COMPETITIVENESS AND INNOVATION FRAMEWORK PROGRAMME

ICT PSP call for proposals 2008 - ICT PSP/2008/1

Project Acronym: **Long Lasting Memories**

Project Number: **238904**

Project Type: **Pilot Type B**

Project Full Title: **Long Lasting Memories**

ICT PSP Main Theme addressed: **1.4: ICT for ageing well with cognitive problems, combining assistive and independent living technologies**

Pilot Quality of Service Assurance

Pilot Site Audit Report Template

Nature:	**Report**
Dissemination Level:	**Confidential**
Version #:	**1.0**
Delivery Date:	**M8**
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Status:	**Draft**

Document History

Version	Issue Date	Stage	Content and changes
#1.0.0	17 January 2010	Draft	Initial Draft for Partner Review
1.0.1	5 February 2010	Draft	Final version including partner comments and input
1.0.2	18 February 2010	Final	Final review

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This document is a template to be used in performing and documenting the internal audit of each pilot site. Each pilot site will be audited over the course of the several pilot iterations on two occasions, including once during the course of iteration 1 and once during one of the subsequent iterations.

Executive Summary

This ***Pilot Quality of Service Assurance Pilot Site Audit Report*** documents the audit performed of the pilot execution being completed at *xxxxxxxxx (name of pilot site and country location) on date(s).* This report includes the following sections:

- **Pilot Site Overview.** This provides a general overview of the pilot site and the timing of the audit activities.

- **Pilot Site Audit Checklist.** This documents specific items reviewed during the audit, focusing upon measurable, quantifiable, or binary conditions (presence/absence of documents, presence/absence of specific procedures, etc.) observed at the pilot site.

- **Pilot Site Summary Audit Report.** A report with a summary of more subjective items observed in the course of the audit is included at the end of the Audit Checklist.

Table of Contents

1 Pilot Site Overview

Pilot Site Location	*Physical Address of the pilot site, and name of facility*
Pilot Partner Organisation	*Name of the LLM Partner responsible for the conduct of the pilot.*
Pilot Start Date	
Pilot End Date	
Audit Date/Pilot Iteration	
Pilot Site Physical Description	*Refer to D4.1 for each pilot site for a physical description. Utilise this as a reference point and modify the description based upon direct observation. Make a note of any significant differences from the planned physical description indicated in the original pilot plan as per D4.1.*
Name of Pilot Partner Representative	*Each pilot site is to assign a partner representative to work with the internal auditor, in particular to identify documentation that is not available in English and to act as a liaison with the pilot team. The name of this responsible individual is to be identified.*

2 Pilot Site Audit Checklist

The following checklist is to be filled out by the staff member performing the audit. Comments area should be used to explain any exceptions.

	TOPIC	Y/N	COMMENTS
1	**Pilot Preparation**		
1.1	Was the pilot subject to an ethical review approval process?		
1.2	Are approval documents, including composition of review board, in trial file/binder?		
1.3	Is summary statement (in English language) in file?		
1.4	Has summary statement been sent to LLM coordinator for central files?		
1.5	Was the pilot subject to IRB approval process?		
1.6	Are approval documents, including composition of review board, in trial file/binder?		
1.7	Is summary statement (in English language) in file?		
1.8	Has summary statement been sent to LLM coordinator for central files?		
1.9	Are the following documents available in the trial file/binder?		
1.9a	Printed copy of all scientific and technical information about the LLM product (specifications), or a statement of the location of electronic files.		
1.9b	Informed Consent Form (English language)		
1.9c	Informed Consent Form (localised)		
1.9d	LLM Information Packet provided to subjects (English language)		
1.9e	LLM Information Packet provided to subjects (localised)		

	TOPIC	Y/N	COMMENTS
1.9f	Recruitment advertisement and description of how advertisement was used (i.e., where published, etc.), in English language		
1.9g	Recruitment advertisement and description of how advertisement was used (i.e., where published, etc.), localised		
1.9h	Insurance statement, if required		
1.9i	Template for Screening Log		
1.9j	Template for Enrolment Log		
1.9k	Template for Subject Identification Code List		
1.10	Is there a list of all individuals involved in the trial programme's execution (including both administrative and clinical staff) in the trial file/binder?		
1.11	Are there CV's for each of the clinical staff involved in the programme's execution		
1.12	Is a copy of the pilot plan for the location in the trial file/binder? (in English language)		
1.13	Is a copy of the pilot plan, localised, if appropriate, in the trial file/binder?		
1.14	Evidence of the completion of training by each staff member involved in the LLM trial (including name of person, type of training, dates of training, and signature indicating attendance).		
1.15	Based upon observation and/or interviews, validate that all data collection and recordkeeping elements of the pilot plan are observed and identify any exceptions.		
1.15a	If there are exceptions, identify whether they are permanent changes to the plan or anomalies.		
1.16	Is there a Data Protection Plan in the trial file/binder? To ensure completeness, does the Data Protection Plan include:		

	TOPIC	Y/N	COMMENTS
1.16a	The steps taken at the pilot site to actively ensure the anonymity of trial subjects and protection of personal data.		
1.16b	Communication to the subjects regarding the use of their personal data and protections available to them, including contact names within the project and at a national level.		
1.16c	The steps taken at the pilot site to provide physical security of all records, including documents in both electronic and paper forms.		
1.16d	Interview pilot site staff responsible for execution of the Data Protection Plan to determine whether they understand and routinely execute the elements of the plan for which they are responsible.		
1.17	Is there evidence that the pilot staff responsible for testing subjects is familiar with the testing material and know how to apply the tests appropriately?		
1.17a	Can the testing staff show documentation for the tests being used (including instructions for performing the tests) and explain when tests are done?		
1.17b	Can the testing staff explain how they analyse the test data?		
1.17c	Can the testing staff explain how they upload the data to the server?		
2	**Pilot Execution**		
2.1	Have there been any adverse events during the course of the pilot, to this point? If so, explain in Comments section.		
2.1a	Have any adverse events been communicated to ethical boards or IRB, if required?		
2.1b	Have any adverse events been communicated to the LLM coordinator?		

	TOPIC	Y/N	COMMENTS
2.1c	Have any adaptations of the LLM service, or other actions been advised as a result of adverse events? If so, explain in the Comments section.		
2.2	Have monitoring visits by IRB or other regulatory boards been conducted at the pilot site?		
2.2a	If so, have the results of such visits been communicated to the LLM coordinator?		
2.3	For each subject, do source document files exist? (auditor: perform a count of all files to determine that there is a match to the number of subjects enrolled in the trial)		
2.4	For the pilot site, is a Screening Log completed? Count the number of individuals included on Screening Log.		
2.5	For the pilot site, is an Enrolment Log completed? Count the number of individuals included on Enrolment Log.		
2.6	For the pilot site, is the Subject Identification Code List completed? Count the number of individuals included on the Subject Identification Code List.		
2.7	For each subject, (randomly review 15% of the subject files), does the file include:		
2.7a	Signed Informed Consent form		
2.7b	Source documents with results of screening tests		
2.7c	Written consent to participate in LLM trial from subject's primary physician		
2.8	Does the number of subjects enrolled, in active and control groups, match the number of subjects according to LLM central database for the pilot site?		
2.9	Indicate whether (and how many) any subjects were observed completing the physical and cognitive training outlined in the pilot plan, and over how many days.		

	TOPIC	Y/N	COMMENTS
2.10	Indicate whether the LLM intervention is being completed in a standardised fashion.		
2.10a	Can the pilot staff explain what the LLM intervention is? Ask them to explain it in the manner in which it is typically explained to the subjects.		
2.10b	Can the pilot staff explain how the LLM equipment is used?		
2.10c	Is all equipment for the LLM intervention available and functioning?		
2.11	Are subjects assigned randomly to study and control groups? If not, how is assignment done?		
3	**Pilot Wrap-Up**		
3.1	Does the pilot plan include steps to be completed at the conclusion of each pilot iteration, including the execution of follow-up testing of subjects?		
3.2	Is a User Survey template included in the pilot file/binder, localised as appropriate?		
3.2a	Are instructions for the use of the User Survey instrument included in the pilot plan?		
3.3	Applicable only for audits performed subsequent to the conclusion of at least one pilot iteration:		
3.3a	Has the User Survey been conducted?		
3.3b	Have all results been provided to the LLM coordinator?		
3.3c	Has the Pilot Staff Survey been conducted?		
3.3d	Have all results been provided to the LLM coordinator?		

3 Pilot Site Summary Audit Report

This section is to be used by the auditor to include a summary statement about the pilot, any exception conditions observed at the site, with recommendations for any procedural changes, additional training, or other actions that will mitigate any risks or enhance the quality of the data from the pilot.