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**

D.4.2 Pilot Quality of Service Assurance & Training Guide

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Abstract

This deliverable presents the Pilot Quality of Service Assurance & Training Guide providing an overview of the key activities that have been designed to assure the effective and consistent conduct of the pilot across the five pilot countries. With this guide we will monitor adherence to defined policies, procedures, training standards, reporting and record-keeping at the pilot sites and in central databases and files maintained for the LLM project.

Document History

Version	Issue Date	Stage	Content and changes
#1.0.0	14 September 2009	Draft	Initial version, in outline form, issued to project partners for comment and preliminary input
1.0.1	22 November 2009	Draft	Outline version, with content changes from project partners
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List of participants:

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Executive Summary

The LLM project is, at its core, focused upon pilot testing the LLM solution, comprised of an independent living solution, a cognitive training component, and a physical training component. The pilot test will not only validate the success of the integration work completed to bring these three elements together, but also each element of the product as a precursor to delivering the LLM solution to the market, including:

- Technical operation
- Installation procedures
- Training programmes
- Support approach
- User acceptance
- Usability
- Accessibility
- Therapeutic outcomes

The pilot is being conducted in five countries (Austria, France, Greece, Spain, and the UK) led by LLM consortium partners, each of which is responsible for managing the pilot conduct in a manner that ensures a consistent approach to produce quality data about the performance of LLM. Each pilot site has defined the details of the pilot programme as it will be conducted at their location, in compliance with national regulatory requirements. These details are described in D4.1 "Pilot Deployment Plan."

This ***Pilot Quality of Service Assurance & Training Guide*** provides an overview of the key activities that have been designed to assure the effective and consistent conduct of the pilot across the five pilot countries. This document will monitor adherence to defined policies, procedures, training standards, reporting and record-keeping at the pilot sites and in central databases and files maintained for the LLM project.

The document is comprised of the following 2 main sections:

Section 1: Quality of Service Assurance, which describes, in detail, the policies, procedures, activities, and checklists, that will be used to monitor and manage consistent performance of the activities of the pilot across each pilot location.

Section 2: LLM Training Activities, which provides an outline of the training activities that will be undertaken in the project. Training is designed to use a train-the-trainer approach, and this Section provides a view of how training will be completed on a centralised basis for all pilot sites, as well as how training will be executed in each country.

In addition, Annexes to this Guide provide reference information and examples of key templates, documents, and sample training materials.

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1 QUALITY OF SERVICE ASSURANCE PLAN

1.1 Background

This pilot of LLM is being conducted in five European countries, and the operation of the pilot is characterized by several unique elements that impact the management and monitoring of the pilot for purposes of quality of service assurance:

- LLM is a system that includes elements designed to enhance independent living as well as elements designed to improve cognitive health. While improvement of physical health is not a specific design goal for LLM, given that a physical training component is integrated into the system, some positive impacts on physical health may logically be anticipated, and will be measured on a nominal level through the course of the pilot as well.
- Given this design, which includes a layered intervention, there are several aspects of the solution that require specific attention in order to assure quality of service throughout the term of the pilot:
    - This is a project that integrates several existing technology components, including software and hardware elements. The quality of the underlying software and hardware, as well as their integration will be assured by testing by the technical team, and the conduct of a pre-pilot in a user setting in Austria.
    - Within the course of the pilot project itself, an internal service/support for the pilot is required to ensure the efficient and accurate installation of the LLM system at each pilot site and to ensure ongoing support for hardware, software, and integration elements of the system are in place and work effectively. This internal service/support aspect includes the training of trainers for each country deployment, which is described in Section 3 of this Guide.
    - The pilot project, because it utilizes human subjects, must comply with all national regulations, the elements of which are described in D6.1 “Report on National & European Legislation.” In some countries, there are no specific regulations related to this type of intervention, while in others, the pilot project may be submitted to the same scrutiny as that applied to clinical trials.
    - The LLM System is being tested in different types of environments, including home settings (Austria), assisted living/group environments (UK), social centres (France), and clinical environments (Greece, Spain). Because of these differences, it is important to recognise the following:
        - Some data collected in the pilot will be consistent across all settings and countries, to enable comparison of specific aspects of the LLM system, its efficacy, and impact on the users.
        - Because of the nature of the different settings, some data collected will be specific to the pilot site, and will not necessarily be able to be compared with data from other sites/countries.
        - Analysis of data from the pilot will distinguish between the results of the various environments versus those results that are based upon data collected from consistently applied testing.

1.2 Methodology

The pilot is not simply intended to validate the technical viability of the LLM system, but also to quantify the effectiveness of the solution through the collection of physical and cognitive measures. To ensure the quality of the data collected on these measures, many of the principles behind Good Clinical Practice (GCP)[1] have been applied within the design of the pilot, including the elements described following. Note that these principles are used to guide the conduct, and provide structure that will ensure that the trial is completed consistently across sites, and assures the safe and ethical treatment of all subjects in the pilot. The key elements that have been established are:

- Clearly defined trial protocols for each site, including the objectives, design, methodology, and organisation of the pilot, including all steps included to protect the well-being of the pilot participants. This will define the length of the intervention, the procedures to be followed to recruit and screen participants, assign them to study and control groups, and monitor their health throughout the course of the study.
- Roles and responsibilities of each of the consortium members in the pilot will be defined, including their conduct within the trial for training, deployment, support and service, as well as internal and external reporting.
- Well-defined pilot execution plan for each country, including all logistics for the pilot, etc.
- Well-defined and consistent inclusion and exclusion criteria across all pilot sites.
- Informed consent procedures to ensure that all participants have a clear understanding of the intervention and any related risks from participating in the pilot. Informed consent procedures will conform to national ethical requirements.
- Consistently applied screening tests across all countries[2], to be applied at the beginning and end of the intervention, along with a post-testing screening to measure retention of any results from the intervention

1.3 Quality of Service Assurance Policy

The LLM Service is being developed and tested in this project, including pilot testing directly with end-users. This pilot test will include testing of all aspects of the service and product. Quality of the technical product will be affirmed through the use of the system in the trial, but quality control testing is not the focus of the pilot. Rather, quality of service for the LLM System will be comprised of:

- Quality of the surrounding services to enable installation and implementation of the product
- Quality of supporting documentation, training, and support services for the product
- Quality of the trial process and adherence to the defined protocol

In addition, quality of service for the LLM project will include:

- Quality of support for the execution of all LLM pilot activities

[1] ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice E6(R1), 10 June 1996. Refer to Annex 4.1 for a list of the Principles of GCP.

[2] Note that some of the screening tests include ones that are subject to cultural difference across countries, and thus, some specific screening tests are different. However, the tests selected for use in each country are deemed to provide similar indicators of cognitive or physical health.

- Quality of scientific data collected through the LLM pilot activities

To provide this quality of service, pre-pilot and pilot activities will be planned to ensure the quality of the LLM system and supporting services, and the details of these activities are described for each pilot site in D4.1 "Pilot Deployment Plan." In addition to complying with each country's requirements relative to either clinical trials (if applicable) and/or testing with human subjects (i.e., ethical guidances) the quality of service will be further assured through the monitoring of pilot activities by a third party within the LLM consortium (GSI).

1.4 Quality of Service Assurance Activities

Quality of service assurance activities include the following:

Pre-Pilot:

- ***Pilot Planning***. Preliminary planning activities, including the selection of inclusion and exclusion criteria, screening tests (basic tests to be executed consistently across all sites, as well as tests used to monitor specific measures that may differ between sites), as well as the details of the intervention to be executed for testing and control groups. Pilot plans are reviewed by all consortium partners to ensure consistency
- ***Pilot Approvals.*** In each country, the pilot partner is responsible for submitting the details of the LLM pilot to appropriate regulatory board(s) for approvals. At a minimum, due to the use of human subjects, the pilot is submitted to an ethical review board, and in some countries, may be required to comply with the requirements of an Institutional Review Board (IRB) for clinical trials.
- ***Training.*** Prior to the beginning of the first iteration of the pilot, training will be held at a central location (date and location to be determined) for representatives of each pilot site. A designated National Technical Expert will be trained in the operation and administration of LLM, and will, in turn, train staff at the pilot site. In addition, the training provided at the pilot site will include training on all procedures that may be required to meet regulatory requirements of national boards or bodies, data protection, and recordkeeping required to ensure quality of scientific data.

Pilot:

- ***Internal Audit.*** During the course of the pilot, an internal audit of each pilot site will be performed on two occasions: once during the first iteration, and once during a subsequent iteration. If there are determined to be significant quality issues with a particular site during the first iteration, a follow-up audit will be scheduled for the second iteration. If there are no observed, significant exceptions during the first audit, a second audit will be scheduled for either Iteration 3 or Iteration 4 of the pilot.

Project month	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	Pre-pilot			Iteration 1				Iteration 2				Iteration 3				Iteration 4			
Austria																			
France																			
Greece																			
Spain																			
UK																			

At the conclusion of the audit, in addition to the detailed checklist, a summary statement will be prepared by the staff member (GSI) performing the audit, and will include the following:

Audit Summary Statement

- Pilot Site Location
- Description of Pilot Setting (overall facility),
- Description of Pilot Deployment Setting (area where LLM System is installed) including photographs of the site
- Pilot Site Staff – description of the number of pilot staff members encountered during the audit, their roles and responsibilities
- Physical location and condition of records and materials related to the pilot, including the security measures taken to control access to records and ensure all subject data is protected in compliance with ethical and legal requirements.
- In addition, any significant anomalies discovered during the audit, as noted in the audit checklist, should be described in more detail in this Summary Statement.

Post-Pilot:

- ***Final Report.*** A final report will be published at the conclusion of the pilot, including a summary of clinical and technical results, as well as user perspectives gleaned from surveys and therapeutic intervention compliance.

1.5 Key Performance Indicators

The following is a list of the key objectives for the pilot, the indicators of success against the stated objective, and the specific goals as stated in the LLM DoW. In addition, this Table provides guidance as to the tool that will be used to complete these measurements. The measurement tools are described in further detail following the section.

No.	OBJECTIVE	INDICATOR	GOAL	How Measured
O1. Integrate two existing ICT solutions with physical training equipment, thus delivering innovative ageing well / independent-living support services for elders				
1.	Ensure that all technology components are effectively integrated in field operation.	Successful technology installation in field is completed by trained staff according to budgeted time frames, and technical workarounds are not required.	For all sites, no or minimal: • Additional installation costs • Additional training costs and staff • Time extensions	Pilot Staff Survey Support Call Log Statistics
2.	Ensure that all technology components, and the integrated solution operate according to design in field operation.	Number of technical support calls for non-training issues is within established threshold. Comparison of log-files and system responses with diary notes of the test persons and/or supporting and trainer persons indicate correct and consistent operation of the system.	For all the rest piloting sites, where the trained staff might help the elderly less than 3 calls per installation. Log files will be correlated with caretaker notes: no discrepancies will be allowed, in the sense that all accidents must be identified by the system.	Support Call Log Statistics Pilot Staff Survey System Log Files
3.	Ensure that all documentation (training and reference) is complete and accurate.	Number of technical support calls for training issues is within established threshold.	For all sites, at most 3 calls per installation.	Support Call Log Statistics

No.	OBJECTIVE	INDICATOR	GOAL	How Measured
4.	Ensure that all user interfaces with the technology meet usability needs of the operators and end-users.	End-user satisfaction levels regarding usability of the technology are within established threshold, based upon interviews with and questionnaires from end-users and operators.	For "At Home" installations, a goal of 75% satisfaction on the service is set, bearing into account that most elders still feel uneasy with technological solutions. For "Day care centre" installations a goal of 80% is set, since the elders are free to use the service at their own discretion, while being provided help by the trained supervising staff. For "Clinical Care Facilities" installations a goal of 85% for user satisfaction is set, since the **LLM** training is included in the services of the clinical centre and will be thoroughly explained to the users.	User Survey
5.	Ensure that the form factors employed are considered attractive by users	End-user satisfaction levels regarding form factor attractiveness are within established threshold, based upon interviews with and questionnaires from end-users and operators	The same as for objective 04.	User Survey

No.	OBJECTIVE	INDICATOR	GOAL	How Measured
O2. Demonstrating the significant impact potential of LLM service in five different countries				
1.	The user experience with the solution is positive, encouraging compliance with a recommended programme for that user.	End-user compliance with specified programme is within established target range.	"At Home" end-users should be in accordance with their testing programme at approximately 85%. "Day care centres" and "Clinical Care facilities" users should be in accordance with their programmes over 90% taking into account that their supervisors set the parameters for each user	System Log Files User Survey
2.	Cognitive and Physical Outcomes	End-users meet or exceed defined primary (neuropsych testing) and secondary (real-world outcome) outcome measures.		Clinical Results Analysis
3a		Primary efficacy endpoint: Improvement of experimental group in standardized cognitive function and cognitive/motor activity in daily living relative to control groups.	These results should be coherent with recent studies on neuroplasticity and cognitive training.	Clinical Results Analysis
3b		Key secondary endpoint: Quality of life related to improvement in cognitive, motor and social function indices and autonomy.	More than 30% of personal interviews and caretaker or relative answers should indicate positive evolutions in these fields. Another 30-40% should denote stable situation for the user. Less than 30% should detect cognitive or physical deterioration.	Clinical Results Analysis
3c		Key secondary endpoint: Changes in abnormal brain waves that correlate with mild cognitive decline and dementia (using MEG-Konstanz or EEG).	These results should be coherent with recent studies on neuroplasticity and cognitive training.	Clinical Results Analysis

No.	OBJECTIVE	INDICATOR	GOAL	How Measured
4.	Legal and Ethical Compliance	Based upon a detailed ethical and legal review, all relevant national and European level requirements are met, enabling the solution to be delivered competitively across the EU.	All pilots should comply with the ethical guidelines in this sector. A minimum set of complains (less than 1% among the service's users) should be expressed.	Internal Audit
O3. Verify the technical, organisational and legal feasibility of LLM service along the complete value chain of stakeholders				
1.	Installation procedures are efficient and require minimal specialised skill for completion.	Technical staff, with defined minimum skill level, is able to effectively install the system without additional training.	All installations take place on time and without problems in the functionality of the system. Possible acceptable problems, if any, may only be attributed to hardware problems, and not software or integration problems.	Pilot Staff Survey
2.	Installation procedures are defined and documented thoroughly and accurately.	Number of technical support calls from installers is within established threshold.	At most 5 calls per installation	Support Call Logs
3.	Training programme for operators is thorough and accurate.	Number of technical support calls from operators for non-fault conditions is within established threshold.	At most 5 calls per "At Home" installation and 3 calls for other installations.	Support Call Logs
4.	Technical support and help desk procedures are effective.	All reported technical problems are addressed on a timely basis and responses are commensurate with the severity of the issue.	Less than 0,1% of the overall testing population should call or email us for not being supported by our staff.	Support Call Logs
5.	Monitoring procedures are well-documented and easy to complete.	Data collected from during and after pilot is complete and effective in providing insight into outcomes for end-users.	All requirements for operational and technical specifications should be able to be addressed in the provided documentation.	Internal Audits Clinical Results

No.	OBJECTIVE	INDICATOR	GOAL	How Measured
O4. Verify the sustainability, scalability and applicability of LLM services across Europe				
1.	End-User Response	Based upon questionnaires and interviews, pilot organisations and end-users report a high level of satisfaction with the use of and results from the solution. The questions will include evaluation of user-friendliness, usability, safety features, usefulness of actuators, correspondence of the personal training programme to the user's own perceived needs.	For "At Home" installations, a goal of 75% satisfaction on the service is set, bearing into account that most elders still feel uneasy with technological solutions. For "Day care centre" installations a goal of 80% is set, since the elders are free to use the service at their own discretion, while being provided help by the trained supervising staff. For "Clinical Care Facilities" installations a goal of 85% for user satisfaction is set, since the **LLM** training is included in the services of the clinical centre and will be thoroughly explained to the users.	User Survey
2.	Pricing	Pricing of the solution is competitive within a group site (i.e., elder care home) setting, and budgetary requirements of elder care facilities can be addressed effectively through the solution.	More than 70% of the answers to a related question in the user questionnaires should differentiate less than 10-15% to the real pricing for the product.	User Survey
3.	Accessibility	The deployment of the solution is shown to be able to be delivered in a range of different elder care environments, and with minimal requirements for enhancement of infrastructure.	All three types of installations should be validated and approved by their end-users. This would demonstrate that **LLM** can be successfully deployed in various situations.	User Survey

No.	OBJECTIVE	INDICATOR	GOAL	How Measured
4.	Differentiation	The solution is sufficiently differentiated in terms of both features and quality of outcomes as compared to other solutions for cognitive exercises, providing competitive advantage through unique solution capabilities.	Less than 25% of the elders having used another ICT solution for independent living or cognitive training (since one that has both components does not exist, yet – hence the innovation of **LLM**), should express the opinion that the other service was more helpful, robust, easier to user or more affordable.	User Survey

The measurement tools that will be developed to support the determination of success in achieving the goals of the programme include, in summary:

- **Pilot Staff Survey**. At the conclusion of the installation of the pilot system, a survey will be completed to identify any weaknesses in the training and documentation, as well as the ease of installation and operation of the pilot system. A second survey will be completed at the end of the first and second pilot iteration to identify any issues with operational issues associated with the LLM system (additional surveys beyond this are deemed not to be effective as survey fatigue would be likely to skew the results).

- **User Survey.** At the conclusion of each pilot iteration users will be surveyed on a range of issues, related to design, ease-of-use, satisfaction with results, pricing, accessibility, etc. In addition to a survey of the users themselves, surveys will also be done with family members who act as caregivers to the users to obtain their perspectives

- **Support Call Log Statistics.** All technical support calls from pilot partners to the Support team will be logged, and at the end of each pilot iteration, and on an overall basis for the entire LLM project, statistics will be provided as indicators of the technical accuracy and effectiveness of the LLM service, effectiveness of the training programme and documentation, as well as whether issues required escalation beyond the first level of support either on the basis of timeliness of responses or technical knowledge of the support staff.

- **System Log Files**. System log files will be analysed at the conclusion of each pilot iteration (and collectively over the entire period of all pilots) to identify technical or other issues that arose during the course of the pilot.

- **User Programme Compliance Statistics.** The LLM system will provide statistical data indicating whether, and to what extent, participants in the trial complied with their recommended training programme. These statistics are expected to provide an understanding of sustainability of user interest in and satisfaction with the programme.

- **System/Technical Errors and Exceptions.** The LLM system will provide statistical data indicating whether there were errors or exception situations that occurred during the conduct of the pilot. These statistics will provide an understanding of the technical accuracy and capability of the system.

- **Internal Audit Results.** Audit checklists from each pilot site will provide input to an overall report on the internal audit. In addition to these checklists, a summary report on subjective observations of the pilot will be made by the staff member providing audit services. These will be published as part of the D4.5 "Post implementation review / Final evaluation report."

- **Clinical Results.** At the conclusion of the pilot, all clinical data will be analysed, and the results will be published as part of the D4.5 "Post implementation review / Final evaluation report."

Following is a view of the schedule on which the various metrics outlined above will be collected and/or published during the course of the pre-pilot and pilot activities.

Project month	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	Pre-pilot			Iteration 1				Iteration 2				Iteration 3				Iteration 4			
Pilot Staff Survey																			
User Survey																			
Support Call Logs																			
System Log Files																			
Internal Audits																			
Clinical Results																			

1.6 Pilot Roles & Responsibilities

Pre-Pilot Activities	Partner(s)
Project Management	TERO
Technical Development Activities	AUTH/RALTEC
Pilot Regulatory (IRB/IEC) Approvals	Pilot site partners: • RALTEC (Austria) • E-Seniors (France) • AUTH/Vyronas (Greece) • INTRAS (Spain) • Milton Keynes Council (UK)
Training Development & Delivery	GSI/UKON/ATHENA RC/AUTH/RALTEC
Installation Procedures	AUTH/RALTEC
Installation/Technical Documentation	AUTH/RALTEC
Support Procedures	AUTH/RALTEC
Quality of Service Assurance Procedures	GSI
Pre-Pilot Screening Tests	UKON/RALTEC
Pre-Pilot Testing	RALTEC (Austria)

Piloting Activities	Partner(s)
Technical Installation	AUTH/RALTEC
Technical Support	AUTH/RALTEC
Pilot Conduct	Pilot site partners: • RALTEC (Austria) • E-Seniors (France) • AUTH/Vyronas (Greece) • INTRAS (Spain) • Milton Keynes Council (UK)
Scientific/Clinical Support	UKON/ATHENA RC
Internal Audit	GSI
Technical Adaptations	AUTH/RALTEC

Post-Pilot Activities	Partner(s)
Technical Data Analysis	AUTH/RALTEC
Clinical Data Analysis	UKON/ATHENA RC
Pilot Wind-down activities	Pilot site partners: • CEIT (Austria) • E-Seniors (France) • AUTH/Vyronas (Greece) • INTRAS (Spain) • Milton Keynes Council (UK)
Assemble Final Report	GSI

1.7 Essential Documents for the Conduct of a Clinical Trial

The following is a summary of the documents deemed to be essential for the conduct of a clinical trial, according to ICH Good Clinical Practice[3]. Included here is an analysis of each of these documents, their relevance to the LLM Pilot, and, if the document is relevant to LLM, the form the document will take for purposes of recordkeeping and internal audit.

1.7.1 Before the Clinical Phase of the Trial Commences

Listed following are the documents that are related to preparations for the clinical phase of a trial, and are largely comprised of documents that ensure consistency of communication between investigators who are conducting the clinical trial and the sponsors, or between the investigators of the trial and the participants. In addition, except in cases where the LLM Pilot is to be conducted as a formal clinical trial, few of these documents are required. However, in keeping with the policy to conform as nearly as possible to GCP, documents will be developed and retained either on a central basis (as applicable to the overall project) or at each pilot site, and the location and form of such documents are described below.

Document	Description	Relevance to LLM Pilot	Location/Form
INVESTIGATOR'S BROCHURE	To document that relevant and current scientific information about the investigational product has been provided to the investigator.	All pilot sites are a part of the LLM consortium, and are intimately involved in a series of meetings to define and discuss the scientific information about the product, and receive copies of all scientific and technical information.	All documents are archived to, and are available to all pilot sites via the LLM website's partner area, and are part of the deliverables of the overall project.
SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF	There is no single protocol, but rather, each pilot site has defined the specific details of the pilot (see D4.1) and will execute in accordance with that plan and in compliance with any country-level review boards (ethical or other).	D4.1 is available on LLM partner website in electronic form.

[3] ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice E6(R1), 10 June 1996.

Document	Description	Relevance to LLM Pilot	Location/Form
INFORMATION GIVEN TO TRIAL SUBJECT			
- INFORMED CONSENT FORM (including all applicable translations)	To document the informed consent	Applicable in all pilot locations. Sample informed consent form is available in D4.1. For each subject, a signed informed consent will be required for participation in the project	Electronic version of sample is part of D4.1; signed paper copies kept in files at pilot site.
- ANY OTHER WRITTEN INFORMATION	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent	Applicable in all pilot locations.	Electronic version of content provided (both English language and localised versions) kept in files at pilot site and copy provided to coordinator for central LLM files.
- ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used)	To document that recruitment measures are appropriate and not coercive	Applicable as required by country review or ethical boards.	At pilot site, based upon requirements from regulatory authorities
FINANCIAL ASPECTS OF THE TRIAL	To document the financial agreement between the investigator/institution and the sponsor for the trial	Not applicable to the LLM pilot.	N/A
INSURANCE STATEMENT (where required)	To document that compensation to subject(s) for trial-related injury will be available	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities

Document	Description	Relevance to LLM Pilot	Location/Form
SIGNED AGREEMENT BETWEEN INVOLVED PARTIES, e.g.: - investigator/institution and sponsor - investigator/institution and CRO - sponsor and CRO - investigator/institution and authority(ies) (where required)	To document agreements	Not applicable to the LLM pilot.	N/A
DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING: - protocol and any amendments - CRF (if applicable) - informed consent form(s) - any other written information to be provided to the subject(s) - advertisement for subject recruitment (if used) - subject compensation (if any) - any other documents given approval/ favourable opinion	To document that the trial has been subject to IRB/IEC review and given approval/favourable opinion. To identify the version number and date of the document(s)	IRB: This is not expected to be applicable in any of the pilot countries, but if it is, it will be the responsibility of the pilot partner to maintain in accordance with the rules set out by their IRB. A summary statement regarding the IRB review, if applicable, shall be provided by the pilot partner to the LLM Project Coordinator. IEC: All countries involved in the pilot will require an ethical review of the pilot project due to the use of human subjects in the testing. Any documents associated with the application for such review and the outcomes of the review process will be retained at the pilot site. A summary statement regarding the ethical review will be provided to the LLM Project Coordinator, and included in relevant project reports.	Summary statements regarding IRB and IEC reviews will be kept electronically by the Project Coordinator in central LLM project files.

Document	Description	Relevance to LLM Pilot	Location/Form
INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE COMPOSITION	To document that the IRB/IEC is constituted in agreement with GCP	Documents regarding the composition of review boards shall be kept at the pilot site and an electronic copy provided to the LLM Project Coordinator	Retained in electronic form by the Project Coordinator in central LLM project files.
REGULATORY AUTHORITY(IES) AUTHORISATION/APPROVAL/ NOTIFICATION OF PROTOCOL (where required)	To document appropriate authorisation/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S)	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL	To document normal values and/or ranges of the tests	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TESTS - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)	To document competence of facility to perform required test(s) , and support reliability of results	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects	Not applicable to LLM service.	N/A

Document	Description	Relevance to LLM Pilot	Location/Form
INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS (if not included in protocol or Investigator's Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials	Not applicable to LLM service.	N/A
SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability	Not applicable to LLM service.	N/A
CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED	To document identity, purity, and strength of investigational product(s) to be used in the trial	Not applicable to LLM service.	N/A
DECODING PROCEDURES FOR BLINDED TRIALS	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment	Not applicable to LLM service.	N/A

1.7.2 During the Clinical Conduct of the Trial

Listed following are the documents that are relevant to the conduct of the clinical aspect of a trial. In countries where the pilot programme will be conducted as a clinical trial, the rules and requirements of the relevant IRB will determine whether the document is required, the form it must take, and where the document will be located. In keeping with the policy to conform as nearly as possible to GCP, some documents will be developed and retained either on a central basis (as applicable to the overall project) or at each pilot site, and the location and form of such documents are described below.

Document	Description	Relevance to LLM Pilot	Location/Form
INVESTIGATOR'S BROCHURE UPDATES	To document that investigator is informed in a timely manner of relevant information as it becomes available	Technical, procedural or administrative updates relevant to the conduct of the pilot (including inclusion/exclusion criteria, screening and monitoring tests, etc.) or operation of the LLM services will be distributed to each pilot partner through electronic means. It is anticipated that at the conclusion of each pilot iteration, some adaptations will be made to the system and will be documented and communicated to the partners prior to the beginning of the subsequent round of pilot testing.	Electronic documents will be emailed to pilot partner representatives and will be posted to the LLM website partner area.
ANY REVISION TO: - protocol/amendment(s) and CRF - informed consent form - any other written information provided to subjects - advertisement for subject recruitment (if used)	To document revisions of these trial related documents that take effect during trial	Same as above.	Same as above.

Document	Description	Relevance to LLM Pilot	Location/Form
DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING: - protocol amendment(s) - revision(s) of: - informed consent form - any other written information to be provided to the subject - advertisement for subject recruitment (if used) - any other documents given approval/favourable opinion - continuing review of trial (where required)	To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favourable opinion. To identify the version number and date of the document(s).	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
REGULATORY AUTHORITY(IES) AUTHORISATIONS/APPROVALS/NOTIFICATIONS WHERE REQUIRED FOR: - protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
CURRICULUM VITAE FOR NEW INVESTIGATOR(S) AND/OR SUB-INVESTIGATOR(S)		As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) INCLUDED IN THE PROTOCOL	To document normal values and ranges that are revised during the trial	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities

Document	Description	Relevance to LLM Pilot	Location/Form
UPDATES OF MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)	To document that tests remain adequate throughout the trial period	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
DOCUMENTATION OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS SHIPMENT		Not applicable to LLM service.	N/A
CERTIFICATE(S) OF ANALYSIS FOR NEW BATCHES OF INVESTIGATIONAL PRODUCTS		Not applicable to LLM service.	N/A
MONITORING VISIT REPORTS	To document site visits by, and findings of, the monitor	As appropriate per pilot country. In addition to monitoring visits relative to the conduct of the pilot as a clinical trial, a record of any internal LLM project audits will be kept, including a copy of a summary report for each visit, along with a review of all summary reports in the final pilot report.	At pilot site, based upon requirements from regulatory authorities for monitoring visits, as well as internal audit reports. Internal audit reports will also be kept centrally in LLM project files (electronically).

Document	Description	Relevance to LLM Pilot	Location/Form
RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS - letters - meeting notes - notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	As appropriate per pilot country. In addition to addressing the requirements of the regulatory authorities, a record of any exceptional issues (i.e., out of expected norm) during the course of the pilot will be maintained by the pilot partner in the form of an Exception Report, and a copy will be provided to the LLM coordinator.	At pilot site, based upon requirements from regulatory authorities, with a copy to the coordinator of the LLM project in electronic form. If not required by regulatory authorities, a record of exceptional issues will be provided to the LLM coordinator in electronic form.
SIGNED INFORMED CONSENT FORMS	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission.	Applicable in all pilot locations. Sample informed consent form is available in D4.1. For each subject, a signed informed consent will be required for participation in the project.	Electronic version of sample is part of D4.1; signed paper copies kept in files at pilot site.
SOURCE DOCUMENTS	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities

Document	Description	Relevance to LLM Pilot	Location/Form
SIGNED, DATED AND COMPLETED CASE REPORT FORMS (CRF)	To document that the investigator or authorised member of the investigator's staff confirms the observations recorded	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
DOCUMENTATION OF CRF CORRECTIONS	To document all changes/additions or corrections made to CRF after initial data were recorded	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS	Notification by originating investigator to sponsor of serious adverse events and related reports.	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, WHERE APPLICABLE, TO REGULATORY AUTHORITY(IES) AND IRB(S)/IEC(S) OF UNEXPECTED SERIOUS ADVERSE DRUG REACTIONS AND OF OTHER SAFETY INFORMATION	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions.	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION	Notification by sponsor to investigators of safety information in accordance with 5.16.2	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
INTERIM OR ANNUAL REPORTS TO IRB/IEC AND AUTHORITY(IES)	Interim or annual reports provided to IRB/IEC	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
SUBJECT SCREENING LOG	To document identification of subjects who entered pre-trial screening	Log of all participants that signed an informed consent form, maintained at pilot site only.	At pilot site only.

Document	Description	Relevance to LLM Pilot	Location/Form
SUBJECT IDENTIFICATION CODE LIST	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject	Code list with identifiable patient data (e.g., name, address, etc.) maintained at pilot site only. As part of ensuring anonymity of subjects in the programme, the subject screening log will not be kept in centralised LLM files.	At pilot site only.
SUBJECT ENROLMENT LOG	To document chronological enrolment of subjects by trial number	Log of patient numbers enrolled in the programme, maintained at the pilot site only.	At pilot site only.
INVESTIGATIONAL PRODUCTS ACCOUNTABILITY AT THE SITE	To document that investigational product(s) have been used according to the protocol	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
SIGNATURE SHEET	To document signatures and initials of all persons authorised to make entries and/or corrections on CRFs	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
RECORD OF RETAINED BODY FLUIDS/ TISSUE SAMPLES (IF ANY)	To document location and identification of retained samples if assays need to be repeated	Not applicable to LLM service.	N/A

1.7.3 After Completion of Trial

Listed following are the documents that are relevant to the wind-down of the trial. In countries where the pilot programme will be conducted as a clinical trial, the rules and requirements of the relevant IRB will determine whether the document is required, the form it must take, and where the document will be located. In keeping with the policy to conform as nearly as possible to GCP, some documents will be developed and retained either on a central basis (as applicable to the overall project) or at each pilot site, and the location and form of such documents are described below.

Document	Description	Relevance to LLM Pilot	Location/Form
INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE	To document that the investigational product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor	Not applicable to LLM service.	N/A
DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION	To document destruction of unused investigational products by sponsor or at site	Not applicable to LLM service.	N/A
COMPLETED SUBJECT IDENTIFICATION CODE LIST	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time.	Kept at each pilot site.	At pilot site only.
AUDIT CERTIFICATE (if available)	To document that audit was performed	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities

Document	Description	Relevance to LLM Pilot	Location/Form
FINAL TRIAL CLOSE-OUT MONITORING REPORT	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files	As appropriate per pilot country.	At pilot site, based upon requirements from regulatory authorities
TREATMENT ALLOCATION AND DECODING DOCUMENTATION	Returned to sponsor to document any decoding that may have occurred	Not applicable to LLM service.	N/A
FINAL REPORT BY INVESTIGATOR TO IRB/IEC WHERE REQUIRED, AND WHERE APPLICABLE, TO THE REGULATORY AUTHORITY(IES)	To document completion of the trial	As appropriate per pilot country. In addition, a final internal LLM report will be issued upon completion of the trial.	At pilot site, based upon requirements from regulatory authorities. The final LLM report will be distributed according to the LLM DoW
CLINICAL STUDY REPORT	To document results and interpretation of trial	A final report of all results from the pilot will include clinical reports by pilot country and across all pilot locations.	The final LLM report will be distributed according to the LLM DoW.

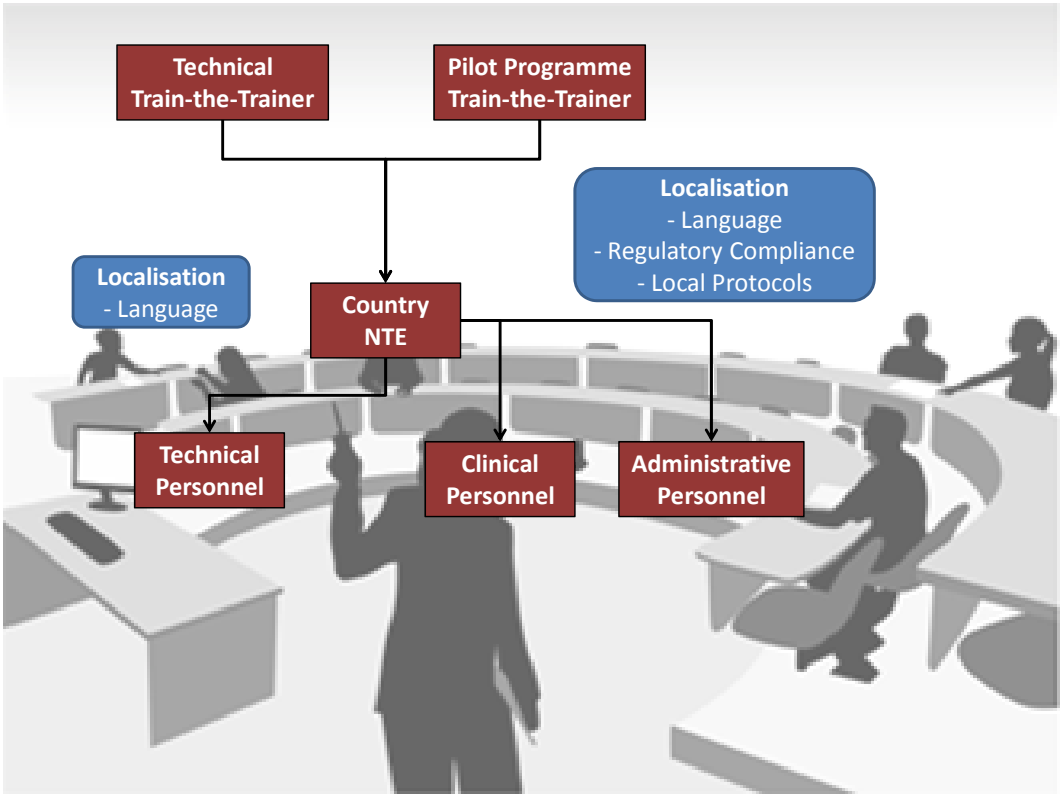
2 LLM Training Activities

2.1 Training plan

The LLM system is, from the user's perspective, designed to be simple and intuitive to use, but as with any technical system, some level of training is required for its effective use. In addition, there are several training elements that are required to ensure that the staff is able to effectively install, operate/administer the system, and to fulfil all the requirements of running the pilot itself (including administrative, technical, and scientific aspects). Training requirements are described following with respect to:

- technical training requirements (installation, use, and administration of the LLM system), and
- LLM pilot-related training requirements
- LLM testing-related training requirements

The LLM project is intended not only to complete the integration of the system to result in a fully functional system ready to take to market in Europe, but also to pilot test the system with users in five countries (Austria, France, Greece, Spain, and the UK).



2.1.1 Technical Training Requirements

2.1.1.1 Audience

Technical training is required for several different audiences, including:

- National Technical Expert/Trainer. In each country where the system will be deployed in a pilot setting, one or more individuals will be designated as a National Technical Expert (NTE) for the LLM system, and will serve as a trainer for the other personnel involved in the pilot programme. The individual selected for this role is expected to have a background with technical systems as an advanced user, and to have strong verbal communication skills, and some experience as a trainer. Depending upon the size of the team involved in the pilot, it may be necessary for the NTE to deliver classroom-based training, but more likely, such training will be performed in a one-on-one setting.

- Pilot Site Personnel/Therapist(s). In each country, pilot site personnel will be involved in various aspects of the execution of the pilot, including involvement in the installation and technical maintenance of the system, responding to any alerts related to the system's use or safety of the users, as well as working with users of the system during the physical and cognitive training sessions.

- Users. Finally, users will require initial training for accessing the system. The design of the LLM system is intended to minimize the level of training required, guiding the user through their interaction with the system and accepting responses via a touch-screen interface (in the future, options are envisioned to add capabilities for audio and visual cues), and collecting data from both the cognitive training and physical training devices integrated within the LLM system. However, some basic level of training to get started is expected for each user.

2.1.1.2 Training approach and schedule

All training will be accomplished in a cascading fashion, with the NTEs attending a centralised training session to be held prior to the deployment of the LLM system at the pilot site (date to be determined). This training will be conducted by the technical team, and will include detailed demonstrations followed by hands-on interaction with the system by the NTEs. The NTEs will complete a training session that will prepare them to effectively train all national level personnel in the use and maintenance of the system. All training will be conducted in English language, and English language materials in the form of PPT presentations will be provided to the pilot partners for localisation.

2.1.1.3 Training Outline

Following is a preliminary outline of a "Train-the-Trainer" programme (this outline is subject to modification as the development of the system progresses). The final outline will be updated upon finalisation of the system itself.

I. Introduction to LLM
   a. System Overview
      1. LLM Applications
         a. Individual Home Environment
         b. Group Living Environment
      2. System Demonstration
         a. Physical Training
         b. Cognitive Training

c. Therapist Use Case
3. Features
b. LLM Components
1. ILC
2. PTC
3. CTC

II. LLM Technical Operations
a. Technical Architecture
b. System Requirements
c. Installation

III. Using the LLM System
a. Account Management
b. Quality Control
c. Administration
d. Post-Pilot

2.1.2 Pilot Procedure Training Requirements

2.1.2.1 Audience

Pilot programme related training is required to ensure that all relevant procedures required to ensure the quality and consistency of the pilot programme is maintained across all pilot locations. This training will be conducted for the following audiences:

- National Technical Expert/Trainer. In each country where the system will be deployed in a pilot setting, one or more individuals will be designated as a National Technical Expert (NTE) for the LLM system, and will serve as a trainer for the other personnel involved in the pilot programme. This is expected to be the same individual as designated for the Technical Training, and, like the technical training, this individual may need to deliver classroom-based training, but more likely, will provide training in a one-on-one setting.

- Pilot Site Personnel/Therapist(s). In each country, pilot site personnel will be involved in various aspects of the execution of the pilot programme, and those who will be involved in the execution of the pilot trial, working directly with the users, or supporting those who do, will need to be trained in specific aspects of the LLM system as well as all the procedures and standards related to the effective execution of the pilot.

- Pilot Site Medical Personnel. Medical personnel who will execute testing with respect to the LLM pilot are expected to have familiarity with all screening tests and be trained in applying them. The medical personnel will be trained in the overall execution of the pilot, as with other personnel for the pilot programme.

2.1.2.2 Training approach and schedule

All training will be accomplished in a cascading fashion, with the NTEs attending a centralised training session to be held prior to the deployment of the LLM system at the pilot site (date to be determined).. This training will be conducted by the technical team, and will include detailed demonstrations followed by hands-on interaction with the system by the NTEs, as outlined in "Technical Training Requirements." This training will prepare the

NTEs to effectively train all national level personnel in the use and maintenance of the system. All training will be conducted in English language, and English language materials in the form of PPT presentations will be provided to the pilot partners for localisation.

Because the specific details of the pilot programme will differ from country to country, depending upon legal/regulatory requirements or ethical guidelines, the training programme will be developed in modules, providing a framework that can be localised to meet the pilot site's specific structure, reporting requirements, etc. For example, if in one country, national regulations require specific forms to be filled out, and reports submitted to an ethics board or IRB for that country, these details will be added to the LLM training programme in that country and reviewed with all appropriate personnel prior to the start of the pilot programme.

2.1.2.3 Training Outline

The following is the outline for the additional module that will be used for the delivery of training to clinical or non-clinical personnel at the pilot site, and to the staff supporting the clinical and/or data collection activities of the pilot. Note that Section II would not be presented to this non-technical audience.

IV. Pilot Programme
   a. Overview of pilot programme
   b. Pilot Objectives
   c. Roles & Responsibilities
   d. Schedule/Timelines
   e. Reporting Requirements
      1. Internal
      2. External (per country)
   f. Ethical Considerations (including Data Protection)

2.1.3 Testing-Related Training Requirements

2.1.3.1 Audience

Testing related training is required to ensure that those staff who will be responsible for administering testing to collect relevant scientific information from the pilot are able to do so, and thus ensure the quality of the data itself. This training will be conducted for the following audience:

- Pilot Site Study Coordinators/Examiners. In each country, pilot site personnel who will be involved in testing the subjects, including one or more who have been previously trained in neuropsychological assessment who will be responsible as examiner(s), will be trained in the execution of the specific tests for screening and measurement of outcomes from the LLM pilot.

2.1.3.2 Training approach and schedule

All training will be accomplished in a cascading fashion, with representatives from each pilot attending a centralised training session to be held prior to the deployment of the LLM system at the pilot site (date to be determined). This training will be conducted by the scientific team, and will include training on each of the screening and pre- and post-tests to ensure that they are conducted in a consistent manner across all sites.

2.1.3.3 Training Outline

The following is the outline for the training that will be conducted for examiners and study coordinators:

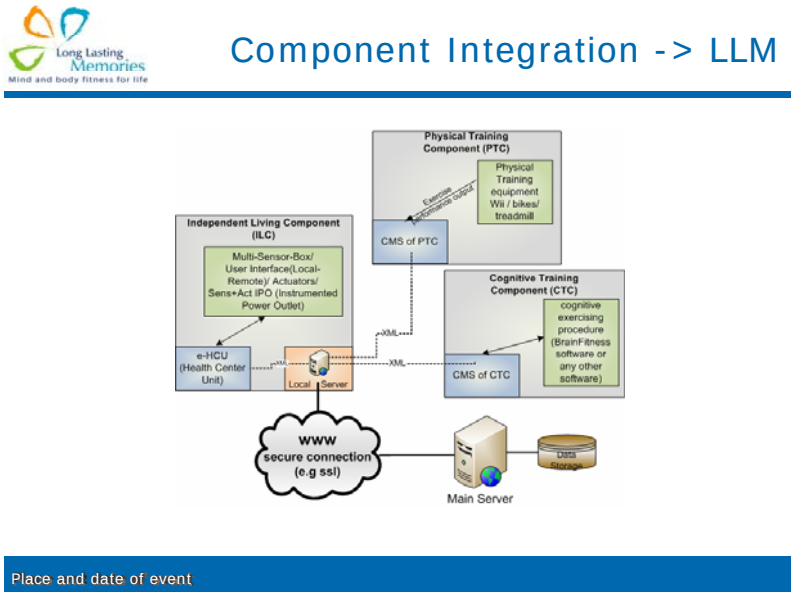
V. Examiner Workshop
   a. LLM Overview
   b. Pilot Overview
   c. Ethical Considerations (including Data Protection)
   d. Blinding of the examiners
   e. Randomized allocation to active and control group
   f. Standardized application of the testing material
   g. Standardized evaluation of the test results
   h. Uploading the data to the server

This training will be completed, utilising the English versions of all testing materials, but prior to the workshop, localised versions of all testing materials will have been identified or developed, as necessary. In addition to the training, a certification process will be defined to ensure that all examiners can successfully and consistently administer the tests.

2.2 Training Materials

Training materials will include:

- Standard PPT presentation decks for each module, including trainer's notes for
  - Technical Training
  - Pilot Programme Training
- Supporting handout materials may also be provided, in case some documents may not be able to be presented effectively via PPT presentations.



The Annex of this Guide includes sample PPT presentation materials for some of these modules to illustrate the format to be used. The full suite of training materials will be written after the LLM system is developed to a prototype stage.

3 ANNEXES

3.1 Principles of ICH GCP[4]

The following are the "Principles of Good Clinical Practice" as developed by the International Conference on Harmonisation (ICH) Expert Working Group. These principles have been consulted, and applied wherever appropriate and applicable to the design of the LLM pilot.

1. *Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).*
2. *Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.*
3. *The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.*
4. *The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.*
5. *Clinical trials should be scientifically sound, and described in a clear, detailed protocol.*
6. *A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.*
7. *The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.*
8. *Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).*
9. *Freely given informed consent should be obtained from every subject prior to clinical trial participation.*
10. *All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.*
11. *The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).*
12. *Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.*
13. *Systems with procedures that assure the quality of every aspect of the trial should be implemented.*

[4] ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice E6(R1), 10 June 1996.

3.2 Sample Forms & Documents

The following pages provide examples of the type of information that is to be included on specific documents/forms that are required in order to assure consistency and compliance with good clinical practices within the context that has been defined for the LLM system. Note that if any of the pilot locations are subject to specific requirements of a local IRB, the requirements of that IRB would supersede those outlined herein.

- Subject Screening Log
- Subject Enrolment Log
- Subject Identification Code list

Subject Screening Log
Long Lasting Memories Study
Pilot Site: _____

Screening Number	Initials	Date of Screening	Eligible? (Y/N)*

*If no, please indicate inclusion/exclusion criteria not met.

Subject Enrolment Log
Long Lasting Memories Study
Pilot Site: _____

Screening Number	Date Enrolled	Enrolment Number	Subject Name

Subject Identification Code List*
Long Lasting Memories Study
Pilot Site: _____

Enrolment Number	Subject Name	Subject Address	Phone Number	Date of Birth	Gender

*This list should include every person who has signed an informed consent form.
*This list cannot be photocopied or removed from the Pilot Site Master Files.

3.3 Sample User Survey

To be developed before the launch of the first pilot iteration. The User Survey will include specific questions related to:

- Overall satisfaction with LLM System
- Physical design elements and usability
- Ease-of-Use
- Accessibility
- Satisfaction with personal health results (physical and cognitive)
- Satisfaction as compared to other physical and cognitive programmes (if any)
- Pricing tolerance (willingness to pay for such a programme oneself, and if willing, pricing levels that are considered reasonable)
- Perceived benefits
- Perceived concerns
- Purchase decision making (influencers, recommenders)

In addition, a brief survey will be developed to obtain input from family caregivers, where possible, in addition to the input provided directly from users.

3.4 Sample Pilot Staff Survey

To be developed before the launch of the first pilot iteration. The Pilot Staff Survey will be focused upon issues related to the completeness of materials and efficacy of the installation procedure to ensure the ability of the LLM System to be installed and used at the pilot site. Specific questions will be included in the survey regarding:

- Ease of installation
- Completeness and accuracy of installation documentation

- Completeness and accuracy of any other related technical documentation or reference materials
- Completeness and accuracy of training programmes
- Effectiveness and accessibility of technical support personnel

3.5 LLM System Sample Training Material

Full training programme to be developed upon completion of a working prototype of the system. Sample training materials have been developed based upon specifications and provide a general view of how the training will be conducted (see separate training PPT file).