

SOCIABLE DELIVERABLE D5.1

“Report on Pilot Sites Preparation and Assessment”



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1.0	Chiara Zaccarelli and Antonella Bandini	AUSL, COFO	07/12/2010	Update of contribution of status of some pilots sites

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Abstract

The present deliverable focuses on detailing the status of each pilot site with respect to the deployment of the SOCIABLE services, along with a description of the actions taken to reach this status.

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Executive Summary

The main objective of the SOCIABLE project is to introduce and pilot a novel ICT based approach to the cognitive training and social activation of elderly individuals. The approach will be piloted with the participation of 350 senior citizens in 7 different pilot sites (TRONDHEIM Kommune, Hygeia Hospital, Morgagni Pierantoni Hospital, Municipality of Forlì, Social Policy Center of the Municipality of Kifissia, Santa Lucia Foundation and PREVI S.L) from 4 European countries (Greece, Italy, Norway, Spain).

Each site will undertake a thorough preparatory study concerning the installation and deployment of the SOCIABLE technology platform and related services. Moreover each pilot site will be thoroughly assessed in terms of participating users, availability of experts, space and technology infrastructure to accommodate the SOCIABLE technology platform as well as required training programmes and social interaction services.

The preparation of the different pilot sites has been based on the pilot requirements identified and listed in Deliverable D1.3. All pilot sites have started their preparation based on this list of requirements. The organization of the pilot operations is associated with a host of different issues, spanning the administrative, organizational, technical, technological and medical perspectives. From an administrative and organization perspective, the various sites will have to secure the appropriate resources (i.e. human resources and materials) in order to successfully organize and carry out the pilots. From a technical/technological perspective, the sites will have to deploy the SOCIABLE ICT infrastructure, in order to blend innovative ICT activities in their existing care services offerings. Finally, from a medical perspective each site will have to define the medical-related activities that will be associated with the tasks of applying the SOCIABLE activities in a way that maximizes the positive effects on the target elderly participants/users.

All pilot sites are regularly submitting detailed reports on the status of preparation at their sites. This deliverable summarizes the status of each pilot site reflected in the pilot site preparation reports.

1. Introduction

SOCIABLE will pilot a novel model for ICT assisted cognitive training and social activation for a wide range of senior citizens including normal elderly, older adults with mild cognitive impairment, as well as patients suffering from mild Alzheimer disease. Pilot operations will be organized across various sites in four European countries (Greece, Italy, Norway and Spain). Senior citizens will participate to the SOCIABLE pilots within leisure/care centres, as well as within their homes. Overall, the organization of the pilot operations is associated with a host of different issues, spanning the administrative, organizational, technical, technological and medical perspectives. From an administrative and organization perspective, the various sites will have to secure the appropriate resources (i.e. human resources and materials) in order to successfully organize and carry out the pilots. From a technical/technological perspective, the sites will have to deploy the SOCIABLE ICT infrastructure, in order to blend innovative ICT activities in their existing care services offerings. Finally, from a medical perspective each site will have to define the medical-related activities that will be associated with the tasks of applying the SOCIABLE activities in a way that maximizes the positive effects on the target elderly participants/users.

The present deliverable provides a detailing status of each pilot site with respect to the deployment of the SOCIABLE services, along with a description of the actions taken to reach this status. The preparation of the pilot sites has been based on the list of specific pilot requirements reflected in Deliverable 1.3 "Pilot requirements and Scenarios". These requirements outline the types of users to be involved, the particular processes to be established and their relationship with existing processes, the technical/technological infrastructure to be used, as well as other administrative and medical requirements.

The deliverable is structured as follows: Section 2 following this introductory describes the critical points that each pilot site has to solve for the graceful commencement and execution of the pilots, and section 3 presents the common agreements achieved by the consortium related to these critical points. Section 4 reflects the current status of each pilot site with a description of the actions taken to reach this status and a detail plan about completing preparations for the pilot. Finally, section 5 concludes the deliverable presenting a summary of the status of all pilot sites, putting special emphasis on the main achievements and also on the problems and risks detected.

2. Main preparatory actions for the pilot sites

Following are described the main actions that have to be done to prepare each site for the pilot operations. These actions cover all the requirements (administrative/organizational, technical, technological and medical) described in deliverable D1.3.

2.1 Infrastructure Issues

2.1.1 Selection of Physical Space

A physical space is needed for the SOCIABLE sessions at the care centres. Room for the Microsoft Surface, the users, the chairs and the therapist will be needed. It is important to determinate the maximum number of users interacting with the SOCIABLE platform at the same time if the physical space is limited at any centre.

2.1.2 ICT Procurement

The platform that will be used at the care centre has to be defined. Each pilot site has to indicate how many platforms needs and buy them.

In the same way, the model of TabletPC that will be used at home during the pilots has to be defined. Each pilot has to indicate how many PCs needs and buy them.

2.2 User Selection Issues

2.2.1 Identification of users

Each site has to define the number of users that will participate in the project pilot. It is important to indicate how the users will be distributed across the different groups A- Healthy (i.e. cognitively intact) elderly, B- MCI and C- Mild AD, and the number of users that will use SOCIABLE services at the care centre and the number of users that will use SOCIABLE services at home.

The minimum number of users engaged in all the SOCIABLE pilots will be 350.

2.2.2 Attraction of users

Each site has to define a plan for recruiting and selecting the users that will be involved in the pilot.

2.3 Medical Issues

2.3.1 Definition of trial protocol and operations

Each site has to define a trial protocol indicating the number of sessions, duration, etc.

2.3.2 Definition of sessions

Each site has to define the kind of session that will organize. There are two types of sessions: individual sessions or group sessions.

2.4 Localization Issues

Each site has to define what resources should be translated to the local language (for example: medical tests, technical documentation, etc)

2.5 Human Resources Issues

2.5.1 Identification of staff required

Each pilot site has to define how many people will be involved in the pilot operations and what their specialities are.

2.5.2 Support needed from other SOCIABLE partners

Each site has to plan the collaboration with technical partners of the project during the pilots.

2.6 Training Issues

Each pilot site has to identify who needs to be trained and in what capabilities. In necessary a plan with specific training sessions organized in conjunction with technical partners should be defined.

2.7 Ethical Issues

2.7.1 National Ethical Management Regulations

All sites have to investigate ethical management issues and procedures, subject to the SOCIABLE ethical management, as well as the national ethical procedures.

3 Common Preparatory Actions

Many of the actions described in the previous section required a common solution for all the pilot sites. This section described common agreements achieved by the consortium.

3.1 Infrastructure Issues

3.1.1 ICT Procurement

The different platforms that will be used for the pilots have been defined. At the care centres the Microsoft surface will be used.

The Microsoft Surface is based on the Windows Vista SP1 operating system and uses cameras and image recognition in the infrared spectrum to recognize different types of objects. Streams from the cameras are accordingly processed by the computer of the platform and the resulting interaction is displayed using rear projection. In this way, the surface can perceive various interactions i.e. interactions of fingers, hands, real-world objects, devices and tags.

A Microsoft Surface unit is built into a table-like form that is easy for users to interact with in a way that feels familiar in the real world. The Microsoft Surface Vision System uses infrared cameras to sense objects, hand gestures, and touch and then process that input. More details about this table can be found at the Deliverable 3.2.

At the elderly home a SurfacePC will be used. Surface PCs provide portability, which facilitate the mobility of the users and decouples them from the need to visit the care centre in order to participate in SOCIABLE sessions. Hence, surface PCs are an ideal solution for the SOCIABLE in-home deployments.

The Pc selected should comply the following features will be used:

- Large Screen (>15")
- Large resolution
- Easy to use and handle
- Powerful processor
- Windows Vista or Windows 7 environment

Different models have been studied and although the decision has not been taken yet, the "Dell Studio 17 Touch" model seems to be the best option since it has the above features and it can provide a more functional and ergonomic interface for elderly users. More details about this model can be found at the deliverable 3.2.

3.2 User Selection Issues

3.2.1 Identification of users

The following table lists the minimum number of users to be involved per sites and user type (healthy elderly, MCI, mild AD) in the scope of the SOCIABLE pilots and respective validation.

Pilot Site & Country	Type	Users at Care Centre	User at their Homes	Total per site
HYGEIA S.A (Greece)	Private Hospital	25 MCI 25 mild AD	5MCI 5 mild AD	60
Social Policy Centre of the Municipality of Kifissia (Greece)	Municipality	55 healthy elderly	5 healthy elderly	60
Commune Forli (Italy)	Municipality	15 healthy elderly 20 MCI	10 MCI	45
Morgagni Pierantoni Hospital (Italy)	Public Hospital	40 MCI	10 MCI	50
Fondazione Santa Lucia (Italy)	Private Hospital	40 AD	7 AD	47
Trodheim Kommune (Norway)	Municipality	5 healthy elderly 43 mild AD		48
PREVI S.L (Spain)	Care Services Provider – Research Centre	20 healthy elderly	20 healthy elderly	40
Total				350

Table 1: Final Distribution of the SOCIABLE Users at the various pilot sites

3.2.2 Attraction of users

A common process for the recruitment and selection of the users that will participate in the pilots has been defined.

For the recruitment and assessment process a SOCIABLE cognitive battery including standardized neuropsychological tests for the cognitive, functional and affective assessment of the elderly has been defined.

The following table summarizes the tests included in this battery.

COGNITION	
Orientation	Mini Mental State Examination
Abstract reasoning	Clock Drawing Test
Verbal memory (long term)	Rey’s Auditory Verbal Learning Test
Constructional praxis	Rey’s Complex Figure (copy)
Visuo-spatial memory	Rey’s Complex Figure (delayed recall)
Verbal memory (short term)	Digit Span
Executive functions	Phonological Verbal Fluency
Attention	Trail Making Test (parts A and B)
Language	Naming Test (specific for each country)
AFFECTION	Geriatric Depression Scale (short form)
FUNCTIONAL ABILITIES	ADL, IADL
SEVERITY OF DEMENTIA	Clinical Dementia Rating
SOCIAL STATUS	LSNS-18, Social interaction preferences

Table 2: Standardized Tests to be used in SOCIABLE

More details about the SOCIABLE cognitive battery can be found at deliverable 2.1

For the selection of the users a set of inclusion/exclusion criteria regulating the enlistment and participation of elderly users in the SOCIABLE programs has been defined. Deliverable 2.1 lists the different inclusion/exclusion criteria for each group of users (A, B and C)

3.3 Medical Issues

3.3.1 Definition of trial protocol and operations

All the pilot sites have agreed the following conditions for the trial protocol:

- The protocol will last 3 months
- There will be 2 sessions per week
- Each session will have a 60 minutes duration, out of which 30 minutes will be dedicated to the cognitive training and the rest to the social activation
- Care centre sessions and home sessions will follow a similar model
- The follow up assessment will take place three months after the elderly participation in SOCIABLE

This protocol is presented in detail in Deliverable D1.2.

3.4 Localization Issues

The SOCIABLE platform will be available in 5 different languages: English, Spanish, Italian, Greek and Norwegian. Moreover each site has to define what other resources should be translated to the local language (for example: medical tests, technical documentation, etc)

3.5 Ethical Issues

3.5.1 Ethical Management Operations

A SOCIABLE Ethical Committee has been constituted, in order to deal with the Ethical Issues and agreed an ethical management methodology to be applied in the project.

This committee is working on the definition of a medical protocol. This protocol includes an informed consent to be used as a basis for informed consent at the different sites. Trondheim, due to its national rules will have to include more information to the common protocol.

The medical protocol also includes a detailed description of the clinician trial protocol to be applied, the data collection, the data processing and analysis processes as well as the target groups of the clinical study.

More details of the protocol will be provided in deliverable 7.1

4 Current Status of each pilot site

4.1 Current Status of HYGEIA S.A

4.1.1 Infrastructure Issues

HYGEIA hospital has selected and secured the availability of the physical space needed for the SOCIABLE sessions. The procurement of the MS Surface Platform and the TabletPCs is in progress and expected to be completed in December 2010.

4.1.2 User Selection Issues

The selection of users is still in progress. The users are selected from the pool of cognitively intact and mildly demented elderly visiting the Memory Clinic of the hospital, informed about the potential of participating in the SOCIABLE project and encouraged to ask questions relevant to the project. Before being formally recruited, elderly considered to be suitable for participating in the project on the basis of the predefined inclusion and exclusion criteria, will undergo cognitive, affective and functional assessment following the procedures described in D2.1.

The distribution of the users will be as follows:

60 users in total (all aged 65+)

- 25 elderly with MCI in the Memory Clinic
- 25 elderly with mild AD in the Memory Clinic
- 5 elderly with MCI at home
- 5 elderly with mild AD at home

4.1.3 Medical Issues

The medical trial protocol is expected to be completed by the end of December 2010, with the contribution of all partners. The Memory Clinic of the HYGEIA hospital has explicitly documented how the pilot will work operationally. Both individual and group sessions will take place in the hospital.

4.1.4 Localization Issues

The Clinical Protocol should be translated into Greek.

4.1.5 Human Resources Issues

HYGEIA has contacted all required staff (i.e. 1 neurologist, 1 cognitive neuropsychologist, 1 psychologist and 1 secretary) and secured their availability for the SOCIABLE pilots. SingularLogic will support HYGEIA on technical issues.

4.1.6 Training Issues

All experts involved in the SOCIABLE pilot operation will receive extensive training on the use of the MS Surface Platform. HYGEIA is in discussions with technical partners (i.e. SingularLogic) in order to organize the required training for the medical and administrative staff involved in the SOCIABLE project.

4.1.7 Ethical Issues

HYGEIA has investigated and documented national-level ethical management requirements and has a detailed plan on the actions to be performed. In detail, before the commencement of the pilot phase of the SOCIABLE project, the Clinical Protocol will be presented for approval to the Ethical Committee of the HYGEIA Hospital.

4.1.8 Assessment

The status of the pilot site is at moment positive and satisfactory; at moment there are not special issues that may create future complications.

4.1.9 Plan for completing the preparation

All the actions and processes needed to be completed before the commencement of the pilot operation will be completed by January 2011.

4.2 Current Status of Social Policy Centre of Municipality of Kifissia (SPC)

4.2.1 Infrastructure Issues

The physical space chosen is the Medical Centre of the municipality of Kifissia which is a public service, supervised by the Social Policy Centre. It provides primary health services at the citizens of Kifissia. In the Medical Centre there are volunteers' doctors of different specialties, who prescribe medicines and medical examinations. Additionally, there is a realization of actions for preventive medicine and informative speeches for the elderly about health issues and mental health.

As for the technological Infrastructure we will pursue 1 Microsoft surface Table and 5 Tablet PC's.

4.2.2 User Selection Issues

The number of users at the medical centre will be 55 healthy elderly aged 65+ and at home: 5 healthy elderly aged 65+

The experts from the centre will explain SOCIABLE services to the elderly who attend the Municipality's programs (Social Attendance and Domestic Attendance Centre and the 2 Social Welfare Centres of the Municipality)

4.2.3 Medical Issues

We will use the medical protocol agreed by the consortium. There will be two sessions per week during three months and each session will have 60 min duration.

4.2.4 Localization Issues

Items to be localized:

- Technical Documentation
- Informed Consent Forms translated
- Sociable services

4.2.5 Human Resources Issues

People who will be involved in our pilot operations:

- 1 cognitive psychologist
- Health personnel (2 persons)
- A technical expert for technological support

4.2.6 Training Issues

Singular Logic will train the carers on the SOCIABLE platform. Hygeia will train on the medical processes of the project (selection, evaluation).

4.2.7 Ethical Issues

In terms of SOCIABLE we will follow the ethical procedure regarding *respect for persons, beneficence, Justice, Privacy* according to the Greek/European law and the SOCIABLE ethical committee

4.2.8 Plan for completing the preparation

Pending issues:

- Purchase Sociable equipment (MS Surface, Surface PCs) – Nov. 2010

- Attraction/Selection of users – until March 2011
- Training – until Jan. 2011
- Finalizing ethical issues with the consortium - Dec. 2011

4.3 Current Status of Local Health Authority of Forli (AUSL)

4.3.1 Infrastructure Issues

4.3.1.1 Selection of Physical Space

A reserved room located in the Specialized Memory Centre has been identified to be dedicated to the SOCIABLE sessions with the MS Surface Platform.

The selected room has the following features:

- adequate safety and illumination
- wide enough and comfortable to house the SOCIABLE Platform
- sufficiently quiet to create a pleasant environment
- placed in a location (within the Hospital) easily accessible by public transport

Concerning the Tablet PCs for the in-home use, they will be located at elderly's homes (selected with regards to specific requirements), and, where it will not be possible, they will be located at the "Alzheimer Cafè" or other Elderly centres.

4.3.1.2 ICT Procurement

AUSL decided to buy 1 Microsoft Surface Platform to be used at Care Centre (Specialized Memory Centre) and 5 Tablet PCs to be used at the elderly home.

The procurement of the MS Surface Platform is in progress and expected to be completed by December 2010 (the ordering process has been completed and is being processed by Microsoft Business Team).

We are still waiting for the final decision by technological partners on the typology of Tablet PCs (with the features required) to be ordered (probably the model "Dell Studio 17 Touch" since it has the required features and it can provide a more functional and ergonomic interface for elderly users).

4.3.2 User Selection Issues

4.3.2.1 Identification of Users

AUSL will select a total of 50 users, all belonging to Target Group B (MCI patients) for the SOCIABLE Pilot: 40 users to be trained with the MS Surface Platform at the Specialized Memory Centre and 10 users to be trained with Tablet PCs at home (or Elderly Centres).

4.3.2.2 Attraction of Users

The users will be recruited from database of the Specialized Memory Centre of AUSL and from Elderly Aggregation Centres through promotional activities.

The selection and recruitment will be set according to the cognitive battery and the procedures outlined in D2.1.

The procedures of selection and recruitment will be performed by medical expert personnel of the Specialized Medical Centre

4.3.3 Medical Issues

The medical Trail Protocol has been discussed and agreed among all the partners and is expected to be completed by December 2010, with a detailed definition of the operations.

AUSL will focus on both individual and group sessions. The group sessions will be organized at the Specialized Memory centre and will be conducted with the use of the MS Surface Platform; the individual sessions will be conducted with the use of the Tablet PCs at elderly homes.

4.3.4 Localization Issues

In addition to the SOCIABLE Platform, the other resources to be translated in to Italian include:

- The Clinical Protocol
- Technical Documentation
- Informed Consent Form
- Cognitive Games
- Book of life Application
- Back Office
- Brochures of the SOCIABLE Project

4.3.5 Human Resources Issues

4.3.5.1 Identification of staff required

AUSL and COFO will work in collaboration during the pilot operations, involving the following human resources:

- Medical Experts (provided by AUSL):
 - 2 Geriatric Physicians
 - 1 Neuropsychologist
 - 2 Nurses
- Carers/Social-Health Professionals (provided by COFO):
 - 2 social-workers
 - 4 social-health carers (provided by CAD cooperative – COFO subcontracting)
- IT Technicians: provided by CEDAF

4.3.5.2 Support needed from other SOCIABLE partners

AUSL will be provided support on technical matters by CEDAF and the collaboration between AUSL and COFO will continue during all phases of the pilot operations.

4.3.6 Training Issues

All professionals involved in the pilot operations will need to be trained in the use of the MS Surface Platform and in the procedures of the Trial defined in the Protocol.

A detailed training plan on technical/technological matters will be organized by CEDAF, according with the different role and specific competence of the professionals involved.

A specific training will be organized and performed by the medical experts to the professionals involved in the Pilot Operations procedures on management of both individual and group sessions and a specific training will be provided to the care givers involved in the in-home sessions.

4.3.7 Ethical Issues

AUSL investigated and documented the ethical management requirements in a national level and identified the specific procedures to be followed in order to submit the Study Protocol to the Internal Ethical Committee for approval.

The Ethical Committee for clinical trials is an independent body which has the responsibility to safeguard rights, safety and welfare of patients participating in a trial and to provide public assurance of this protection.

The Ethical Committee normally meets once every three weeks and expresses its opinion about:

- Clinical Trials assessing pharmacological interventions
- Clinical Trials assessing medical and diagnostic devices
- Observational studies and clinical trials in general medicine

AUSL start collecting the documentation required in order to finalize the process of approval of the Clinical Protocol by the Ethical Committee (expected time from delivery of all the documentation required will last about 1-2 months)

4.3.7.1 Ethical Management Operations

A SOCIABLE Ethical Committee has been constituted, in order to deal with the Ethical Issues and agreed an ethical management methodology to be applied in the project.

An Informed Consent Form has been agreed and defined by all pilot sites. It includes a detailed description of the clinical trial protocol, the data processing and analysis processes. Each user will sign the Informed Consent Form prior to enlisting in the SOCIABLE Project.

Secure data storage and collection processes will be applied, and all data will be anonymous.

4.3.7.2 National Ethical Management Regulations

AUSL needs to ultimate the definitive Study Protocol in order to submit it to the internal Ethical Committee for approval.

The Ethical Committee for clinical trials is an independent body which has the responsibility to safeguard rights, safety and welfare of patients participating in a trial and to provide public assurance of this protection.

The Ethical Committee normally meets once every three weeks and expresses its opinion about:

- Clinical Trials assessing pharmacological interventions
- Clinical Trials assessing medical and diagnostic devices
- Observational studies and clinical trials in general medicine

4.3.8 Assessment

The Specialized Memory Centre has all the characteristics identified for proper installation and use of Microsoft Surface Platform.

The status of the pilot site is at moment positive and satisfactory; at moment there are not special issues that may create future complications.

4.3.9 Plan for completing the preparation

Our plan for completing the Pilot Site preparation includes:

- The process of ordering the Tablet PCs, as soon as technological partners will be finalized the decision about the Surface PC platform considered as the most suitable.
- To ultimate the process of Ethical Approval of the definitive Clinical Protocol
All the actions and procedures need to be completed before the commencement of the pilot operation, by January 2011

4.4 Current Status of City of Forli (COFO)

4.4.1 Infrastructure Issues

4.4.1.1 Selection of Physical Space

A reserved room located in the Aggregation Centre for Elderly "2Tigli" has been identified to be dedicated to the SOCIABLE sessions with the MS Surface Platform. The Aggregation Centre "Due tigli" is one of the three Aggregation Centres for Elderly people of the Municipality of Forli

The selected room has the following features:

- adequate safety and illumination
- wide enough and comfortable to house the SOCIABLE Platform
- sufficiently quiet to create a pleasant environment
- placed in a location (within the Aggregation Centre) easily accessible by public transport

Concerning the Tablet PCs for the in-home use, they will be located at elderly's homes (selected with regards to specific requirements), and, where it will not be possible, they will be located at the "Alzheimer Cafè" or other Elderly centres.

4.4.1.2 ICT Procurement

COFO decided to buy 1 Microsoft Surface Platform to be used at Aggregation Centre "2 Tigli" and 5 Tablet PCs to be used at the elderly home. We are in progress in the process of ordering the MS Surface platform, supported by CEDAF for procurement processes.

We are still waiting for the final decision by technological partners on the typology of Tablet PCs (with the features required) to be ordered (probably the model "Dell Studio 17 Touch" since it has the required features and it can provide a more functional and ergonomic interface for elderly users).

4.4.2 User Selection Issues

4.4.2.1 Identification of Users

COFO will select a total of 45 users (15 healthy - Target Group A and 30 MCI – Target Group B): 35 users (15 normal; 20 MCI) trained with the MS Surface Platform at Care Centre and 10 users (MCI) trained with Tablet PCs at home/Elderly Centres CAD.

For the users trained at home will be involved social-health care provided from cooperative CAD (added as subcontractor for COFO), and care givers.

4.4.2.2 Attraction of Users

The users will be recruited from database of the Specialized Memory Centre of AUSL and from Elderly Aggregation Centres through promotional activities.

The selection and recruitment will be set according to the cognitive battery and the procedures outlined in D2.1.

The procedures of selection and recruitment will be performed by medical expert personnel of the Specialized Medical Centre

4.4.3 Medical Issues

The Trail Protocol has been discussed and agreed among all the partners and is expected to be completed by December 2010, with a detailed definition of the operations.

COFO will focus on both individual and group sessions. The group sessions will be organized at the Aggregation Centre "2 Tigli" and will be conducted with the use of the MS Surface Platform; the individual sessions will be conducted with the use of the Tablet PCs at elderly homes.

4.4.4 Localization Issues

In addition to the SOCIABLE Platform, the other resources to be translated in to Italian include:

- Games
- Book of life Application

- Medical Tests
- Back Office
- Technical documentation
- Informed Consent Form
- Brochures of the SOCIABLE Project

4.4.5 Human Resources Issues

4.4.5.1 Identification of staff required

COFO and AUSL will work in collaboration during the pilot operations, involving the following human resources:

- Medical Experts (provided by AUSL):
 - 2 Geriatric Physicians
 - 1 Neuropsychologist
 - 2 Nurses
- Carers/Social-Health Professionals (provided by COFO):
 - 2 social-workers
 - 4 social-health carers (provided by CAD cooperative – COFO subcontracting)
- IT Technicians: provided by CEDAF

4.4.5.2 Support needed from other SOCIABLE partners

COFO will be provided support on technical matters by CEDAF and the collaboration between COFO and AUSL will continue during all phases of the pilot operations.

4.4.6 Training Issues

All professionals involved in the pilot operations will need to be trained in the use of the MS Surface Platform and in the procedures of the Trial defined in the Protocol.

A detailed training plan on technical/technological matters will be organized by CEDAF, according with the different role and specific competence of the professionals involved.

A specific training will be organized and performed by the medical experts to the professionals involved in the Pilot Operations procedures on management of both individual and group sessions and a specific training will be provided to the care givers involved in the in-home sessions.

4.4.7 Ethical Issues

4.4.7.1 Ethical Management Operations

A SOCIABLE Ethical Committee has been constituted, in order to deal with the Ethical Issues and agreed an ethical management methodology to be applied in the project.

An Informed Consent Form has been agreed and defined by all pilot sites. It includes a detailed description of the clinical trial protocol, the data processing and analysis processes. Each user will sign the Informed Consent Form prior to enlisting in the SOCIABLE Project.

Secure data storage and collection processes will be applied, and all data will be anonymous.

4.4.8 Assessment

The Aggregation Centre "2 Tigli" has all the characteristics identified for proper installation and use of Microsoft Surface Platform.

The status of the pilot site is at moment positive and satisfactory; at the moment COFO is working for the implementation of Telecommunication Infrastructure – ADSL.

4.4.9 Plan for completing the preparation

Our plan for completing the Pilot Site preparation includes:

- To complete the procedure of ordering the MS Surface Platform as soon as possible, in order to finalize the procurement of the platform
- To start the process of ordering the Tablet PCs, as soon as technological partners will be finalized the decision about the Surface PC platform considered as the most suitable.

4.5 Current Status of Fondazione Santa Lucia (FSL)

4.5.1 Infrastructure Issues

4.5.1.1 Selection of Physical Space

A reserved room located in the Day Hospital has been identified to be dedicated to the SOCIABLE sessions with the MS Surface Platform. The dedicated room offers all the requirements need to guarantee safe and comfortable training session like adequate lighting , silence, adequate space, ecc.

Concerning the Tablet PCs for the in-home use, they will be located at elderly's homes selected with regards to specific requirements.

4.5.1.2 ICT Procurement

FSL has bought 1 Microsoft Surface Platform to be used at the day centre and we will buy 5 Tablet PCs to be used at the elderly home. The Platform has already arrived at FSL.

We are still waiting for the final decision by technological partners about the tablet PCs, at the moment it seems that Dell Touch could satisfy the requirements.

4.5.2 User Selection Issues

4.5.2.1 Identification of Users

FSL will select a total of 47 users: 40 users - Target Group C - trained with the MS Surface Platform at FSL Day Hospital Care Centre and 7 users - Target Group C - trained with Tablet PCs at home.

4.5.2.2 Attraction of Users

FSL will recruit users from Alzheimer Evaluation Unit and Neuro-motor Day Hospital.

The selection and recruitment will be set according to the cognitive battery and the procedures outlined in D2.1.

The procedures of selection and recruitment will be performed by medical expert personnel of the Specialized Medical Centre

4.5.3 Medical Issues

4.5.3.1 Definition of trial protocol and operations

The clinical protocol has been defined agreed with the other partners:

- The protocol will last 3 months
- There will be 2 sessions per week (a total of 24 sessions)
- Each session will last 60 minutes, out of which 30 minutes will be dedicated to the cognitive training and the rest to the social activation
- Care centre sessions and home sessions will follow a similar model
- The follow up assessment will take place three months after the elderly participation in SOCIABLE

This protocol is presented in detail in Deliverable D1.2.

4.5.3.2 Definition of sessions

FSL will be involved in individual and group sessions. The group sessions will be organized at the Neuro-motr Day Hospital and will be conducted with the use of the MS Surface Platform; the individual sessions will be conducted by the use of the Tablet PCs at elderly homes.

4.5.4 Localization Issues

In addition to the SOCIABLE Platform, the other resources to be translated into Italian include:

- Games
- Book of life Application
- Medical Tests
- Back Office
- Technical documentation
- Informed Consent Form
- Brochures of the SOCIABLE Project

4.5.5 Human Resources Issues

4.5.5.1 Identification of staff required

- Clinical Experts:
 - 2 Geriatric Physicians
 - 1 Neurologist Physician
 - 2 Neuropsychologist
 - 2 Speech therapists
 - 2 Nurses
- IT Technicians: provided by CEDAF
 - 1 Technicians: provided by CEDAF
 - 1 Technicians: provided by FSL

4.5.6 Training Issues

All professionals involved in the pilot operations will need to be trained in the use of the MS Surface Platform and in the procedures of the Trial defined in the Protocol.

A detailed training plan on technical/technological matters will be organized by CEDAF, according with the different role and specific competence of the professionals involved.

A specific training will be organized and performed by the medical experts to the professionals involved in the Pilot Operations procedures on management of both individual and group sessions and a specific training will be provided to the care givers involved in the in-home sessions.

4.5.7 Ethical Issues

4.5.7.1 Ethical Management Operations

A SOCIABLE Ethical Committee has been constituted, in order to deal with the Ethical Issues and agreed an ethical management methodology to be applied in the project.

An Informed Consent Form has been agreed and defined by all pilot sites. The Informed Consent includes a detailed description of the clinical trial protocol, the data collection, processing and analysis procedures. All data to be collected will be anonymized.

FSL will submit the final version to the FSL Ethical Committee before to start the pilot phase.

4.5.8 Assessment

The status of the pilot site is at moment positive and satisfactory; at moment there are not special issues that may create future complications.

4.5.9 Plan for completing the preparation

Our plan for completing the Pilot Site preparation includes:

- To buy the 5 Tablet PCs, as soon as technological partners will be finalized the decision about the Surface PC platform considered as the most suitable.

4.6 Current Status of PREVI

4.6.1 Infrastructure Issues

4.6.1.1 Selection of Physical Space

A reserved room located in the Day Centre “Tres Forques” has been identified to be dedicated to the SOCIABLE sessions with the MS Surface Platform. It is a service from the municipality with private management. The room located is wide enough and comfortable to house the SOCIABLE platform.

The centre provides care to adults from 60 years and older who wants to stay in their homes but need specialized care attention due to aging problems and psychosocial problems.

Concerning the Tablet PCs for the in-home use, they will be located at elderly's homes, selected with regards to specific requirements.

4.6.1.2 ICT Procurement

PREVI has bought 1 Microsoft Surface Platform to be used at the day centre. 10 Tablet PCs to be used at the elderly home are going to be bought, supported by UPV.

We are still waiting for the final decision by technological partners on the typology of Tablet PCs (with the features required) to be ordered (probably the model "Dell Studio 17 Touch" since it has the required features and it can provide a more functional and ergonomic interface for elderly users).

4.6.2 User Selection Issues

PREVI will select a total of 40 users, all belonging to Target Group A (healthy elderly) for the SOCIABLE Pilot: 20 users to be trained with the MS Surface Platform at the Day Centre and 20 users to be trained with Tablet PCs at home.

PREVI will interview experts from the day centre. These experts will indicate the most appropriate users to use SOCIABLE. PREVI will then offer the application to the users and explain the procedure. Afterwards the SOCIABLE assessment protocol will be applied. Following the exclusion/inclusion criteria we will select the final sample and ask them to sign an informed consent form.

The selection and recruitment will be set according to the cognitive battery and the procedures outlined in D2.1.

PREVI will provide one psychologist with expertise in neuropsychological assessment, psychological rehabilitation, and clinical psychology in elderly (at least five year experience).

4.6.3 Medical Issues

PREVI will follow the trial protocol agreed with the rest of the partners.

PREVI will focus on both individual and group sessions. The group sessions will be organized at the Day Centre and will be conducted with the use of the MS Surface

Platform; the individual sessions will be conducted by the use of the Tablet PCs at elderly homes or at the Day Centre with the MS Surface.

4.6.4 Localization Issues

In addition to the SOCIABLE Platform, the other resources to be translated into Spanish include:

- Games
- Book of life Application
- Medical Tests
- Back Office
- Technical documentation
- Informed Consent Form
- Brochures of the SOCIABLE Project

Currently the Informed Consent Form and the Medical Tests are now available in Spanish.

4.6.5 Human Resources Issues

The people involved in the pilot operation are:

- 1 Neuropsychologist
- 2 Carers/Social-Health Professionals
- 1 IT Technician, provided by UPV

UPV will support PREVI on technical matters during all phases of the pilot operations.

4.6.6 Training Issues

All professionals involved in the pilot operations will need to be trained in the use of the MS Surface Platform and in the procedures of the Trial defined in the Protocol.

A specific training on the use of the SOCIABLE platform and services will be organized by UPV, according to the different role and specific competence of the professionals involved.

A specific training on the medical processes of the project (selection, evaluation, management of sessions) will be organized and performed by PREVI to the professionals involved in the Pilot Operations.

4.6.7 Ethical Issues

Before the commencement of the pilot phase of the SOCIABLE project, the Clinical Protocol will be presented for approval to the Ethical Committee of the "Tres Forques" day centre.

4.6.8 Assessment

The status of the pilot site is at moment positive and satisfactory; at moment there are not special issues that may create future complications.

4.6.9 Plan for completing the preparation

Our plan for completing the Pilot Site preparation includes:

- To purchase the 10 Tablet PCs. This should be done before the end of the year (month 20)
- Translation of Sociable services and technical documentation. This should be done before the end of the year (month 20).

4.7 Current Status of TRONDHEIM- Kommune

4.7.1 Infrastructure Issues

To perform the pilot site operation Trondheim has chosen 3 day care centre which are located in Valentinlyst Health and Welfare centre. The day care centres have about 60 formal users. Two of the centres are specialised for people with dementia. These patients are frail both physical and cognitive and they may have several diagnoses. They stay in day care center because they can't handle their daily life at home. We have to presume that some of them will drop out of the sessions because of their health condition. A Sociable platform will be placed in a special room where the sessions will take place. Trondheim shall include 43 users with Alzheimer`s disease. These users will be recruited from the day care centre. 5 healthy users will be recruited by announcing the Sociable project in the local senior centres and by using the staff at the information centre for seniors to inform about the project.

Trondheim pilot site will need 12 months to be able carry through the pilot site operation from 01.04.11- 31.03.12.

Technical equipment and time for delivering are investigated and identified. A plan for how to handle drop outs will be finished in December 2010.

4.7.2 User Selection Issues

43 users with Alzheimer`s disease MMSE 20 – 24 will be included and 5 healthy users. Inclusion criteria are described in the protocol.

4.7.3 Medical Issues

Trondheim pilot site has made plans for how to perform the training sessions. There will be group sessions and individual sessions at the day care centre for group C. For the healthy users group A the plan is to have individual sessions.

4.7.4 Localization Issues

The Sociable platform has to be translated into Norwegian. Most of The assessment battery is validated into Norwegian. Technical documentation is going to be translated where that might be necessary.

4.7.5 Human Resources Issues

To be able to carry through the sessions both in the day care centers and at home for individuals, the service from several social workers may be needed.

About 20 employees will be involved in the pilot site operation.

- 1 technical expert
- 1 doctor
- members from the local project group
- 14 employees from the day care centre

There are already made contact with our technical partner Singularlogic, and a plan for collaboration will be ready in December.

4.7.6 Training Issues

About 20 employees have to be trained to perform and organize the sessions and to be able to use the back office. That includes members of the local project group and the local staff at the day care centres. Detailed plans for the training sessions will be ready in January 2011. Training sessions will take place in February – March 2011 in cooperation with the technical partners. To perform the assessment battery Trondheim pilot site has to buy these services from a doctor who also needs to be trained. The time estimated to be used for the assessment is about 200 hours.

4.7.7 Ethical Issues

An ethical protocol in Norwegian will be presented to The Regional Committee for Medical and Health Research Ethics in December. This protocol will describe the purpose and goal of Sociable, the target groups, the intervention and the ethical procedure. An approval is expected in January or in February. The protocol will follow all Norwegian laws and research criteria.

4.7.8 Assessment

Sociable will demand a lot of effort, time and resources from Trondheim pilot site in 2011. At the same time the daily activities in the day care centre shall continue. The pilot site operation demands a thorough plan for logistics to recruit users and to carry through the training sessions. The operation also needs a dedicated, motivated and stable group of employees with competence and skills to perform the training sessions. At this moment there is a problem with recruiting a doctor to perform the assessment battery.

4.7.9 Plan for completing the preparation

Period	Activities
Dec. 2010	<p>Ethical protocol is finished.</p> <ul style="list-style-type: none"> - That includes to define the inform of consent <p>Plan for training sessions for the social works is finished</p> <p>Planned activities according to the dissemination plan are done</p> <ul style="list-style-type: none"> - Norwegian leaflets - Information to the elderly council - Attending a national dementia congress <p>Contact with the technical partner is established</p> <ul style="list-style-type: none"> - The technical equipment is defined and ordered <p>Plan for how to recruit healthy users is described</p> <p>Recruit a doctor to perform the assessment battery</p> <p>Attend the partner meeting in Athens</p>
Jan. 2011	<p>Meeting with the technical partners</p> <ul style="list-style-type: none"> - Set up the technical equipment - Make the equipment ready for the implementation of games <p>Carry through the plan for training sessions</p> <p>Information to users and family members</p> <p>Plan for how to handle drop outs is finished</p>
Febr. – March 2011	<p>Training sessions are running.</p> <p>Plan for how to perform the training sessions with the users</p>

	are ready. Recruit users and perform the assessments battery for the first groups
April 2011- April 2012	The pilot site operation is running. - Carry through adjustments and evaluation continually Dissemination activities are done according to the plan

Table 3: Trondheim planning

4.8 Summarize status of the pilot sites

The following table summarizes the status of the pilot preparation, providing a level of accomplishment of each relevant action point.

	TRONDEIM	HYGEIA	AUSL	FSL	COFO	SPC	PREVI
Infrastructure Issues - Physical Space Selection	100%	100%	100%	100%	100%	100%	100%
Infrastructure Issues- Platform Procurement	100%	80%	80%	80%	80%	50%	100%
User selection- Attraction and selection plan	70%	50%	50%	80%	50%	50%	75%
Medical Issues- Trial protocol specified	100%	100%	100%	100%	100%	100%	100%
Human resources – Staff recruitment	100%	100%	100%	100%	100%	100%	100%
Localization Issues- Translation of platform and documentation	0%	50%	50%	70%	50%	50%	70%
Training Issues- Definition of training sessions	50%	0%	50%	50%	50%	50%	50%
Ethical Issues- Definition of medical protocol	100%	100%	100%	100%	100%	100%	100%
Ethical Issues- Ethical Committee Approval	0%	0%	70%	50%	70%	50%	50%

Table 4: Summarize status of the pilot sites.

5 Conclusions

This deliverable has presented the current status of each pilot site as well as the actions done to reach this status.

Firstly the list of critical point that each pilot site has to solve for the graceful commencement and execution of the pilots has been presented. This list covers all the requirements (administrative/organizational, technical, technological and medical) described in deliverable D1.3.

After that a detailed status of each pilot site, based on the list of points previously described has been presented. In addition each pilot site has provided a detailed plan for completing the actions that are still pending.

From the description of the status of the pilot sites we can conclude that currently status of the different pilot sites is positive and satisfactory. Most of the critical points have been solved and the ones that are still pending will be solve before the end of 2010, in time for trials.

The main achievements obtained until the moment, in all the pilot sites, are:

- Selection of the platforms to be used at the centres and at home. The platforms have been ordered in all pilot sites and some of them have received it.
- Definition of a common recruitment protocol that includes user selection (inclusion and exclusion criteria) and a battery of tests for the cognitive, affective and functional assessment. The recruitment protocol is detailed in deliverable D2.1.
- Definition of a common trial protocol, that details the duration of the trials, the number of sessions and how they will be scheduled, the duration of the sessions, the follow up process, etc. The trial protocol is described in detailed in deliverable D. 1.2.
- Creation of an ethical committee to deal with the Ethical Issues and agreed an ethical management methodology to be applied in the project.
- Definition of a common medical protocol that includes detailed description of the clinician trial protocol to be applied, the informed consent form, the data collection, the data processing and analysis processes as well as the target groups of the clinical study.

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Also some risks have been detected, but all the pilot sites (and the whole consortium) are working for solving them. The risks identify are:

- Availability of the Microsoft platform in time in some pilot sites.
- How to recruit and motivate healthy users for using SOCIABLE services