSION – Patients with Systolic pressure levels between 120 and 139mmHg or with Diastolic pressure levels between 80 and 89mmHg.

3) HYPERTENSION STAGE 1 – Patients with Systolic pressure levels between 140 and 159 mmHg or with Diastolic pressure levels between 90 and 99mmHg.

4) HYPERTENSION STAGE 2 – Patients with Systolic pressure levels above 160mmHg or with Diastolic pressure levels above 100 mmHg.

5) HYPERTENSIVE CRISIS – Patients with Systolic pressure levels above 180mmHg or with Diastolic pressure levels above 110 mmHg.

Suggestion: Display an automatic alert message to the Formal Caregivers, Informal Caregivers and OLA Support if the patient is registering results of Level 4 or 5 (Hypertension Stage 2 and Hypertensive Crisis).

2. Glycemia Measurement

The results for the Glycemia can be classified in two major groups, considering if the user is assessing on fasting or two hours after meals. The results will be classified in Milligrams per Decilitre (mg/dl).

A. Fasting:

1) Hypoglycemia **–** Patients with Glycemia Levels lower than 70mg/dl.
2) Normal – Patients with Glycemia Levels between 70 and 100mg/dl.
3) Pre Diabetes – Patients with Glycemia Levels between 100 and 126mg/dl.
4) Diabetes – Patients with Glycemia Levels above 126mg/dl.

B. Two Hours after meals

5) Hypoglycemia **–** Patients with Glycemia Levels lower than 70mg/dl.
6) Normal – Patients with Glycemia Levels between 70 and 140mg/dl.
7) Pre Diabetes – Patients with Glycemia Levels between 140 and 200mg/dl.
8) Diabetes – Patients with Glycemia Levels above 200mg/dl.

Suggestion: Display an automatic alert message to the Formal Caregivers, Informal Caregivers and OLA Support if the patient is registering results of Level 4 or 8 (Diabetes on fasting or with 2 hours after the meal).

5 Informed Consent

This Chapter presents the informed consent form which will be distributed to all the users which will participate on the pilot activities. The participants should read and sign to agree on the terms described below.

5.1 Informed Consent – OLA introduction

OLA is a European research project, coordinated by Inovamais, S.A., bringing together a consortium of partners from three different countries: Portugal, Hungary and Sweden. This project aims to provide an answer to societal challenges by providing an innovative Organizational Life Assistant (OLA), a virtual presence that supports instrumental activities relating to daily living needs of older adults, allowing them to be more independent, self-assured and to have a healthier, safer and organized life, while facilitating caregiving by supporting them on offering high-quality assistance.

Different ways of interacting with the OLA platform will be developed in order to facilitate communication and collaboration between older-adults, informal caregivers and other services or professionals.

To develop an iterative development process, users will need to be involved in different phases of the project, allowing the collection of data that will help the consortium develop and improve the existing interaction modalities. These features and prototypes must be tested and improved through user involvement in:

- Qualitative interviews;
- Workshops;
- Prototype testing;
- Field trials.

5.1.1 Data Collection

In order to evaluate and improve the developed application, data will be collected at several phases in the project through observations, interviews, sensors and the actual user. The data will be used only within the OLA project framework: it will not be made accessible to any third party and will not be stored beyond the time allowed by law.

Participants' anonymity will be ensured: the data will not contain the names or addresses of participants and will be edited for full anonymity before being processed (e.g. in project reports or research papers).

In this experiment we will collect the following data types:

- Health-related data;
- Physiological data;
- Physical activity data;
- Circle of trust;
- Interaction data;
- User feedback.

To collect the data, we will use the following devices:

- Face-to-face interview (orally or written);
- Microphone;
- Physiological sensors (some Bluetooth-enabled): blood pressure, glycose meter, body weight and variance;
- Physical activity sensors (combined in a wearable): optical heart rate monitor, accelerometer / gyrometer (includes walks taken; distance ran; calories burned).
- Touchscreens;

5.1.2 Audio-visual Material

Video, image and / or audio recordings can also be collected as qualitative data. Participants will be informed of these recordings and a specific authorization will be asked before initiating any of these activities. These videos and pictures may be used only for dissemination and research activities, either in public forums, websites or conferences. The participant may demand the removal of photographs or videos from public forums and websites by a simple request.

Participation and Code of Conduct

The participant may end his or her participation in the project at any time, without having to justify him / her-self or incurring in any responsibility. Should the participant leave the project, any hardware or software provided by OLA is to be returned to the project. All participants' conduct towards other users and researcher should always be appropriate and never offensive or depreciating.

After having stated these general conditions and rules, we would like to thank you in advance for your participation and collaboration in the OLA project.

5.1.3 Consent

I agree with the above conducts and certify that I have given my consent to participate in the OLA project. I voluntary decided to participate in this project based on my full responsibility and understanding of what my participation implies and of my rights.

Date:

Participant's Name:

Participants' Signature:

Researcher's Name:

Researcher's Signature:

6 Evaluation Surveys

The Surveys Functionality consists of two surveys with the objective to collect information to be provided by the user:

- A Questionnaire about the initial evaluation (personal information);
- A Questionnaire to evaluate the Quality of Life.

Considering the different locations, Portugal, Sweden and Hungary, the surveys will be available on the platform at their respective native languages.

I - User Information

6.1.1 Seniors' Initial Evaluation Survey

Name: _____

Address: _____ Post Code: _____

_____

Telephone: _____ Mobile: _____

Birth Date: ____/ _____/ _____

Responsible Information

Name: _____

Address: _____ Post Code: _____

_____

Telephone: _____ Mobile: _____

Degree of Relationship: _____

II - Type of residence where you live

House □ Apartment □

Institution □ Nursing Home □

_____

III - Services that you attend

Home Support	□	Social Center □
Community Center	□	Parish Center □
Day Center	□	Night Center □
Community Center	□	Senior University □

IV - Clinical History

Alzheimer's □	Dementia □	Language difficulties □
Arthritis □	Diabetes □	Respiratory distress □
AVC □	Hearing difficulties □	Visual Difficulties □
Cancer □	Difficulties of balance □	Heart Disease □
Chronic Pain □	Blood Pressure □	Allergies □
Pressure ulcer □	Memory Problems □	Incontinence □
Tremors □	Osteoporosis □	Paralysis □
Surgery □		

Other: _____

_____

V - Medical Supports

Support	Use	Need
Glasses		
Hearing Aid		

Support	Use	Need
Transfer Elevator		
Articulated Bed		

Denture			Protection grids		
Walker			Protection grids		
Walking Stick			Bath support bars		
Wheelchair			Bedpan		
Transfer Ramp			Oxygen		
Ramp			Panic Button		
Other(s):					

VI - Did you ever used this equipment before?

Equipment	**No**	**Yes, but just a few times.**	**Yes, regularly.**
Glucose meters			
Heart Rate meter			
Balance Scale			
Panic Button			
Smart Band			
Tablet			

Date

___/___/_____

Signature

_____

6.1.2 Quality of Life Bref

The Quality of Life Bref, developed by WHOQOL Group, is a quality of life assessment used cross-culturally. The OLA consortium will used this survey to assess level of impairments and diseases which can be helpful during the evaluation of the pilot activities to identify tendencies of the users considering their impairments and to study on how OLA can be an answer to the difficulties identified by the users at their respective quality of life.

Please find the assessment asks, evaluation criteria and other information in these two links below:

WHOQOL - Bref introduction, administration, scoring and generic version of the assessment

The World Health Organization Quality of Life (WHOQOL)-BREF

6.2 Usability Survey

Based on the need to know the opinion of the various stakeholders in this phase of the OLA project, we will promote the execution and collection of some questionnaires, to be filled after the conclusion of the pilot phase. Later, it will be asked them to complete this inquiries when the process is completed, which were divided by the different profiles (personas) in OLA, i.e.:

Seniors / Formal caregiver / Informal caregiver

6.2.1 Seniors

1. Which OLA module you prefer most?

   _____

2. Which OLA module you dislike most?

   _____

3. Did the system demonstrate any issue on recognizing your voice?*

   No □ Yes □ If Yes, which were the most problematic commands?

   _____

   _____

4. Which is the OLA module you think you would be using more?

   _____

5. Which is the OLA module you think you would be using less?

   _____

6. Is the size of elements (figures e buttons) on screen suitable to use?

   No □ Yes □

7. Is the voice of the application loud and clear?*

   No □ Yes □

8. Which interaction mode from OLA will you be using more? (speech, touch, etc.)*

   _____

9. Was it easy to use your contacts through the application?

   No □ Yes □ If No, please justify.

   _____

10. Was it easy to use the agenda for your commitments?

    No □ Yes □ If No, please justify.

    _____

***Note:** Question 3, 7 and 8 was taken when the speech module could not be included on the pilot.

6.2.2 Formal Caregivers Survey

1. Was it easy to check the health status of the senior with OLA?

   No □ Yes □

2. Was it easy to contact with the informal caregiver and respectively family through OLA?

   No □ Yes □

3. Was it easy to use the Agenda for your commitments?

   No □ Yes □ If No, please justify.

   _____

4. Do you think OLA might be useful to assist the seniors which you are responsible for?

   No □ Yes □

5. Which was the biggest limitation you detected on the seniors' interaction with OLA?

   _____

6. Can OLA offer you a satisfactory level of trust and comfort based on the seniors which you were taking care?

   No □ Yes □

7. Do you think using OLA will allow time/cost savings?

   No □ Yes □

8. Which suggestion could you give us in order to improve OLA?

   _____

   _____

6.2.3 Informal Caregivers Survey

1. Was it easy to verify the senior's health status on OLA?

   No □ Yes □

2. Was it easy to manage the seniors' Agenda through OLA?

   No □ Yes □

3. Was it easy to contact the senior through OLA?

   No □ Yes □

4. Was it easy to contact the seniors' formal carer through OLA?

   No □ Yes □

5. Can OLA offer you a satisfactory level of trust and comfort based on the seniors which you were taking care?

   No □ Yes □

6. Do you think using OLA will allow time/cost savings?

   No □ Yes □

List of Figures

Annexes

1 – Investigation Protocol

The main goal of this document is to describe the experimental procedures, i.e. pilots, made in the context of the Organizational Life Assistant project.

The OLA project aims to provide an answer to the societal challenges by developing an innovative Organisational Life Assistant product that acts like a virtual presence. This virtual presence supports instrumental activities related to daily living needs of older adults, allowing them to be more independent, self-assured and to have a healthier, safer and organized life, while facilitating caregivers by supporting them on offering high-quality assistance.

OLA will mediate and facilitate interaction (communication and collaboration) between elderly and their caregivers and other services or professionals, through technological devices such as standard computers, mobile devices (tablets) and well-being devices. These ICT devices will be based on an innovative human-computer interaction (HCI) module, embracing various physical / health and cognitive characteristics of the older adults; it will also be specifically oriented to increase the level of independence of the elderly, by supporting the possibility of caregivers' remote assistance and by improving the accessibility to existing services on the web.

OLA addresses also a major issue that elderly are facing related to memory degradation and gradual decreasing of their cognitive capabilities, enabling them to remember primary healthcare and medical obligations (e.g. personal hygiene, medical appointments).

The primary end-users are the big group of older adults of 65+ living alone with or without light physical or cognitive age-related limitations, who needs support from care systems. OLA will be also targeting users in pre senior age to better monitor and be a medical support in prevention of diseases and dysfunctions. Secondary end-users are both formal and informal caregivers from public or private sectors, supporting them to cope with the increased demand for care.

Previous Request for Portugal

This investigation protocol, named Pre-pilots and Pilots, follows the elaboration of a previous one called Data Collection, which was submitted in October of 2015 to the Ethics Committee of ISCTE-IUL. That investigation protocol and the project it encompasses (OLA) were validated according to that organism in December of 2015, with the suggestion of using a psychometric evaluation tool, which is applied in this very investigation protocol (see 3.d). That first protocol was related to the initial data gathering stages of the project, which saw the need to collect user data for: 1) user requirements, 2) the development of data models and 3) introductory / preliminary specific data to be gathered within the scope of the field trials. This new protocol follows mainly the third component of that first request in light with the more solidified understanding of what the project should deliver to its users (attained through the study implicit in the first request). Therefore the consortium has put together a set of features and services that will be implemented and what are the user data types specifically needed for each one of them. Since this new set of data may uncover new ethical requirements, the consortium felt it was important to create another investigation protocol to match the future (and last) stages of the project. However, it's important to mention that first request, and how this new protocol is a natural continuation, or an expansion, of the first (validated) one.