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LUMINOUS

Language Augmentation for Humanverse



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Table 1: List of Abbreviations

Term / Abbreviation	Definition
DPIA	Data Protection Impact Assessment
EEAB	External Ethics Advisory Board
FAIR	Findability, Accessibility Interoperability and Reusability
GDPR	General Data Protection Regulation
IDS	Intrusion Detection Systems
LLM	Large Language Models
nFADP	New Federal Act on Data Protection
TRL	Technology Readiness Level
XR	eXtended Reality

1 INTRODUCTION

1.1 PURPOSE OF THE DOCUMENT

WP5, Ethics Requirements, encompasses three deliverables: **D5.1 for overseeing human participation**, D5.2 for personal data protection, and D5.3 for managing ethics risks related to AI, research participants, and end-users. These deliverables focus on ethical monitoring throughout the project's duration. Additionally, the project planned the appointment of an External Ethics Advisory Board (EEAB) in M1. The EEAB's role includes overseeing ethical and legal compliance aspects during the project.

The EEAB provides feedback to the project's Ethics Manager, Prof. Eleni Mangina from University College Dublin, who coordinates the LUMINOUS consortium's internal ethics monitoring activities.

The current document is covering the activities involving the ethics requirements of the LUMINOUS project related to the involvement of human participants throughout the project duration.

1.2 STRUCTURE OF THE DOCUMENT

The structure of the document that follows addresses all ethics requirements as raised in LUMINOUS ethics appraisal, as shown in Table 2.

Table 2: Structure of D5.1

Section 1	Introduction and rationale of the document
Section 2	Project Description
Section 3	Description of human participants in LUMINOUS
Section 4	Policy for incidental/unexpected findings
Section 5	Non-disclosure of non-material incidental or unexpected findings
Section 6	On-going monitoring of the project and review in terms of ethics requirements
Section 7	Protection of vulnerable individuals/groups
Section 8	Ethics during and after the research
Section 9	Compliance with ethical and legal standards
Section 10	Conclusions
Annexes	Supporting documents for all 3 pilots' ethics requirements.

2 PROJECT DESCRIPTION

The LUMINOUS consortium hereby affirms its commitment to abide by the ethical principles and to act in accordance with all applicable national, EU and international laws, including GDPR, with due consideration given to relevant ethical, legal and privacy concerns. In addition, the LUMINOUS consortium, given the developments within the project in AI, will adhere to the ethics guidelines for Trustworthy AI¹ published on the 8th of April 2019 by the High-Level Expert Group on AI and the latest EU AI Act published in 2024². UNESCO recommendations³ will be also applied (Pilot 1 - Switzerland and UK), which will be the basis for AI Treaty for Council of Europe (March 2024). In order to ensure responsible and ethical research practices, the LUMINOUS consortium will adhere to the following principles with respect to research participants: provision of a project information sheet; provision of information on the context of the study; confirmation of the voluntary nature of participation; respect for the dignity of persons; provision of anonymity; consideration of the concerns raised by the research and building a common understanding that all the benefits of this research are for the good of society; protection from harm, discomfort and stigmatization; respect for the principle of proportionality, so as not to exceed the stated objectives; and the right to withdraw from the study.

Detailed information will be provided on the procedures to be implemented for data collection, storage, protection, retention and destruction, and confirmation that they comply with national and EU legislation. To ensure proper administration and processing of this data, the project and consortium members will comply with the Data Protection and Privacy legal framework⁴, including the General Data Protection Regulation⁵. LUMINOUS consortium will comply with all ethical directives and regulations related to the processing of data. Stakeholders involved in the project, will be required to sign an informed consent and be provided with an information sheet. The LUMINOUS consortium reiterates its commitment to act in accordance with all the above-mentioned legislation and Horizon Europe's ethical principles, in relation to any individual involved in the project, whether as a participant or not.

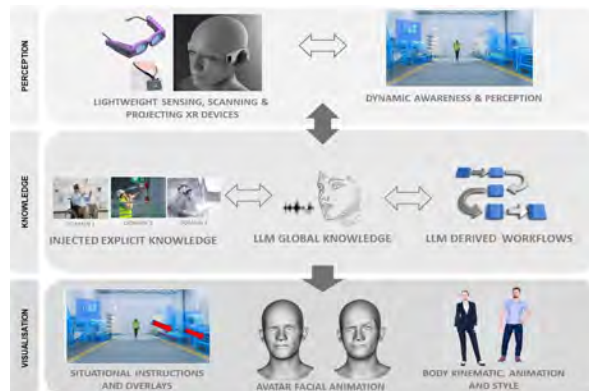


Figure 1: LUMINOUS conceptual overview as per Grant Agreement

¹ <https://data.europa.eu/doi/10.2759/346720>

² <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai#:~:text=The%20AI%20act%20allows%20the,of%20high%20risk%20AI%20systems%3F>

³ <https://www.unesco.org/en/artificial-intelligence/recommendation-ethics#:~:text=Recommendation%20on%20the%20Ethics%20of%20Artificial%20Intelligence&text=The%20protection%20of%20human%20rights,human%20oversight%20of%20AI%20systems.>


⁴ https://edpb.europa.eu/about-edpb/about-edpb/legal-framework_en

⁵ <https://gdpr.eu/what-is-gdpr/>

The LUMINOUS approach: The foreseen solution will contribute towards the creation of the next generation of Language Augmented extended reality (XR) systems and applications, as shown in the conceptual diagram in Figure 1, where natural language-based communication and Large Language Models (LLM) redefine the future interaction with novel XR technology and enhances understanding of the users' situation and environment even in situations that are encountered for the first time.

2.1 DESCRIPTION OF PILOTS

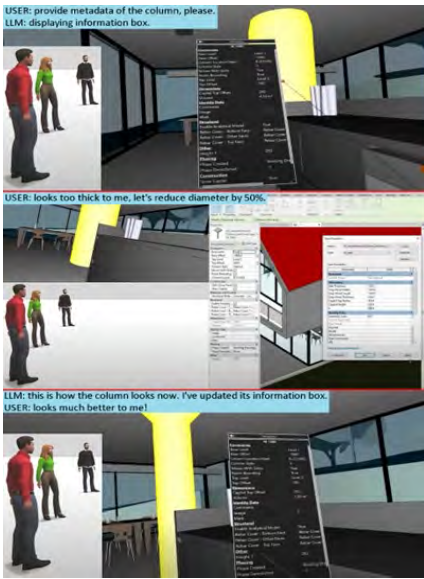
2.1.1 Pilot #1: Neurorehabilitation

<p>Type of site: Hospital, clinic, and home. Countries: CH, UK</p>	<p>User profile (s): Neurological patient, clinicians LUMINOUS Technologies involved: XR, LLM, avatars TRL transition: 1 to 4</p>	<p>Expected Results and Impact Metrics</p>
<p>Description of the scenario: Neurorehabilitation: treating aphasia after brain damage.</p>  <p>A stroke patient presents severe communication deficits, in particular speech production. Available treatment stops at decontextualized single word retrieval, which poses a serious problem for return to work and social integration.</p> <p><i>Figure 2: LUMINOUS Pilot 1 – Example of avatar</i></p> <p>Here we propose to include in existing high-intensity personalized training, a novel patient-centric LLM adjusted, i.e. dynamic and XR-empowered linked to each unique context & environment.</p> <p>In addition, high-fidelity virtual characters help with conversation production using natural language-based bidirectional models, ensuring generalization to other daily life activities, thus enabling better restoration and reinsertion. While using the XR device, objects in the scene (including people) will be recognized in real time using eye-tracking and object recognition algorithms. The patient will then be able to prompt the LLM to either provide the name of the item (in 'aid mode'), the whole word cue for them to produce, or (in 'therapy mode') the initial phoneme or speech sound which will prompt them to retrieve the word for that item/person.</p> <p>Project Innovations to be exploited: Natural language-based bidirectional conversation delivered by high-fidelity avatar. Training material is adapted to the context/environment without previous specific knowledge. The rehabilitation program is personalized based on the patient's impairments, dynamically adapting language, and cognitive load.</p> <p>Co-design and validation: A total of 20 acquired brain injury patients in Switzerland & the UK will be involved in the co-design & evaluation of the system.</p>		<p>Results</p> <ol style="list-style-type: none"> 1. Functional prototype 2. Validation of usability based on classic neuropsychological therapy approach. <p>Expected Impact</p> <p>Clinically significant functional recovery of patients after XR-based neurorehabilitation program. High construct validity (based on the prompted by the LLM model verbalised by patient)</p> <p>Metrics</p> <ul style="list-style-type: none"> – Specific neuro-Corpus – Acceptability of rehabilitation program and user experience rate – Willingness to use by clinicians. – Questionnaire

2.1.2 Pilot #2: Health, Safety and Environment training

<p>Type of site: Industrial sites. Country: Spain</p>	<p>User profile (s): Worker, students, Rescue agents LUMINOUS Technologies involved: XR, LLM, avatars. TRL transition: 2 to 5</p>	<p>Expected Results and Impact Metrics</p>
<p>Description of scenario(s):</p>  <p>3 scenarios selected from a range of 6 important use cases with challenging functional characteristics and content (Plant risk prevention, plant risk assessment, safety in construction, postural ergonomics, forklift risks, first aid). Focus will be on how to handle a completely different approach on the user-machine interaction.</p> <p>Currently the user is expected to interact with the system through a series of panels, switches, and physical touch points. However, there will be a completely new range of possibilities available to the user as voice interfaces will allow a new and more natural way of giving inputs to the system. That new scenario will be considered from the very beginning of the design process and will involve a complete redesign of the current state of the art.</p> <p>Project Innovations to be exploited: The avatar trainer style (interaction, communication, explanation) is modelled using support from LLMs injected with domain specific knowledge. The training material /content is broken into a sequence of steps (workflow) and a series of instructions using LLM injected with domain specific Knowledge. The material is conveyed to the trainees by a virtual teacher-avatar selected from a domain adaptable set of styles. Training material based on LLM is adapted to the context/environment without previous specific knowledge.</p> <p>Co-design and validation: 30 internal and external users will use and validate LUMINOUS prototypes adapted to 3 different use cases (10 per use case prototype).</p>		<p>Results</p> <ol style="list-style-type: none"> 1. Generic Functional prototype 2. Adaptation to 3 specific use cases 3. Validation <p>Expected Impact</p> <ul style="list-style-type: none"> – Improve training experience that will be more interactive and engaging. – Cost and time savings: Development of VR training with LLMs will be more cost-effective and time-efficient than current methods (LLM based scalability) – Increase of effectiveness and efficiency of training programs, leading to improved safety outcomes and better-prepared workers. <p>Metrics</p> <ol style="list-style-type: none"> 1. Comparison of development time and costs for new XR training applications to relevant current standards. 2. User Acceptance (Subjective metrics measuring realism of simulation and suitability of avatar style) 3. Level of speech recognition accuracy 4. Comparison of the quantity and quality of the held information

2.1.3 Pilot #3: BIM & architectural design review

<p>Type of site: Remotely located users reviewing architectural designs.</p> <p>Country: Italy</p>	<p>User profile (s): Architects, Construction & real estate professionals and their customers.</p> <p>LUMINOUS Technologies involved: XR, LLM, Situational Awareness, avatars, CAD.</p> <p>TRL transition: 2 to 5 (Starts at TRL 2, reaches TRL 5 by end of project)</p>	<p>Expected Results and Impact Metrics</p>
<p>Description of scenario(s): BIM & architectural design review</p>  <p>Even in the well-established hypothesis of using three-dimensional CAD systems to carry out architectural design, it is always very difficult to have an exact perception of the spaces when filtered by a computer screen. Luminous XR technologies will allow professionals such as architects, interior designers and engineers to access a 3D multiuser space, in the form of digital avatars, allowing them to explore their projects thanks to an immersive technology which is capable of providing a better perception and understanding of the context and the surrounding space. Users will be able to seek information and BIM metadata relating to the surrounding objects, have a better perception of architectural designs, make live changes to the project and communicate with an LLM who will be capable of understanding the surrounding space in order to provide/display requested information such as filtered and contextualized BIM metadata referring to one or multiple objects/components installed within the space, performing references to norms and rules on how certain parts of the project should have been done in order to be compliant, reporting project anomalies and design errors detected by the LLM itself and suggest possible corrections. This will dramatically speed up the process of design review allowing for an improved level of efficiency and error reduction leading to significant savings and better time to market.</p> <p>Co-design and validation: Involvement of architecture and interior design firms to carry out in-field tests on the use of the platform within a professional environment.</p>		<p>Results</p> <ol style="list-style-type: none"> 1. Basic structure of a working and scalable software platform. 2. Improved design review sessions resulting in a significant reduction of design errors. 3. Easier access and filtering of BIM metadata. <p>Expected Impact</p> <p>Significant reduction of costs related to reworks caused by design errors, improvement of time to market, better understanding of the environment and easier access to any available information. Development of a new product extending existing product range offering, significantly increasing current market share.</p> <p>Metrics:</p> <ul style="list-style-type: none"> • Acceptance level of the system by Architects and Construction & real estate professionals. • Number of errors detected during design review sessions. • Wider introduction/use of BIM. • Easier compliance with rules involved in AEC. • Willingness to extend the use of the platform

3 HUMAN PARTICIPANTS IN LUMINOUS

This section provides an overview of the ethical monitoring of human participants in the LUMINOUS Project. It maps out the process for obtaining informed consent from participants and outlines how ethical oversight will be carried out for each case, organized in work packages (WPs). To this end, the relevant cases are presented, as scheduled per WP, describing the following:

- The activity in which human participation is expected to take place within the project framework.
- The method by which ethical monitoring will be implemented, ensuring that all documentation and approvals are obtained prior to the start of the relevant activities.
- The deliverable in which all documentation related to ethics will be reported, ensuring transparency and accountability in the ethical oversight process.

3.1 INFORMED CONSENT PROCEDURES

An information sheet and a consent form will be handed out to any individual participating in the LUMINOUS activities, which may lead to the collection of data; such activities may cover the following:

- interviews for user needs' elicitation workshops through personal interviews and /or focus groups,
- organization of pilot activities and workshops,
- community-building activities,
- creation of a network of potential users.

The LUMINOUS consortium will provide all participating individuals with information on the procedures undertaken and how their data are being handled so that every individual will be able to have access and control over its own data as well as to provide his/her or their consent.

3.1.1 Data protection of the voluntary participants

The "data subject" refers to the natural person participating in the research activity, while the "Data Controller" is the partner conducting the research. The EU Regulation 2016/679 requires that the data subject's consent for processing personal data must be freely given, specific, informed, and unambiguous. The Data Controller is responsible for demonstrating that the data subject has given their consent for processing personal data. To ensure that the data subject's consent is valid, the request for consent must be presented in an easily accessible and understandable form, using clear and plain language. The data subject has the right to withdraw their consent at any time, without stating a reason or facing repercussions. The Data Controller must provide the data subject with all relevant information, including the Controller's identity and contact information, the intended purpose of data processing, the legal basis for processing, and any other relevant details such as the recipients or categories of recipients of the data. If applicable, the Controller must inform the data subject about their intent to transfer personal data to a third country, the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period. Additionally, the data subject has the right to access and rectify their data, the right to data portability, and the right to be informed about automated decision-making, including profiling and VR experience. The Controller must provide this information to the data subject at the time when personal data is obtained.

Informed consent should include the following:

1. Clear explanation of the study's purpose and how it involves human subjects.
2. A disclosure of the expected duration of participation to allow the participant to plan accordingly.
3. Assurance that participation is voluntary, and the participant can withdraw at any time without penalty.
4. Identification of the organization and funding sources for the research, which can help build trust in the research process.
5. A clear and detailed description of any foreseeable risks, discomforts, or disadvantages to the participant.
6. A description of any benefits that the participant or others can reasonably expect from the research, avoiding any unrealistic expectations.
7. Clear procedures for data protection, confidentiality, and privacy, including the storage and handling of personal data.
8. A description of how incidental findings will be handled, including when and how the participant will be informed.
9. A reference to contact information for questions about the research and the participant's rights, along with whom to contact in case of withdrawal from the study.
10. A statement that the participant can ask questions and withdraw from the research at any time without negative consequences.

Arrangements will be prepared by the researchers to carefully protect the confidentiality of participants and their data. All collected personal information will be considered privileged information and be dealt with in such a manner as not to compromise the personal dignity of the participant or to infringe upon his/her right to privacy. Before consent is obtained, the researchers will inform prospective participants of any potential risks related to confidentiality or anonymity of personal information aspects that may not be guaranteed and the purpose for which personal information provided will be used.

Whenever participants are requested to submit personal data, they will be informed that this data is stored and processed by the partner(s) in charge of the activity and for the purposes of the project only. They will be also informed about their rights to access, modify and erase their personal data and how to enforce this. Individual participants' data will not be mined or used for any purpose other than those explicitly and clearly needed for the running of the activity within the LUMINOUS. However, if data would be usefully held for future analysis, specific informed consent will be sought from participants for this purpose. Otherwise, data will only be held for the period defined at Annex 2 (RoPA) or based on the relevant regulations (D5.2, Table 4).

3.1.2 Obtaining participants' consent.

Informed consent is an essential part of all research activities. It is the responsibility of the researcher to fully explain the research and ensure that participants understand the information provided through the informed consent. The information sheet will be translated into relevant languages and can be accessed in electronic or hard copy formats. If necessary, the researcher will verbally summarize the information sheet. Participants will be asked to provide voluntary informed consent after confirming their complete understanding of the information. No pressure will be put on participants to participate

in the project, and they will have the opportunity to ask questions before deciding. The informed consent form will reiterate the rights of the individual participants and ensure that they are aware of the data collection and processing that will occur. Ongoing informed consent will be obtained throughout the project. The research participant will be asked to sign, date, and return the informed consent form. The receipt of signed informed consent form will ensure that all the voluntary participants are aware of the data collection and processing that will occur within the scope of the LUMINOUS.

3.1.3 Recording and storing consent.

The participant and the researcher will each retain one copy of the consent and the information sheet. The completed consent sheets will be stored by the respective partners that have initially collected them separately and will not be shared with the rest of the consortium.

3.1.4 Template of the LUMINOUS informed consent and scope

The LUMINOUS project provided partners with a comprehensive set of guidelines and for the completion of the informed consent forms required for their research activities, as part of WP5 Ethics requirements. These guidelines were designed to facilitate the development of an informed consent template that meets the project's ethical standards and is intended to be updated as needed to reflect the evolving research activities of the project. Partners were given the option to either use the LUMINOUS template or adapt their existing informed consent form, to meet the project's requirements, ensuring that all necessary information is included. Additionally, partners were encouraged to provide the consent form in the native language of the research participants, with wording, style, and format adapted to ensure easy comprehension. The LUMINOUS informed consent template has been available from the Ethics Manager and in Annex 3 the partners have used or adapted, as needed per pilot.

3.2 ETHICAL OVERSIGHT PER WP

3.2.1 Templates of the informed consent/assent forms and information sheets

The development of the LUMINOUS informed consent template was a collaborative effort between the coordination team and the Ethics Manager. The template was then adapted by the WP Leaders and the pilot partners.

3.2.2 Pilots' Implementation (WP6)

The purpose of the pilot phase is to understand the stakeholders' needs from advanced technological systems. To do this, LUMINOUS consortium will work with stakeholders and end-users to design the different parts of the system, figure out what it should be able to do, and make sure it is meaningful, useful, and easy to use. The input of users will be taken integrated for the evaluation of the outcome.

3.2.2.1 *Description of the procedures and criteria used to identify/recruit research participants per pilot site.*

Pilot #1 The participants, hospitalized patients with acquired brain damage and healthcare professionals, will be recruited from the University Hospital of Lausanne and the Institution of Lavigny (Switzerland). All participants for the study will be provided a participant information sheet and a consent form describing the study and providing sufficient information for participants to make an informed decision about their participation in the study. Each participant will be informed that the

participation in the study is voluntary and that he/she may withdraw from the study at any time and that withdrawal of consent will not affect his or her subsequent medical assistance and treatment. A copy of the signed informed consent will be given to the study participant.

Pilot #2 The participants will be invited to test first-hand the inclusion and implementation of LLM in an occupational health and safety training platform through VR (LUDUS GLOBAL). They will test different applications of LLM on this platform and will be required to evaluate different aspects of their experience in comparison to the same experience without LLM. To invite participants to the pilot, an email will be sent to the first selected participants from among our clients and/or organisations that have collaborated in previous projects and that meet some basic criteria:

1. Are workers, students, or rescue agents.
2. Have previous experience with VR applications.
3. Have the possibility to participate in Bilbao, Spain.
4. Are willing to participate.

In case the representative sample is not completed with this method, the invitation will be opened publicly through the publication on our website and social networks.

Pilot #3 The participants will be invited to test the integrated language-augmented multimodal platform that will enable future XR users to interact fluently with their environment while having instant access to constantly updated global as well as domain-specific knowledge sources to accomplish novel tasks.

They will test different applications of LLM on this platform and will be required to evaluate different aspects of their experience in comparison to the same experience without LLM.

To invite participants to the pilot, an email will be sent to the first selected participants from among our clients and/or organizations that have collaborated in previous projects and that meet some basic criteria:

1. have minimum 3 years of experience in usage of CAD/BIM software
2. are pre-service or in-service professionals
3. are willing to participate
4. have an XR-headset

In case the representative sample is not completed with this method, the invitation will be opened publicly through the publication on our website and social networks.

3.2.2.2 *Templates of the informed consent/assent forms*

Within the framework of WP6, informed consents are developed, tailored to the needs of the pilot's partners and the participants planned to be involved. All consent forms and information sheets were written in a language participants would understand taking care of the length and complexity of the forms, highlighting the importance of being simple and easy to understand. All informed consents must be approved by the EEAB. As soon as the content is finalized, informed consents (translated if needed) will be available in Annex at D6.1, D6.2 and D6.3 deliverables for the respective pilots.

3.2.3 Stakeholders' engagement and outreach (WP7)

DFKI, as WP7 leader, in collaboration with the relevant task leaders will coordinate the organization of workshops with stakeholders within the framework of all tasks of the WP (T7.1 to 7.4.), with the view to widely disseminating the project results and building upon liaisons with relevant research initiatives under similar and/ or close thematic areas. More specifically, T7.1 involves participation in scientific

and business-related events, Task T7.2 includes organizing outreach and promotional activities. Task T7.3 involves managing the development of standards in the context of the LUMINOUS project and liaising with standardization organizations and technical representative bodies. Finally, Task T7.4 involves organizing at least one business model workshop and driving contact with interested parties and organizations for long-term exploitation and commercialization of the project outcomes.

The Ethics Manager will identify the steps to follow, to design and run all activities in an ethically compliant manner, ensuring communication with the DPOs of task leaders in charge of the drafting, reviewing, and signing off all the relevant documentation.

DFKI team, in cooperation with the involved partners, will make sure that all the ethics documentation is in place before any human participant is involved in any research/ dissemination/ outreach activity under WP7; all the ethical requirements, as followed, and the relevant documentation will be reported in a separate section in the relevant deliverables (namely, D7.1- D7.4) under a section named, Ethical Monitoring.

4 POLICY FOR INCIDENTAL/UNEXPECTED FINDINGS

The European Commission's ethics issues checklist for research involving human participants⁶ includes a policy on incidental findings. This highlights the importance of addressing the possibility of discovering incidental findings in advance and clearly stating the procedures that will be followed if unexpected findings arise, including whether participants have the right to know or not to know about such findings. Researchers have an ethical obligation to address incidental findings and should take proactive measures, such as acquiring consent forms from participants, as well as ensuring confidentiality and appropriate communication with research participants. The LUMINOUS consortium has established a policy for handling incidental findings and their disclosure to research participants. This policy is designed to ensure that the participants' well-being and autonomy are respected, while also promoting the responsible use of research findings.

4.1 DEFINITION OF THE INCIDENTAL FINDING

An incidental finding is any unexpected discovery made during research that is unrelated to the primary objectives of the study. If the finding is deemed to have a significant impact on the welfare of the participant or prospective participant, it is referred to as a material incidental finding. These findings can arise at any stage of the research process, including during the initial screening process, data collection, study procedures, or follow-up assessments.

4.2 DETERMINATION OF THE MATERIALITY OF THE FINDING

Researchers are obligated to disclose any material incidental findings to the participant within the bounds of the consent and provide information on how they plan to disclose such findings, if applicable. The management and communication of incidental findings will be included in the Ethics Application submitted to the Ethics External Advisory Board (EEAB), seeking for approval before the

⁶ How to complete your Ethics Self-Assessment, available at https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

involvement of any human participant to any research activity within the framework of the project. The determination of whether a finding is material requires expertise relevant to the finding. If researchers lack the necessary expertise to interpret or determine the materiality of a finding, assess the analytical validity, potential significance, and actionability of the finding, they will seek guidance from professionals with the appropriate expertise and/or consult relevant professional practices and standards.

Even if material incidental findings are not reasonably foreseeable, they can still be discovered unexpectedly during the research process. If such a finding is discovered, the researcher will assess whether it is material, and report the discovery to the local Ethics Board/Committee or DPO in accordance with the guidance provided.

4.3 DISCLOSE OF THE FINDINGS TO THE RESEARCH PARTICIPANTS AND COURSE OF ACTION

To ensure respect for human participants' autonomy, the disclosure of material incidental findings can only occur with their explicit consent or that of their authorized representatives. However, there are certain limitations to obtaining consent for receiving material incidental findings, especially when it involves vulnerable individuals such as children. In such cases, authorized third parties, such as parents or legal guardians who have legal authority or permission to act on behalf of the participant, will receive any actionable findings immediately or during the participant's childhood. This is because authorized third parties are mandated by law to act in the best interest of the individual. Researchers handling the disclosure of material incidental findings that may have negative implications for participants' well-being will approach the situation with sensitivity and care. They will assist participants in understanding the significance of such findings and may suggest seeking advice from trusted sources, such as family members, friends, experts, or professionals. When necessary, researchers will refer participants to qualified professionals who can provide guidance on the potential implications of material incidental findings on their overall well-being.

If an incidental finding is discovered from the analysis of anonymized data belonging to another partner, the partner who made the discovery will first consult with the partner who owns the data to ensure the accuracy and validity of the finding. Once it is established that the finding is genuine, the two partners will collaborate to develop a communication plan for informing the participant. This plan will consider the potential impact of the finding on the participant, as well as any ethical or legal considerations that may be relevant. Typically, communication with participants should be handled by the partner who collected the data. However, there may be situations where another partner with specialized knowledge or expertise in the area may be better suited to communicate the finding to the participant. Regardless, the communication process will be clear, accurate, and appropriate to the participant's level of understanding. The participant will be informed about the nature of the finding, the potential implications for their well-being, and any available options for follow-up or further testing. It is crucial to ensure that the privacy and confidentiality of participants are protected throughout the communication process, with partners taking precautions to avoid inadvertently revealing the participant's identity.

In cases where the partner who discovered the finding is located within the EU and the partner providing the anonymized data is located outside the EU, or vice versa, the partners must ensure compliance with relevant data protection regulations. They should also consider any differences in

legal or ethical frameworks between the EU and non-EU countries, taking appropriate measures to address these differences.

The Internal Ethics Advisory Board and the project's Ethics Manager will provide guidance and support to the partners in navigating these variations and identifying suitable solutions and all cases will be resolved within twenty-four (24) hours. Additionally, the competent Ethics Bodies within the partnership will offer expertise and guidance on the specific legal and ethical requirements applicable in their respective countries, ensuring that the communication of incidental findings aligns with these requirements.

5 NON-DISCLOSURE OF NON-MATERIAL INCIDENTAL OR UNEXPECTED FINDINGS

Non-material incidental or unexpected findings will not be disclosed to the participant or their authorized representative. These findings will be documented in the participant's record and stored securely for future reference, but not disclosed to the participant or their representative. The reason for this is that these types of findings may not have any direct impact on the participant's well-being, and disclosure may cause unnecessary anxiety or concern. The determination of an incidental finding as non-material will be based on a careful assessment of the potential risks and benefits to the participant (as identified in step 2 of the policy). Additionally, researchers will be transparent about their policies and procedures for handling non-material incidental or unexpected findings and should explain these policies clearly to participants during the informed consent process.

6 ONGOING MONITORING AND REVIEW

The research team will monitor and review any incidental or unexpected findings throughout the course of the study. The policy on incidental/unexpected findings will be reviewed by the Ethics Manager periodically to ensure that it remains up-to-date and in compliance with ethical and legal requirements.

7 PROTECTION OF VULNERABLE INDIVIDUALS/GROUPS

When conducting research involving vulnerable groups, it is crucial to prioritize their safety and well-being by implementing adequate measures to protect them from harm, coercion, or undue inducement. In the LUMINOUS project, vulnerable groups (neurological patients) were listed as key stakeholders in the piloting campaign (Pilot 1). LUMINOUS consortium identified the steps to be followed for their protection; the processes and procedures to be adhered entail the following:

7.1 INFORMED CONSENT

In the case of vulnerable, adult participants, informed consent will be provided by the lead partner of Pilot#1, and MindMaze, DFKI, VICOM, EHU, UCL partners in plain language that participants can easily

understand, avoiding using technical or academic jargon that may be difficult to comprehend. If the population is illiterate, the use of visual aids can be very helpful in explaining the research and obtaining consent. This would ensure that information is accessible to individuals with varying levels of literacy. Additionally, pictures or diagrams to explain the purpose of the study will be alternatively used, providing info related to the procedures involved, and the potential risks and benefits. In case the vulnerable participants speak a different language, pilot partners will provide a translator to explain the research and obtain consent. It is essential to use a qualified translator who can accurately translate the information and ensure that the participants fully understand the study. If/when needed a trusted intermediary will be used, who will explain the research and obtain consent on behalf of the researcher. This intermediary could be a community leader or someone who is familiar with the population and can act as a liaison between the researcher and the participants. Informed consent is especially important when working with vulnerable stakeholders. The spatial neglect will be appropriately assessed and documented by healthcare professionals. This will involve neuropsychological assessments, imaging studies, or clinical observations that take place as standard practice within the institutions involved in Pilot#1. The mitigation strategy includes standardised assessments and offer verbal instructions.

7.2 ETHICAL CONSIDERATIONS

All activities involving vulnerable groups in general will be designed to ensure their safety, privacy, and protection or exploitation to minimize any risks of harm or stigmatization. To this end an ethics risk assessment will be conducted prior to their participation in any research activity, to ensure that the research's benefits outweigh any potential harm, and appropriate measures can be implemented to mitigate any identified risks.

7.3 DATA PROTECTION

All personal data and information of the vulnerable, adult participants will be handled with utmost care and in compliance with relevant data protection regulations. Measures will be taken to ensure that their privacy is protected, and that their personal information is not shared or used inappropriately. It should be noted that within the partnership there is one partner based in UK (UCL) and two associated partners in Switzerland (MindMaze & Centre Hospitalier Universitaire Vaudois) and stakeholders will be recruited from these countries. As described in D5.1 Table 3, all partners involved have current practices aligned with GDPR and the pilot manager has an approved [clinical protocol](#) in place.

7.4 SUPPORT AND CARE

Vulnerable, adult participants will be provided with appropriate support and care throughout their participation in the project. This includes ensuring that they are comfortable, engaged, and that their needs are met, such as access to food, water, and breaks when needed. Researchers should also be sensitive to any special requirements or accommodations that participants may need, such as physical disabilities, cultural differences, or language barriers. Any concerns or issues that arise will be addressed by the respective partners promptly and appropriately, identifying the following steps:

1. Partners will establish a designated point of contact to address participant concerns or issues promptly and appropriately.

2. Regular check-ins will be scheduled with participants to ensure their comfort and meet their needs.
3. A supportive and inclusive environment will be fostered, promoting open communication and respecting participants' privacy.
4. Clear reporting mechanisms will be established, including confidential channels, to encourage participants to report any concerns or issues. The concerns will be reported in writing or verbally and documented anonymously from the partner linked with the participants and reported to the pilot manager for action to be taken if needed.
5. Partners will respond promptly to raised concerns, acknowledging, and investigating the matter as necessary.

Special requirements or accommodations, such as accessibility measures or language support, will be accommodated for participants with specific needs.

8 ETHICS DURING AND AFTER THE RESEARCH

Researchers not only need to obtain consent and address ethical concerns prior to conducting their research, but they also need to be mindful of issues that may arise during the research process itself. Researchers must be sensitive to the needs and experiences of vulnerable groups. They must ensure that the research is conducted in a respectful and non-discriminatory manner. Vulnerable Participants (Pilot 1) who may have experienced trauma or other adverse experiences should be provided with adequate support during and after the research study. Researchers should have a plan in place to provide participants with support services if necessary. Researchers will make sure that a respectful and non-discriminatory policy is followed by applying the following:

1. Establish a clear policy against discrimination, explicitly stating that no participant will be discriminated against based on age, gender, race, ethnicity, religion, disability, or socio-economic status.
2. Provide training to project personnel to promote cultural competence and ensure respectful inclusion of diverse perspectives.
3. Utilize inclusive communication methods, such as translation services and clear language, to ensure equal access to information for all participants, addressing language barriers as needed.
4. Ensure equal opportunities for participation and engagement, avoiding preferential treatment or exclusion based on personal attributes.
5. Regularly monitor and oversee the project to ensure adherence to the non-discrimination policy and ethical guidelines, promptly addressing any reported concerns regarding participant interactions

Actively seek and value ongoing feedback from participants to assess potential discriminatory practices or unintended biases, making necessary improvements to promote fairness and inclusivity.

9 COMPLIANCE WITH ETHICAL AND LEGAL STANDARDS

To ensure compliance with ethical and legal standards, LUMINOUS Ethics Manager in collaboration the EEAB, will consult with local laws and regulations related to all pilots with the view to

- a) prioritizing the safety and well-being of all individuals involved in the research process,
- b) being compliant with data protection.

10 CONCLUSION

In conclusion, D5.1 serves as a comprehensive overview of the ethical monitoring procedures to be implemented in the LUMINOUS project. This technology is human-centric by design; the ethical monitoring is put in place to safeguard well-being and fundamental rights of participants. The document outlines the rationale behind the ethical considerations and provides a structured framework for ensuring the protection of participants' rights and well-being.

The ethical guidelines and principles governing EU research are emphasized, highlighting the commitment of the LUMINOUS project to adhere to the AI governance framework, beyond research. The document further delves into the specific ethics considerations within the project and the description of each pilot, highlighting the unique ethical challenges associated with different contexts. Regarding human participants, **the importance of informed consent procedures is emphasized**. The document describes the process of obtaining participants' consent, including the recording and storage of consent documents. A template for the LUMINOUS informed consent and scope has been provided from the Ethics Manager, ensuring consistency and clarity in the consent process.

Ethical oversight within different work packages (WP) is addressed, outlining the procedures and criteria used to identify and recruit research participants for each pilot site. Templates for informed consent/assent forms and information sheets are provided, ensuring that participants are fully informed about the project and their involvement.

The policy for incidental/unexpected findings is discussed, demonstrating the project's commitment to handling unexpected information in an ethical and responsible manner. Measures are put in place to protect vulnerable individuals or groups, ensuring their well-being, and minimizing potential harm. Looking ahead, the LUMINOUS consortium, in collaboration with the Ethics Manager and the EEAB will continue to refine and update the ethical monitoring processes as the project progresses. The ethical considerations and documentation will be further developed and documented in subsequent deliverables (D6.1, D6.2 and D6.3), ensuring ongoing compliance with ethical guidelines and standards.

In summary, D5.1 provides a comprehensive framework and roadmap for ethical monitoring in the LUMINOUS project and all supplemented information is provided in the Annexes. It outlines the processes and documentation necessary for involving human participants, while adhering to EU research ethics guidelines. The document reflects the commitment of the consortium to prioritize the protection of participants' rights, well-being, and privacy throughout the project's lifecycle.

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11 ANNEXES

11.1 Annex 1 – LUMINOUS EEAB Terms of reference

11.1.1 LUMINOUS Ethics Governance

In order to properly address the ethical, social, and legal issues, the LUMINOUS consortium has a dedicated work package (WP5) within the project. The ethical governance model (based on systematic guidance, monitoring and reporting on the implementation of ethical requirements and guidelines), is embedded in the structure of WP8. From the viewpoint of ethics management, the key actors are the Coordinator, WP leaders and the EEAB. The WP5 leader will monitor and report on the status of the project with respect to ethical compliance and the ethical implications of innovation at each plenary meeting. Each WP Leader will be responsible for decisions about the protection and management of data gathered during the WP development and deployment or use within the project if gathered previously and advise on the safe, secure and compliant management and use of real data during and beyond the lifetime of the project. The role of the EEAB is to review D5.1, D5.2 and D5.3 deliverables, as shown in Figure 1, and provide *ad hoc* consultancy on ethical issues that emerge during the LUMINOUS project. The EEAB provides independent input to the Consortium on ethical compliance based on the reports and project meetings.

<p>D5.1: Humans (H) - Requirement No. 1 (M2) Public report</p> <ul style="list-style-type: none"> • Ethics approval for evaluation activities prior to pilots • Description of pilots • Ethical considerations • Documents required per pilot: <ul style="list-style-type: none"> - Recruitment of participants - Information Sheets - Consent Forms - Record of Processing Activities (RoPA) - Assessment Strategy - Intervention Strategy - Data Flow Diagrams - Measurement Tools • Incidental findings policy • Roles and responsibilities of project partners 	<p>D5.2: POPD- Requirement No. 2 (M2) Public report</p> <ul style="list-style-type: none"> • LUMINOUS Principles for the Protection of Personal Data (POPD) • Evaluation of ethical risks at each WP • Ethical Criteria relevant to the LUMINOUS Project <ul style="list-style-type: none"> - Protection of Personal Data - Procedures for Personal Data Collection - Procedures for Data Storage, Protection and Retention - Procedures for Data Destruction - Informed Consent Procedures for Surveys and Interviews - Informed Consent Procedures for Events, Surveys, and Interviews with External Participants - Ethics Requirements for Non-EU/EU countries, Stakeholders and External Ethics Advisory Board members • Compliance with European Union Ethical Principles - Data Protection Impact Assessment (DPIA) 	<p>D5.3: Trustworthy AI - Requirement No. 3 (M6) Public report</p> <p>LUMINOUS Assessment List for Trustworthy AI:</p> <ul style="list-style-type: none"> • Human agency and oversight • Technical Robustness and safety • Privacy and data governance • Transparency • Diversity, non-discrimination, and fairness • Societal and environmental well-being • Accountability
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Figure 1: EEAB Public reports/deliverables

11.1.2 External Ethics Advisory Board Terms of Reference (ToR)

11.1.2.1 Purpose of EEAB

The LUMINOUS project will include **user tests to validate the performance of the AI & XR-based solutions designed within the project**. The aim is to minimise the risk to human rights and values associated with the development of these solutions. As described in the proposal, three pilots will be performed and users will be asked to interact with LUMINOUS technologies and answer questionnaires regarding their interaction. **The users will include neurological patients, trainees, trainers, architects and engineers**. The data collection for this project includes language recordings (for the Neurorehabilitation pilots), questionnaires and results from interacting with LUMINOUS technology.

A work package lead by partner UCD is dedicated to the definition of Ethics Requirements (WP5). The purpose of the EEAB is to review the project progress and outcomes from the ethics perspective. The members of the consortium will provide the Commission a written confirmation that it has received favourable opinions of the relevant ethics committees of the institutional authorities in which the research is to be carried out. Copies of the official approvals from the relevant national or local ethics committees will be provided to the EC prior to the start of the respective research and the EEAB will be informed. Feedback on research findings will be provided to participants as part of acknowledging their contribution to the work and seeking their views on outputs and dissemination.

11.1.2.2 Compliance with ethical principles and relevant legislations

All beneficiaries and associated partners will follow local, national and EU regulations regarding data protection and will obtain approval from the local/national authority in charge of data protection, if applicable. In the UK, the following guidelines/laws will be considered: Data Protection Act 2018, Privacy and Electronic Communications Regulations 2018, Data Ethics Framework, Ethics, Transparency and Accountability Framework for Automated Decision-Making. In Switzerland, the following guidelines/laws will be obeyed: Federal Act on Data protection and Ordinance to the Federal Act on Data Protection. In addition, FFHS complies the guidelines of Swiss Academies of Arts and Sciences (May, 2021): Code of conduct scientific integrity.

LUMINOUS keeps a strategic overall approach based on appropriately structured data. The foreseen solution will be thoroughly evaluated and validated in a series of real contexts to define “best practices”. Such practices will take into consideration the profiles of both individuals and organisations, which are considered as dynamic entities. LUMINOUS Consortium has appointed EEAB, with relevant ethics expertise, to carry out a risk-benefit analysis of the intended research and to suggest appropriate safeguards to cover ethics’ risks (during and beyond the lifetime of the project) and inform the researchers, since even the solution at a glance denotes a number of ethical issues to be considered at the early stages of the project.

External Ethics Advisory Board (EEAB): A suitably experienced *ethics advisory board* will assist to deal with ethical issues and putting into place the procedures to handle these appropriately. The advisory board members are **external to the project and to the host institution; totally independent; and free from any conflict of interest**. EEAB will maintain an overview of the work throughout the whole course of the project and help to think ahead about possible problems that might arise and how they can be addressed. Their experience will help to check for compliance with ethical standards within the relevant research fields. EEAB members will also be responsible for reporting to the Coordinator, on a regular basis, on ethics concerns as they arise and the continuing probity of LUMINOUS project. Their oversight role should be fully integrated into the LUMINOUS research activities, and they must be fully aware of all the developments. EEAB is an essential element in the LUMINOUS project management structure.

Necessarily, given the nature of ethical debate, there might be differences of opinion and interpretation that remain to be resolved. Nevertheless, whenever possible, consensus has to be reached and action points proposed to the Coordination Board. The aim is to offer a focused and practical guidance for the ethical issues of the LUMINOUS Horizon Europe project delivery.

11.1.2.3 The role of EEAB

1. To foster an awareness of ethical principles and practices for **performance of the AI & XR-based solutions** for research and stakeholder community.
2. To facilitate excellence in **performance of the AI & XR-based** research and innovative practice for the well-being of the stakeholders the consortium works with.
3. To advise the LUMINOUS consortium members through the LUMINOUS ethics board on ethical issues related to **performance of the AI & XR-based solutions within the different pilots**.
4. To consider, at the request of the LUMINOUS consortium members, specific ethical issues raised before, during and after the intervention of the LUMINOUS pilots.
5. To prepare position statements on ethical issues on behalf of the LUMINOUS consortium.
6. To initiate and inform debate on ethical issues within the LUMINOUS consortium.

Nature of the advisory role

- a) The EEAB must maintain an overview of operations throughout a project, helping with preparation in terms of thinking ahead about possible problems and how they can be addressed. Any sense of static, 'tick-box' approvals must be avoided. EEAB members are resources for advice and guidance when ethical dilemmas arise during a project. EEAB with oversight functions will usually check compliance with ethical standards within the relevant research fields. Independence and freedom of any conflict of interests are requirements for the participation in the EEAB.
- b) The Chair of the EEAB is allowed to actively participate in plenary meetings. EEAB is fully integrated into the management structure. This active engagement facilitates ongoing liaison between the various agents and groups and helps ensure thorough knowledge of overall project activities and better acceptance and integration of the EEAB into the consortium activities.
- c) EEAB keeps up regular contact with any partner bearing Work Package (WP) responsibilities for ethics-related actions and that both know what actions the other is taking and planning. This should ensure consistency and help avoid any unnecessary duplication of effort. Principal link to the consortium has to be established between the Chair of the EEAB and the consortium. This is also important for ensuring consistency of advice and avoiding confusion – as controversial issues might need discussion among all members of the EEAB prior to the formulation of clear advice.
- d) Clarity in all communications coming from the EEAB is essential. Advice offered must be understandable by the partners so that appropriate actions can be taken – it must be pragmatic/workable. Direct communications between advisors and partners are vital.
- e) A culture of mutual respect and understanding of the other's position should be cultivated during all meetings
- f) Transparency and critical detachment are important components of ethical oversight. Being open and clear about decision, actions to take and the rationales behind them is good practice. All other project groups (partners and advisors) should be encouraged to raise issues with the EAB knowing they are to be treated with discretion.
- g) Ethics advisors should include independent summaries of discussions and issues arising in formal meetings in their regular reports.

In summary, the EEAB should do whatever is necessary to diligently monitor the aims, objectives, methodology and implications of the research to ensure that it conforms to the highest ethical standards and ensures that the researchers, the Commission and the general public are not exposed, by the work of the project, to activities that would be considered to be ethically unacceptable. As research activity is dynamic and evolves along unpredicted pathways advisors must be prepared to tackle new issues and concerns as they arise and the ethical perspective will need to be modified throughout the lifetime of the project. The role and tasks of the EEAB members vs. working practices are summarized in the table below.

Table 1: Tasks of the EEAB

Task	Annual meeting	Ad Hoc telco's or emails	Individual work
- Advice on ethics deliverables	X		X
- Advice on specific ethical questions and regulatory frameworks	X	X	X
- Reports to LUMINOUS project consortium and to EU commission	X		X

We can estimate that members of the EEAB will allocate their time to LUMINOUS ethics minimum 10 days during the whole project in years 2024-2026. The EEAB will participate with at least 1 representative yearly face-to-face permitted at the general assembly project meetings. In summary, EEAB will review and advice on the deliverables noted in Figure 1.

11.1.2.4 Definitions and Declarations

- (a) “External Ethics Advisory Board” (EEAB) is defined as a group of ethics experts giving advice to LUMINOUS project consortium partners in the context of a European Commission (EC) Horizon Europe funded project. The work of EEAB experts should facilitate, build upon and complement existing oversight regimes by competent ethical and legal authorities.
- (b) ‘Ethics’ is including questions of legal and regulatory compliance as well as a branch of philosophy. It is part of a process of ‘governance’. In this vein, the EC document “A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research” asserts that ethics is a “key oversight mechanism” to ensure that EU funded research is not misused.
- (c) The consideration of ethical issues, starting at the conceptual stage of a proposal, enhances the quality of research, increases its likely social impact, promotes research integrity, promotes a better alignment of research with social needs and expectations and, finally, supports the societal uptake of the fruits of research because high ethical standards generally merit public trust. EEAB members will be part of a positive research quality assurance strategy. However, EEAB members must retain the courage to be unpopular in cases where significant ethics problems arise and their intervention is necessary to maintain research ethics standards. Such challenges must be equally backed by effective powers.

- (d) Ethics advice will be incorporated into a project either as part of WP5. EEAB members' consultation is subcontracted activity due to the size of the project and the geographical impact.
- (e) Ongoing liaison between the EEAB and project partners might be optimized by the WP5 Leader taking the responsibility for communicating with the EEAB and informing the consortium. The Chair of the EAB must have extensive expertise in research ethics, data protection and/or privacy issues within EU projects.
- (f) Attendance by members at as many relevant meetings as possible (whether virtual or face-to-face) is important for consistency and continuity. If a member's formal attendance is limited for any reason, they should employ other means to ensure they are fully acquainted with how the project is progressing.

11.1.3 External Ethics Advisory Board (EEAB) Recruitment

According to the EU guidelines the members of the EEAB must be external to the project and to the host institution, as well as totally independent and free from any conflict of interest (EU 2019). LUMINOUS project has an Ethics Board composed from both external and internal members. With regard to the external members, it was suggested that their expertise should cover both technology and ethics legal regulation to represent the needs of the project. The role of the internal members is to be part of the ethics review but also, to inform the external partners of the background and context of the project without prejudicing their views.

The recruitment of the external EEAB members has entailed a collaborative process within the remit of WP5. All the partners in LUMINOUS were asked to propose suitable persons for EEAB either from their own organisations, from relevant stakeholders or from outside partner organizations after the kick off meeting in **January 2024 (4) proposals** were received and due to the complementarity of the expertise and relevance to the project all proposals were accepted and the consortium confirmed that there was no conflict of interest with none of the external experts recruited.

11.1.3.1 External Ethics Advisory Board (EEAB) Recruitment

The EEAB will consists of four (4) members. The chairperson has been appointed by the EEAB members and serve for the duration of the project but may be replaced if needed. The Chair of EEAB shall have the authority to invite other members to temporarily advise the committee on specific issues within their field of expertise. EEAB will meet at least two times per year, in person or electronically and request all documents needed from the project coordinator and WP5 leader. The Chair of the EEAB will report on its activities to the designated plenary meetings. Communication between EEAB members will primarily be by email records of all meetings and decision with supporting documentation will be maintained in the project's Google Drive under the WP5 folder (Ethics Requirements).

Declaration of Conflict of Interest

EEAB members should perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. Proper observation of these principles will protect the EAB and its members and will ensure it retains public confidence.

EEAB members attend meetings and undertake EEAB activities as independent persons responsible to the consortium. Members are not appointed as representatives of professional organizations or

community bodies. The EEAB should not, therefore, assume that a particular group’s interests have been considered because an EEAB member is associated with this group.

Members should declare, and the committee regularly review, their actual and potential conflicts of interest. When EEAB members believe they have a conflict of interest on a subject that will prevent them from reaching an impartial decision or from undertaking an activity consistent with the EEAB’s functions, they should declare that conflict of interest and withdraw themselves from the discussion and/or activity.

A member of the EEAB who is involved with an issue brought before the EEAB shall not take part in the EEAB’s assessment of that issue. The member may be present to answer questions but should take no part in the discussion surrounding the consideration of the issue or any decision relating to the issue. This will allow each issue to be considered in a free and frank manner. The EEAB must demonstrate transparency in avoiding or managing any real or perceived conflict of interest.

11.1.4 External Ethics Advisory Board (EEAB) Leadership

11.1.4.1 External Ethics Advisory Board (EEAB) Membership

The EEAB has a Chair, who has been elected from all Ethics Board members. The tenure of the chairs is for the duration of the project. The Chair have the following roles:

- Organizing representation of the EEAB at annual and ethics reviews.
- Communicating relevant information from the Ethics Manager (WP5 Leader) to the EEAB members.
- Working closely with the Ethics Manager in planning and carrying out meetings, agendas etc.

Table 2 shows the external and internal members of the EEAB. If one or more members become unavailable to participate, there will be a substitution of the member of the EAB. This will be agreed together with project consortium.

Table 2: Members of the LUMINOUS Ethics Board

#	External EAB Member	Expertise
1	Georgia Livieri	Horizon Europe projects’ Ethics Manager and Bioethicist
2	Roberto V. Zicari	Assessment of Trustworthy AI systems
3	Frank Hopfgartner	Data Science & Human-centred AI
4	Marta Bienkiewicz	AI: Governance x Policy x Landscape Human and Tech: Neuroscience, Societal Impact, Responsible Innovation, Inclusion and Ethics.

#	Internal EAB Member	Role
5	Eleni Mangina	Ethics Manager/WP5 Leader
6	Daniel Perez-Marcos	Pilot #1 Leader
7	Marco Bianchi	Pilot #2 Leader
8	Veronica Zennaro	Pilot #3 Leader / BIM & Architecture Design review
9	Florendia Fourli	All Pilots WP Leader

11.1.5 External Ethics Advisory Board (EEAB) Standard Operating Procedures

1. A ‘division of labour’ between the EEAB members should be formally agreed and clarified from the outset and applied to WP5 specific project deliverables according to EEAB members’ expertise in order to increase the efficiency of operations.
2. An EEAB Chair will be elected from the membership and may speak on their behalf. The consortium will interact with the EEAB via the Chair of the EEAB (e.g. advice on approval requirements, risk benefit assessments, guidance on specific ethical questions, reporting obligations, guidance concerning the relevant legal framework and regulatory requirements in the countries where the research takes place).
3. Ethical issues can become quite formidable or can be capable of being addressed in a straightforward way – largely dependent on the primary substantive focus of the project. In all cases ‘proportionality’ is of the utmost importance EEAB members are encouraged to meet via teleconference to discuss between the following calendar dates of the plenary meetings. Project partners should be invited to EAB meetings in case specific questions need to be addressed.
4. Securing the ‘best interests’ of the general public and civil society is one of the main goals. EEAB exists to offer guidance, advice, monitoring and recommendations for future work. Boards and advisors should operate while neither dominating the work nor obstructing it unnecessarily. They should be facilitative.
5. Fees and expenses: it is estimated that the EEAB members workload will be reimbursed for the duration of the project per EEAB member from project budget. Additionally, any travel/subsistence expenses occurred to attend the plenary meetings will be reimbursed from the project budget.
6. Although face-to-face meetings are advantageous in solving complicated issues, it is often not feasible to convene all members together at a certain place and time due to time and financial constraints. Alternatives will be organised from the Project Coordinator either e-mail conversation or videoconferences or one-off site visits.
7. The individual members of the EEAB should cooperate to work out consensus-based recommendations. In cases where no consensus can be reached, it is recommended that the EEAB provide a transparent overview on its discussion to the project management, detailing why no definitive advice was possible.

8. All meetings of the EEAB should be based on an agreed agenda to ensure efficient decision-making. Relevant documents should be circulated beforehand to allow for adequate preparation. Meetings should be co-ordinated by the Chair and a report should be prepared for each plenary meeting and communicated to the project management. The EEAB meetings will be organized in connection/conjunction with the other LUMINOUS plenary meetings (if possible) or as a virtual zoom meeting.
9. The EEAB will additionally have ad-hoc teleconferences when needed and at least one EAB member should attend the WP5 monthly meetings when deemed appropriate.
10. All EEAB meetings will be based on an agreed agenda to ensure efficient decision-making. Relevant documents should be circulated beforehand to allow for adequate preparation.
11. Communication: The EEAB will use email to communicate relevant information to all of its members. All members should be kept up to date electronically and should receive LUMINOUS dissemination materials, such as newsletters.
12. Meetings of the EEAB will be attended by:
 - EEAB external and internal members
 - LUMINOUS WP5 Leader (Ethics Manager) (where appropriate)
 - Further invited participants (where appropriate)

11.1.6 Identifying Ethical Principles and Criteria to Apply

- a. Ethics needs to permeate all parts of the project ‘culture’ to be effective. Table 3 denotes the LUMINOUS ethical challenges and other criteria for EEAB members consideration. In the interests of raising and maintaining ethical awareness, all aspects of the project’s activities require the maintenance of an ethical perspective. A sound ethics policy requires transparency and balance.
- b. EEAB will assist the consortium partners by establishing a set of ‘core values’ or ‘principles’ to adhere to. Additionally, an ethics checklist to act as an aide memoire and modified to apply specifically to the project in hand can be a focus for ethical practice for the duration of the project. Application of the checklist can highlight misunderstandings of terminology and conceptual problems associated with the rationales that lie behind conventional ethical principles. This together with applicable legal provisions, codes of conduct and guidance documents provided by the European Commission should form a base for the work of any EEAB. The Ethics Board should ensure, to the best of their ability, that the consortia adhere to the Fundamental Rights Declaration of the European Union¹.
- c. EEAB should ensure that both ethics screening reports and ethics review reports are fully available to partners, that they are acted upon and, as far as is possible, there is consistency of advice and practice across all ethics experts. The partners’ actions are consistent with their responses to the Ethics Issues identified within WP5 deliverables. Any subsequent amendments should be reported and explained to the EEAB. Where differences of opinion, judgment and/or interpretation exist within the EEAB, these should be explained to partners to assist in their application to practice.

¹ https://www.europarl.europa.eu/charter/pdf/text_en.pdf

Table 3: LUMINOUS Ethical Challenges and other criteria for EEAB members

Ethical challenges
R&D process (>research integrity during the LUMINOUS project)
- R&D challenges with vulnerable stakeholders (including consents)
- Data management and openness of the research data
- Incidental Findings during the research
Ethical features of the LUMINOUS project solution (>ethically, legally and societally sustainable LUMINOUS project)
- Vulnerable end-users and co-creators of AI-based data sources
- Agreements (with end-users)
- Challenges with the technology
- Challenges and possibilities of ethical AI development
- Data management on the LUMINOUS AI platform
- Privacy and Data protection: GDPR and data subject's rights in practise
- GDPR and organizational responsibilities in the LUMINOUS AI platform beyond the lifetime of the project
- Data & Cyber Security (both personal data and other)
Specific challenges within the 3 pilots
- Managing the collaboration with the end-users participating both in the research and using the LUMINOUS AI platform
- Privacy and Data protection during the pilots where the AI systems are still on the development phase
- Incidental findings during the processing of LUMINOUS data on the AI platform
Other criteria
- Independence of the person (coming outside the partner organizations)
- Person coming from Industry/business
- Person coming from regulation sector
- Person coming from user sector
- Person coming from academic sector

11.1.7 Consortium partners' GDPR experts/DPOs

Partner	GDPR Expert / DPO
DFKI	DPO: Dr. Roland Vogt roland.vogt@dfki.de. Phone: +49 681 85775 4131
Mindesk Srl	GDPR EXPERT: DataPro Srl https://dataprogdpr.com/ DPO: non-appointment (Annex DOC005 "Reason for the non-appointment of the DATA PROTECTION OFFICER")
VICOM	Naroa García de Eulate [GDPR expert] pi@vicomtech.org
VICOM	Dorleta García [DPO] dgarcia@vicomtech.org
LUDUS	Marco Bianchi GDPR company expert marco.bianchi@ludusglobal.com
UCD	UCD DPO, email: gdpr@ucd.ie
Hypercliq	Florendia Fourli, CEO & GDPR expert f.fourli@hypercliq.com
MindMaze	DPO Details: External Company Name: DPO Centre Ltd Email: advice@dpocentre.com Email: dpo@mindmaze.com
Fraunhofer HHI	GDPR expert: Charlotte Frank charlotte.frank@hhi.fraunhofer.de
CHUV	DPO: dpo@chuv.ch

Mindesk S.r.l
CF / P.IVA 07716840728
Via Volga c/o Fiera del Levante Impact Hub Padiglione 129, CAP 70132
E Mail: info@vection.com.au

Annex: DOC005 Reason for the non-appointment of the DATA PROTECTION OFFICER

Rev: 1

(Data Protection Officer o DPO)

Data controller

MIndesk S.r.l. Via Volga c/o Fiera del Levante Impact Hub Padiglione 129, CAP 70132

Art. 37 Reg. UE n. 679/2016 (GDPR)

PROVIDES

"1. The controller and the processor shall designate a data protection officer in any case where:

- a) the processing is carried out by a public authority or body, except for courts acting in their judicial capacity;
- b) the core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale; or
- c) the core activities of the controller or the processor consist of processing on a large scale of special categories of data pursuant to Article 9 or personal data relating to criminal convictions and offences referred to in Article 10."

It is clear that the Company is not a public authority or a public body.

In addition, whereas:

- the number of data subjects involved in the processing of data is very small in absolute terms, representing a small percentage with reference to the population of the geographical area in which the Company mainly provides its services;
- the amount of data processed is normal, with the Company usually requesting only the data for the identification of the data subjects and the email address;
- the data processed are of a normal type, as no special categories of personal data are processed;
- the processing lasts for the time necessary to provide the services to the data subject and, in any case, until the data subject withdraws his/her consent;
- the size of the Company is extremely small, as is its turnover, falling within the in the SME category; it is not considered reasonable to consider the Company's business as "on a large scale".

Finally, the Company does not process special categories of personal data or data relating to criminal convictions. For these reasons, it is not considered mandatory for the Company to appoint a data protection officer pursuant to art. 37, EU Reg. no. 679/2016 (GDPR).

Reason for the non-appointment of the Data Protection Officer		Codice: DOC005	
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Figure 2: Reason for the non-appointment of the DATA PROTECTION OFFICER (Mindesk Srl)

11.1.8 Meetings' Frequency and Consultation with other EC projects

11.1.8.1 Meetings' Frequency

The format and frequency of meetings reflect the proportionality of the EEAB within WP5 of the project, as the reporting function. EEAB members are encouraged to meet via teleconference to discuss between the following calendar dates of the project meetings. Project partners should be invited to EEAB meetings in case specific questions need to be addressed. The frequency of activities and meetings with the LUMINOUS consortium are as follows:

- (a) EEAB members finalised (M2)
- (b) EEAB members appoint a Chair and informs Project Coordinator (M2)
- (c) EEAB receives documents for reviewing (M2)
- (d) EEAB sends the ethics feedback report to Project Coordinator (M2)
- (e) EEAB Chair presents report and feedback to LUMINOUS Consortium at 2nd project meeting (TBC 2024)
- (f) EEAB receives documents prior to intervention of pilots (M10)
- (g) EEAB Chair presents report and feedback to LUMINOUS Consortium at 3rd project meeting (TBC 2024)
- (h) EEAB receives documents on evaluation of pilots (M22)
- (i) EEAB Chair presents report and feedback to LUMINOUS Consortium at 4th project meeting (TBC 2025)
- (j) EEAB Chair presents the report feedback to LUMINOUS Consortium at final project meeting (TBC 2026)

11.1.8.2 Expert Advice and Consultation with other EC projects

- a) EEAB should be aware of, and able to liaise with, other relevant EC funded projects. Many EC-funded projects have faced and continue to face very similar ethical issues. It should be possible for each new project to learn from them. A range of factors inhibits open cross-fertilisation and interaction between projects. These include intellectual property rights, security and confidentiality. But unless such 'obstacles' are overcome there is likely to be considerable duplication of effort, which is wasteful of resources and impedes the building of foundational work that could enable more rapid and widespread ethical awareness.
- b) Other EU projects that have established 'codes of conduct' could provide the basis for similar ethics progress elsewhere. One excellent model for large scale EC collaborative project that could inform practice is the ARETE H2020 Project (completed successfully April 2023 and the Ethics Manager has been the Coordinator of this project): <https://www.areteproject.eu/> The main point is to be aware of foundational advice, since they are dealing with vulnerable stakeholders at pilots' interventions.
- c) Any liaison activities between EEABs directly related to project actions should be discussed and agreed at the plenary meeting in advance, to ensure that no confidential, project-specific information is exchanged between competing research consortia. This could be contained in a confidentiality agreement. An exception should be included in any such agreement for the option to report ethical misconducts directly to the European Commission, to ensure adequate and timely information of the funding institution.

- d) Advice may be sought from recognised experts with
- Specialist knowledge in particular fields of emerging technologies
 - An understanding of relevant perspectives in AI and XR
 - An understanding of developing AI platforms
 - Expertise in ethical theory

It should be noted that the above list gives examples, without restricting the range of external expertise that may be sought. Where external consultation has taken place or advice has been sought, this should be documented and recorded where appropriate in the EEAB's decision on an issue.

11.1.9 Conclusion

The LUMINOUS project is related to sensitive personal, corporate and public data, so their protection and privacy is valued at all stages of the project. The technologies chosen to be used for the implementation of the project should primarily focus on the protection and privacy of the above data. An assessment of the technologies to be utilised within the proposed novel pedagogical framework and for the end-user privacy and protection policy (citizens, businesses, etc) must be provided prior to the implementation phase and the interventions of the pilots.

This document has provided all the basic information in relation to the composition of the EEAB for the LUMINOUS project, as well as the description of the working practices and tasks of the EEAB. It is a consultative body, which will ensure and improve the high ethical standard and the quality of whole project and to support the consortium on ethical issues arising.

Revision of this deliverable can be done if any of the described processes is altered.

References

1. LUMINOUS Grant Agreement (2023): <https://cordis.europa.eu/project/...>
2. European Commission (2021). Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects. July 2021:
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/roles-and-functions-of-ethics-advisory-ethics-advisory-boards-in-ec-funded-projects_he_en.pdf
3. European Commission (2021). How to complete your ethical self-assessment. European Commission July 2021:
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf
4. Research Ethics: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research:
https://ec.europa.eu/research/participants/data/ref/fp7/89797/improper-use_en.pdf
5. Ethics Guidelines for Trustworthy AI: Building trust in human-centric AI:
<https://ec.europa.eu/futurium/en/ai-alliance-consultation.1.html>

11.2 Annex 2 – LUMINOUS RoPA

The **General Data Protection Regulations** (GDPR) came into force in May 2018, in which Article 30 included a requirement for all public bodies to produce a Record of Processing Activities, or a ROPA, as outlined below:

Article 30 *Records of processing activities*

1. Each controller and, where applicable, the controller's representative, shall maintain a record of processing activities under its responsibility. That record shall contain all of the following information:

- (a) the name and contact details of the controller and, where applicable, the joint controller, the controller's representative and the data protection officer;
- (b) the purposes of the processing;
- (c) a description of the categories of data subjects and of the categories of personal data;
- (d) the categories of recipients to whom the personal data have been or will be disclosed including recipients in third countries or international organisations;
- (e) where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1), the documentation of suitable safeguards;
- (f) where possible, the envisaged time limits for erasure of the different categories of data;
- (g) where possible, a general description of the technical and organisational security measures referred to in Article 32(1).

2. Each processor and, where applicable, the processor's representative shall maintain a record of all categories of processing activities carried out on behalf of a controller, containing:

- (a) the name and contact details of the processor or processors and of each controller on behalf of which the processor is acting, and, where applicable, of the controller's or the processor's representative, and the data protection officer;
- (b) the categories of processing carried out on behalf of each controller;
- (c) where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1), the documentation of suitable safeguards;
- (d) where possible, a general description of the technical and organisational security measures referred to in Article 32 (1).

3. The records referred to in paragraphs 1 and 2 shall be in writing, including in electronic form.

This document is an inclusive and non-exhaustive list of the processes undertaken by sections within the LUMINOUS Consortium that utilise personal data; by nature it takes the form of a living document, which will be updated regularly with changes and amendments.

DATA CONTROLLER & Data Processor details

per Pilot per Partner are provided in D5.1 Annex 2 RoPA of WP5

11.2.1 Pilot 1

Partner Name/Participant Stakeholders	Pilot No	Name of Record	Data Subjects	Categories of Personal Data	Special Category data	Purpose of processing	Source of data	General Description Of Technical And Org. Security Measures	Retention Period	Categories Of Recipients	Basis For Transfer	Role Of Partner In Data Sharing	Third Countries/ Internat. Orgs That Personal Data Are Transferred To	Safeguards For Exceptional Transfers Of Personal Data To Third Countries Or International Organisations
CHUV		Consent 1 form	Neurological patients	Name, school, signature	N/A	Consent to participate in the project studies	Data subject	Data stored in secured CHUV storage	5 years	N/A Data stored at CHUV	N/A	Data controller	Switzerland	CHUV constantly reviews, audits and updates its technologies, processes, and practices designed to protect networks, computers, programs, and data from unauthorized access or damage. It does regular staff training, regarding the best practices and procedures related to cyber-security.
CHUV		Personal 1 data form	Neurological patients	gender, age, years of education, medical, clinical and behavioral information and assessments, training performance	N/A	Research study	Data subject	Pseudonymized (coded) data are stored in secured CHUV servers. Data sharing agreements with other involved partners of the consortium are in place.	5 years	LUDUS project Team for Pilot 1 LUMINOUS Consortium	N/A	Data controller, data processor	Switzerland	CHUV constantly reviews, audits and updates its technologies, processes, and practices designed to protect networks, computers, programs, and data from unauthorized access or damage. It does regular staff training, regarding the best practices and procedures related to cyber-security.
MindMaze / DFKI / VICOM / EMI		Personal 1 data form	Neurological patients	gender, age, years of education, medical, clinical and behavioral information and assessments, training performance	N/A	Research study	Data subject	Pseudonymized (coded) data are stored in secured MindMaze / DFKI / VICOM / EMI servers. Data sharing agreements with other involved partners of the consortium are in place.	5 years	LUDUS project Team for Pilot 1 LUMINOUS Consortium	N/A	Data processor	Switzerland	MindMaze / DFKI / VICOM / EMI constantly review, audits and updates its technologies, processes, and practices designed to protect networks, computers, programs, and data from unauthorized access or damage. It does regular staff training, regarding the best practices and procedures related to cyber-security.
CHUV		Consent 1 form	Healthcare professionals	Name, profession, age, years of experience, signature	N/A	Consent for media recordings	Data subject	Data stored in secured CHUV storage. Pseudonymized (coded) data are stored in secured CHUV servers. Data sharing agreements with other involved partners of the consortium are in place.	5 years	UCL	N/A	Data controller	Switzerland/UK	CHUV constantly reviews, audits and updates its technologies, processes, and practices designed to protect networks, computers, programs, and data from unauthorized access or damage. It does regular staff training, regarding the best practices and procedures related to cyber-security.
UCL		Consent 1 form	Neurological patients and healthcare professionals	Name, profession, age, years of experience, signature	N/A	Consent for media recordings	Data subject	Data stored in secured UCL storage. Pseudonymized (coded) data are stored in secured UCL servers. Data sharing agreements with other involved partners of the consortium are in place.	31/12/2026	N/A Data stored at UCL	N/A	Data controller, data processor	UK	UCL constantly reviews, audits and updates its technologies, processes, and practices designed to protect networks, computers, programs, and data from unauthorized access or damage. It does regular staff training, regarding the best practices and procedures related to cyber-security.

11.2.2 Pilot 2

Partner Name/Participant Stakeholders	Pilot No	Name of Record	Data Subjects	Categories of Personal Data	Special Category data	Purpose of processing	Source of data	General Description Of Technical And Org. Security Measures	Retention Period	Categories Of Recipients	Basis For Transfer	Role Of Partner In Data Sharing	Third Countries/ Internat. Orgs That Personal Data Are Transferred To	Safeguards For Exceptional Transfers Of Personal Data To Third Countries Or International Organisations
LUDUS	2	Invitation acceptance	Professionals, Personals	Name, company, city, country, contact details	No	Acceptances to the invitation will be collected through direct mails. A pdf of the email will be generated and managed in accordance with LUDUS' own information classification policy (ISO 27001). On the other hand, the same will be done with the acceptance document that collects the data of the participant.	Data subject	ISO 27001	According to national law and ISO 27001	LUDUS project Team LUMINOUS Consortium	N/A	Processor Controller	No	No
LUDUS	2	Consent forms	Professionals, Personals	Name	No	managed in accordance with LUDUS' own information classification policy (ISO 27001)	Data subject	ISO 27001	According to national law and ISO 27001	LUDUS project Team LUMINOUS Consortium	N/A	Processor Controller	No	No
LUDUS	2	Pilot participant datasheet	Professionals, Personals	Name, company, role in company, city, country, contact details, age, gender, category of participant	No	Pilot participant datasheet will be collected through direct mails. A pdf of the email will be generated and managed in accordance with LUDUS' own information classification policy (ISO 27001). On the other hand, the same will be done with the Pilot participant datasheet	Data subject	ISO 27001	According to national law and ISO 27001	LUDUS project Team LUMINOUS Consortium	N/A	Processor Controller	No	No
LUDUS	2	User details	Professionals, Personals	Name, company, city, country, contact details, user	No	User details will be collected through direct mails. A pdf of the email will be generated and managed in accordance with LUDUS' own information classification policy (ISO 27001). On the other hand, the same will be done with the Pilot participant datasheet	Data subject	ISO 27001	According to national law and ISO 27001	LUDUS project Team LUMINOUS Consortium	N/A	Processor Controller	No	No
LUDUS	2	Evaluation form	Professionals, Personals	Name, company, city, country, contact details, aae, sender	No	Evaluation form will be collected through direct mails. A pdf of the email will be generated and managed in accordance with LUDUS' own information classification policy (ISO 27001). On the other hand, the same will be done with the Pilot participant datasheet	Data subject	ISO 27001	According to national law and ISO 27001	LUDUS project Team LUMINOUS Consortium	N/A	Processor Controller	No	No

11.2.3 Pilot 3

Partner Name/Participant Stakeholders	Pilot No	Name of Record	Data Subjects	Categories of Personal data	Special Category data	Purpose of processing	Source of data	General Description Of Technical And Org. Security Measures	Retention Period	Categories Of Recipients	Basis For Transfer	Role Of Partner In Data Sharing	Third Countries/ Internat. Orgs That Personal Data Are Transferred To	Safeguards For Exceptional Transfers Of Personal Data To Third Countries Or International Organisations
MINDESK	3	Call for pilot architecture studio	Professionals	Name, surname, email	N/A	Authentication and authorization	Data subject	Mindesk Encrypted Server	1 year post project completion	Design Reviewer	N/A	Data controller Data Processor	N/A	N/A
MINDESK	3	Call for pilot engineering studio	Professionals	Name, surname, email	N/A	Authentication and authorization	Data subject	Mindesk Encrypted Server	1 year post project completion	Design Reviewer	N/A	Data controller Data Processor	N/A	N/A

11.3 Annex 3 – LUMINOUS Information Leaflets & Consent Forms

11.3.1 Pilot 1

Vaudois University Hospital Center
Department of Clinical Neurosciences
University Neurorehabilitation Service



Neuropsychology and Neurorehabilitation Department
av. Pierre Decker 5
CH-1011 Lausanne

Phone : +41 21 314 13 10
E-mail : sonia.crottaz-herbette@chuv.ch

Patient information form

Study title: Virtual reality exercises for the treatment of attentional deficits in brain-injured patients

This project is sponsored by MindMaze SA which is the promoter. It is conducted by the University Neurorehabilitation Service (formerly the Neuropsychology and Neurorehabilitation Department, at the Vaudois University Hospital Center) in Lausanne and Lavigny.

1. Objectives of the research project

We invite you to participate in a research project that aims to evaluate the use of innovative exercises of cognitive functions through video games presented with a virtual reality headset in patients suffering from cognitive deficits after the onset of brain damage.

Read this information carefully and do not hesitate to ask further questions if you require additional information (see section 16 for contact details). Please let us know if possible within 3 days whether or not you agree to participate in this study.

● 2. Selection of people who can participate in the study

Participation is open to all people who have brain injuries and who have a cognitive deficit in the area of attention and/or executive functions measured by a specialized test.

If you have this information sheet in your hands, it is because the doctor or neuropsychologist who is monitoring your care has estimated, on the general basis of your profile, that you could be eligible and potentially interested in participating in this study. He sent us, with your consent, your contact information. Please note that at this stage, your participation will still depend on the detailed study of your medical file and the results of the examinations that will be carried out.

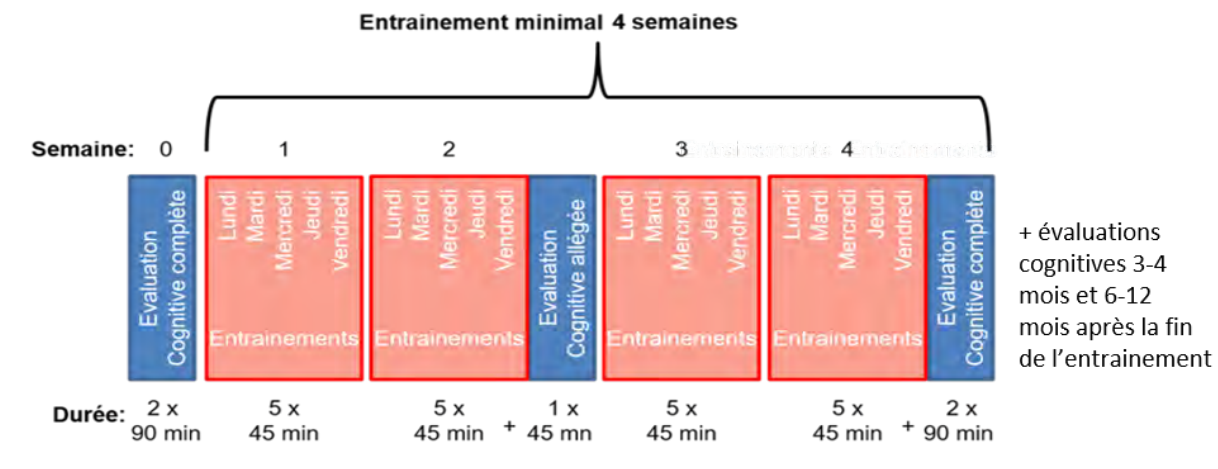
3. General information about the project

This study aims to evaluate the effectiveness, motivation, satisfaction, and safety of cognitive function exercises using virtual reality. This is a study carried out over 36 months within the University Neurorehabilitation Service in Lausanne and Lavigny. For this study, we are recruiting a total of 165 patients. The patients are distributed into 3 different groups. We carry out this study in compliance with the requirements of Swiss legislation. The competent cantonal ethics commission controlled and authorized the study.

You will participate in this study while following your usual rehabilitation sessions in parallel.

4. Procedure for participants

Study design:



If you give your consent to participate in this study, the investigators will assign you to a group, with equal probability. Each group will follow a slightly different type of training for 20 sessions. You will not be able to choose which group you will be assigned to. All training and testing sessions will be carried out in addition to the treatments offered to you as part of your treatment, we will not remove any of your treatment sessions to carry out these training or assessment sessions. You will be permanently under the supervision of a collaborator with certification in good clinical practices (ICH-GCP). In addition, at certain sessions, it is possible that a person responsible for ensuring the smooth running of the study is present. All training and evaluations will take place on the CHUV or Lavigny Institution site depending on where you are hospitalized.

Cognitive assessment

There will be several cognitive assessments as shown in the diagram above. These assessments will contain computerized tests, paper tests, and questionnaires to assess your cognitive abilities in several areas, your difficulties in your daily life, and determine whether you enjoy your training.

It is possible that during a clinic evaluation, outside of our study, you will do a test that we need in our study. In these cases, in order not to repeat the same tests, we will take the results of these tests from your medical file.

Cognitive training

The cognitive training contains 20 sessions, they will ideally be done every day, Monday to Friday, but at least 3 times a week. You will carry out these sessions individually, under the supervision of one of our colleagues. We will adjust the difficulty of the training sessions according to your performance as well as your state of fatigue. We will organize the exercises in small blocks of 5 minutes with breaks. In addition, we will regularly ask you how you feel, how tired you are, and your motivation. Each session normally lasts 45 minutes.

During these training sessions, you will be seated in a chair, and we will ask you to do exercises using, for example, sheets of paper, a computer, or a virtual reality headset with a controller that you hold in one hand. We will offer you exercises adapted to your difficulties. We will explain what you will have to do and allow you to practice.

Recordings made during sessions

During certain sessions, we will place sensors on your arms, legs, and trunk to record your movements. Additionally, during some sessions, we will make audio or video recordings of you and the therapist. These audio and video recordings will be done to better understand how patients and clinicians interact. You have the option to opt out of audio or video recordings at the end of this document.

5. Benefits for participants

You are not guaranteed any direct individual benefit from participation in this study and it is not a medical examination. The results of this study will allow us to better evaluate the potential of computerized training as a tool for the rehabilitation of cognitive functions in patients who have suffered brain injuries like you, and by extension, in patients suffering from other neurological diseases and/or or psychiatric with cognitive deficits.

6. Rights for participants

Voluntary nature of participation

Your participation in this study is voluntary, as a free choice. No one has the right to push you or influence you in any way. You are free to accept or refuse to participate in the project. If you choose to participate and reconsider your decision during the course of the project, or if you choose not to participate,, you will not have to justify yourself if you do not wish to do so. This will not change anything in your usual medical care. You can ask as many questions as you need about the study at any time. Please contact the person indicated at the end of this information sheet to do this.

Involuntary termination of the study

Your participation may also be interrupted by the investigator before the planned end. This could happen, for example, if your medical situation changes or if you have to change your place of hospitalization.

7. Obligations for participants

If you decide to participate in the study, we will ask you to respect a certain number of rules essential for the smooth running of the study, for your safety and your health. We will help you as best we can.

As a study participant, you will be required to :

- to show up for visits as agreed and be punctual, we will accompany you if necessary;
- to follow the instructions of the person assisting you in the study;
- to inform the person assisting you in the study of the evolution of your health and to report any new symptoms, any new disorders, and any changes in your condition;
- to inform the person assisting you in the study of all the medications you may be taking, even complementary medicine medications or those taken as self-medication.

8. Risks

By participating in this project we believe that the associated risks are no greater than during everyday activities, such as when watching television, using your smartphone, or playing video games. No major risks are associated with the use of our equipment.

A few people may report feelings of dizziness, fatigue, or headache, but these phenomena are generally mild and transient. If this is the case, the training session may be stopped at your request, or at the request of the person supervising the session.

9. Discoveries during the project

The project investigator will notify you during the study of any new discovery likely to influence the benefits of the study or your safety, and therefore your consent to participate. In the event of incidental discoveries that, in your case, could contribute to the prevention, diagnosis, and/or treatment of existing or probable diseases in the future, the investigator with the project doctor will inform you.

10. Data confidentiality

For the purposes of the study, we will record personal and medical data. Only a limited number of people can view your data in uncoded form, and exclusively to be able to accomplish tasks necessary for the progress of the project. Next, the data collected for research purposes is coded (coding means that all data that identifies you, e.g., name, date of birth, is replaced by a code (coding method) accepted by Swiss ethics). The code remains permanently within the hospital. In the case of a publication, any published data is therefore not attributable to you as a person. Your name will never appear on the internet or in any publication.

All persons involved in the study in any way are bound by professional secrecy. All data protection guidelines are complied with, and you have the right to view your data at any time.

The coded data from this study will be shared via a secure channel between the two sites (CHUV and the Lavigny Institution) and the study sponsor, the Lausanne-based company MindMaze SA. A legally binding contract has been

established that binds the different parties to respect the strictest rules in terms of confidentiality of the transfer, processing, and storage of your data, meeting Swiss standards in this area.

During its progress, the project may be subject to inspections. These can be carried out by the ethics commission which was responsible for its initial control and authorized it, but also be mandated by the organization which initiated it. Project management may be required to disclose your personal and medical information for the purposes of these inspections. In the event of damage, an insurance representative may also be required to view your data. However, this can only concern elements absolutely necessary for the investigation of the file. All people involved are bound by professional secrecy.

The investigator or doctor responsible for the study may contact your treating physician in the future to obtain information about your state of health relevant to this project.

11. Withdrawal from the project

You can withdraw from the project at any time if you wish, without justifying the reason and with no disadvantage to your treatment and to the patient-doctor relationship. The data collected so far will nevertheless be analyzed, so as not to compromise the value of the study as a whole, unless we expressly object to this. After your withdrawal, and once the analysis of your data is complete, we will anonymize your data, permanently erasing the code linking it to your person. After that, no one will be able to know that this data is yours.

12. Compensation

If you participate in this project, you will not receive any remuneration for this. However, you will be reimbursed for any expenses, such as transportation costs, that arise directly from participation in the study.

13. Repair of damage suffered

Any health damage you may suffer as a result of this study is the responsibility of the company that initiated it. The conditions and procedures are set by law. In the event of possible damage caused to participants as part of the study, the company MindMaze SA will be liable for this damage in its capacity as promoter of this project in accordance with the applicable legal provisions. The company MindMaze SA (chemin de Roseneck 5, 1006 Lausanne) has taken out insurance with the company Chubb Insurance (Bärengasse 32, 8001 Zurich) to be able to repair the damage falling under its responsibility. If you have suffered any damage, please contact the investigator or doctor responsible for the project or the insurance company mentioned above.

14. Funding of the study

The study is partly financed by the Lausanne-based company MindMaze SA, which develops medical products for neurorehabilitation, as well as by an Innosuisse fund from the Swiss Confederation.

15. Interlocutors

In case of doubt, fear or need for information during or after the study, you can contact one of the following contacts at any time:

Principal investigator of the study:

Professor Stephanie Clarke
Vaudois University Hospital Center (CHUV)
Department of Clinical Neurosciences
Neuropsychology and Neurorehabilitation Department

Avenue Pierre Decker 5
CH-1011 Lausanne
Email : stephanie.clarke@chuv.ch
Telephone: +41 21 314 13 10

Study coordinator at CHUV:

Sonia Herbette
Vaudois University Hospital Center (CHUV)
Department of Clinical Neurosciences
Neuropsychology and Neurorehabilitation Department

Av.Pierre Decker 5
CH-1011 Lausanne
E-mail : sonia.crottaz-herbette@chuv.ch
Telephone : +41 21 314 13 10

Study coordinator at the Lavigny Institution:

Samanta Simioni

Rte du Vignoble 60
CH-1175 Lavigny
Email: samanta.simioni@ilavigny.ch
Telephone: +41 21 821 45 81



Vaudois University Hospital Center Institution of Lavigny

Teacher. Stephanie Clarke

Vaudois University Hospital Center (CHUV)

Neuropsychology and Neurorehabilitation Department

Avenue Pierre Decker 5

CH-1011 Lausanne

Email : stephanie.clarke@chuv.ch

Telephone: +41 21 314 13 10

Written declaration of consent for participation in a study

- Please read this form carefully.
- Don't hesitate to ask questions when you don't understand something or want clarification.

BASEC number of the study	2021-01598
Study title:	Virtual reality exercises for treatment deficits in brain-damaged patients
Study promoter:	MindMaze SA, ch. de Roseneck 5, 1006 Lausanne
Location of the study:	University Neurorehabilitation Service, Av. Pierre Decker 5, 1011 Lausanne And Lavigny Institution, University Neurorehabilitation Service, route du Vignoble 60, 1175 Lavigny
Responsible for the study at CHUV:	Sonia Herbette Department of Neuropsychology and Neurorehabilitation , Av. Pierre Decker 5, 1011 Lausanne 021 314 13 10 sonia.crottaz-herbette@chuv.ch
Responsible for the study at the Institution from Lavigny	Samanta Simioni Institution of Lavigny Rte du Vignoble 60, 1175 Lavigny 021 821 45 81 samanta.simioni@ilavigny.ch
Participant	
First and last name:	
Date of birth :	

- I declare to have been informed, by the undersigned study manager providing information, orally and in writing, of the objectives and progress of the study as well as the presumed effects, advantages, possible disadvantages, and possible risks.



- I am taking part in this study voluntarily, as a choice under free will, and I accept the content of the information sheet given to me on the aforementioned project. I had enough time to make my decision.
- I received satisfactory answers to the questions I asked in relation to my participation in the project. I keep the information sheet and receive a copy of my written declaration of consent.
- I accept that the competent specialists of the institution, of the project promoter, of the Ethics Commission responsible for this study, may consult my raw data in order to carry out checks, provided however that the confidentiality of this data is strictly insured.
- I will be informed of (incidental) findings that have a direct impact on my health. If I do not wish to obtain this information, I will notify the investigator.
- I know that my data may be transmitted for research purposes only within the framework of this project and in encoded form, also abroad.
- In the event of subsequent treatment outside the location of this project, I authorize my physician(s) to provide the investigator or physician responsible for the project with post-study data relevant to the project.
- I can, at any time and without having to justify myself, revoke my consent to participate in the study, without this having any adverse impact on the continuation of my medical care, not on the patient-physician relationship. I know that the data that has been collected so far will however be analyzed.
- I am informed that the civil liability of the sponsor MindMaze covers any possible damage attributable to the project that I may suffer.
- I am aware that the obligations mentioned in the participant information sheet must be respected throughout the duration of the study. The study management may exclude me at any time in the interest of my health.

PHOTO and AUDIOVISUAL RECORDING

By affixing my signature below:

- I agree to be the subject of a photo or audiovisual recording.
- I agree to be the subject of an audio recording.
- I understand that this photo/recording is for research purposes only.
- I understand having the ability to view this photo and/or view/listen to this recording.
- I have been informed that at my request, at any time, this photo/recording may be deleted.
- I want my face blurred and my voice altered or transcribed if the photo or recording is released for research purposes.

Place date :	First and last name : Signature of participant
--------------	---

Investigator's Certification: I hereby certify that I have explained to the participant the nature, importance and scope of the project. I declare that I satisfy all obligations in relation to this project in accordance with the law in force. If I become aware, at any time during the completion of the project, of elements likely to influence the participant's consent to take part in the project, I undertake to inform them immediately.

Place date :	First and last name :
	Signature of the investigator

Authorization form for sound and video recording

Introduction: As part of a research project in collaboration with the Lausanne University Hospital (CHUV), MindMaze SA would like to record patient-therapist interactions during rehabilitation sessions with the aim of analyzing how these interactions are structured.

Any information that could identify you will be deleted. These recordings will be analyzed by MindMaze SA, as well as by MindMaze SA partners, in Switzerland and abroad, for research purposes only.

These may be sound recordings only (audio), or video recordings (audiovisual). Below you have the option to accept or refuse one or both types of recordings.

Authorizations granted:

Considering the above, MindMaze SA may carry out audio or audiovisual recordings according to the agreements you have given:

- I agree to be the subject of an audiovisual recording (a video).
- I agree to only be the subject of an audio recording, not video.
- I agree that this recording may be shared with MindMaze partners and for research purposes only.
- I understand I have the possibility to view/listen to this recording.
- I have been informed that at my request, at any time, this recording may be deleted.
- I want my face blurred and my voice altered if the recording is released for research purposes.

I hereby waive any right to compensation for these recordings.

I have read and accepted the conditions of use, which must be interpreted and applied in accordance with Swiss law.

PARTICIPANT'S SURNAME AND FIRST NAME	
PLACE DATE	SIGNATURE

11.3.2 Pilot 2



LUMINOUS

INFORMATION FOR THE LUMINOUS PILOT 2 PROJECT

Main information

WHAT IS THIS RESEARCH ABOUT? The LUMINOUS – The LUMINOUS project is looking for volunteers to try out and test a pilot LLM system applied to the LUDUS GLOBAL platform. The platform is aimed at HSE training.

WHO IS DOING THIS RESEARCH? This pilot (Pilot 2) is one of three pilot studies of HORIZON funded LUMINOUS project which is coordinated by Prof. Didier Stricker from the DEUTSCHES FORSCHUNGSZENTRUM FÜR KUNSTLICHE INTELLIGENZ GMBH (DFKI) in partnership with Ludus Tech SL, MindMaze, Centre Hospitalier Universitaire Vaudois, University College London, Fraunhofer Gesellschaft Zur Förderung Der Ang, Universidad Del Pais Vasco/ Euskal Herriko Uniber, Fundacion Centro De Tecnologias De Interaccion, University College Dublin, Hypercliq Ike, Ricoh International Bv.

WHY WOULD YOU CONSIDER PARTICIPATING IN THIS RESEARCH? By taking part in this pilot, you will contribute to improve training experience that will be more interactive and engaging – Cost and time savings: Development of VR training with LLMs will be more cost-effective and time-efficient than current methods (LLM based scalability) – Increase of effectiveness and efficiency of training programs, leading to improved safety outcomes and better-prepared workers.

WHAT ARE THE SELECTION CRITERIA TO TAKE PART? To help us in this research project, we are looking for people who:

- Are workers, students or rescue agents.
- Have previous experience with VR applications.
- Have the possibility to participate in Bilbao, Spain.
- Are willing to participate.

WHEN WILL THE RESEARCH START? We aim to start in March 2026 after the recruitment stage is completed.

WHAT DO WE EXPECT FROM YOU? Before starting, we will ask you to sign consent forms and some other datasheet. Then, you will be invited to come to our office or another place (to be defined) where you will try the already existing platform LUDUS GLOBAL and the pilot, using LLM, developed during the LUMINOUS project.

We will ask you to provide us with feedback on both of the experiences.

We expect the process to start in March 2026, and it would take you a total of 1 hour max to participate in the study and be confident in the software usage.

HOW WILL YOUR DATA BE USED?

The data collected during the Pilot 2 include minimal personal data (name, surname, mail, etc.) during registration. Furthermore, the same data will be used for evaluation and feedback.

The methods of data collection for Pilot 2 include:

- 1. Recruitment:** The recruitment of all volunteers will take place via company mails directed to the stakeholders. All personal identifiable data collected during recruitment will remain and will be in the possession of LUDUS TECH S.L. and will be exclusively shared with the members of the Luminous project team. **Only anonymized data will be shared with the other members.**
- 2. Direct observations**
2.1 Data exchange between the Pilot applications and the LUMINOUS application stack: The data collected will be used for training and validation of the LLM. Data will be exchanged via secure streams to guarantee privacy and integrity of the exchanged data. Pilot 2 does not (seek to) collect any sensitive data.

WHAT WILL HAPPEN IF YOU DECIDE TO TAKE PART IN THIS RESEARCH STUDY? With this pilot study (LUMINOUS Pilot 2), we intend to make further progress in providing and sharing the benefits of cutting-edge technologies in the training sector for industry.



This project has received funding from the European Union's HORIZON research and Innovation program under grant agreement No 101135774. Content provided and information within this document is the sole responsibility of the LUMINOUS Consortium and does not necessarily represent the views expressed by the European Commission or its services.



The consortium confirms that volunteers will have been provided with information on all recipients of their data in advance of any processing of their personal data.

HOW WILL YOUR PRIVACY BE PROTECTED? Volunteers consent forms will be collected and stored by LUDUS TECH S.L. The LUMINOUS consortium will follow the GDPR rules and inform the participants how their data will be used.

WHAT ARE THE RISKS OF TAKING PART IN THIS RESEARCH STUDY? There is no risk to participants in taking part in this research project. The LUMINOUS project follows the high ethical guidelines and standards required for EU HORIZON-CL4-2023-HUMAN-01-21 — Next Generation Extended Reality (RIA) Project.

CAN YOU CHANGE YOUR MIND AT ANY STAGE AND WITHDRAW FROM THE STUDY? Yes, if you decide that you do not wish to participate, you may withdraw at any time, and you do not need to provide a reason and with no disadvantage. Just please inform LUDUS TECH S.L. of your decision. All data linked to your participation will then be immediately destroyed.

HOW WILL YOU FIND OUT ABOUT THE OUTCOMES OF THIS PROJECT? Once the project is completed and the results have been published, the information will be uploaded onto the LUMINOUS website.

CONTACT DETAILS FOR FURTHER INFORMATION: For more information on this project please visit our project website and email us at: marco.bianchi@ludusglobal.com.

If you feel that your private data or your rights were infringed under the GDPR, you have the right to make an official complaint to the data protection authorities in your country or the data protection authority where the infringement occurred https://edpb.europa.eu/about-edpb/aboutedpb/members_en.

VOLUNTEERS CONSENT FORM

LUMINOUS Pilot 2: Health, Safety and Environment training.

Note: All personal identifiable data collected in this form will be collected by and remain in the possession of LUDUS TECH S.L. and will be exclusively shared with the members of the Luminous project team. Please refer to the privacy section in the Information handout for further details.

- I have read and understood the Designer information leaflet for the LUMINOUS Pilot 2.
- I understand what the study is about and what my results will be used for.
- I consent video and audio recordings to take place during the intervention.]
- I have had time to consider whether to take part in the study and ask as many questions as possible.
- I understand that my personal information will not appear on any research data from this pilot study and any audio/video recordings will be deleted permanently once information for the project is collected and will be exclusively shared with the members of the Luminous project team.
- I am aware of the procedures involving my participation and of possible risks and benefits associated with the study.
- I understand that my **participation is voluntary** (choice under free will) and that I am free to withdraw from the research study at any time without disadvantage and without giving any reason. Therefore, I **agree to take part in this research** (please tick the box):



This project has received funding from the European Union's HORIZON research and innovation program under grant agreement No 101135724. Content provided and information within this document is the sole responsibility of the LUMINOUS Consortium and does not necessarily represent the views expressed by the European Commission or its services.



Name of Participant (in block letters): _____

Signature: _____ Date: _____

Please return this form to: project@ludusglobal.com.

CONTACT DETAILS FOR FURTHER INFORMATION:

For more information on this project please visit our project website. If you have any questions about the protection of your personal data or if you wish to exercise your rights under the GDPR to access, rectify or, as the case may be, to erase any personal data relating to you or restrict the processing of your personal data, you may contact us at marco.bianchi@ludusglobal.com.

If you feel that your private data or your rights were infringed under the GDPR, you have the right to make an official complaint to the data protection authorities in your country or the data protection authority where the infringement occurred:



11.3.3 Pilot 3



INFORMATION FOR THE LUMINOUS PILOT 2 PROJECT

Main information

WHAT IS THIS RESEARCH ABOUT? The LUMINOUS – The LUMINOUS project is looking for volunteers to try out and test a pilot LLM system applied to the LUDUS GLOBAL platform. The platform is aimed at HSE training.

WHO IS DOING THIS RESEARCH? This pilot (Pilot 2) is one of three pilot studies of HORIZON funded LUMINOUS project which is coordinated by Prof. Didier Stricker from the DEUTSCHES FORSCHUNGSZENTRUM FÜR KÜNSTLICHE INTELLIGENZ GMBH (DFKI) in partnership with Ludus Tech SL, MindMaze, Centre Hospitalier Universitaire Vaudois, University College London, Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung, Universidad Del Pais Vasco/ Euskal Herriko Uniber, Fundacion Centro De Tecnologias De Interaccion, University College Dublin, Hypercliq Ike, Ricoh International Bv.

WHY WOULD YOU CONSIDER PARTICIPATING IN THIS RESEARCH? By taking part in this pilot, you will contribute to improve training experience that will be more interactive and engaging – Cost and time savings: Development of VR training with LLMs will be more cost-effective and time-efficient than current methods (LLM based scalability) – Increase of effectiveness and efficiency of training programs, leading to improved safety outcomes and better-prepared workers.

WHAT ARE THE SELECTION CRITERIA TO TAKE PART? To help us in this research project, we are looking for people who:

- Are workers, students or rescue agents.
- Have previous experience with VR applications.
- Have the possibility to participate in Bilbao, Spain.
- Are willing to participate.

WHEN WILL THE RESEARCH START? We aim to start in March 2026 after the recruitment stage is completed.

WHAT DO WE EXPECT FROM YOU? Before starting, we will ask you to sign consent forms and some other datasheet. Then, you will be invited to come to our office or another place (to be defined) where you will try the already existing platform LUDUS GLOBAL and the pilot, using LLM, developed during the LUMINOUS project.

We will ask you to provide us with feedback on both of the experiences.

We expect the process to start in March 2026, and it would take you a total of 1 hour max to participate in the study and be confident in the software usage.

HOW WILL YOUR DATA BE USED?

The data collected during the Pilot 2 include minimal personal data (name, surname, mail, etc.) during registration. Furthermore, the same data will be used for evaluation and feedback.

The methods of data collection for Pilot 2 include:

1. Recruitment: The recruitment of all volunteers will take place via company mails directed to the stakeholders. All personal identifiable data collected during recruitment will remain and will be in the possession of LUDUS TECH S.L. and will be exclusively shared with the members of the Luminous project team. **Only anonymized data will be shared with the other members.**

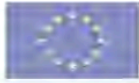
2. Direct observations

2.1 Data exchange between the Pilot applications and the LUMINOUS application stack: The data collected will be used for training and validation of the LLM. Data will be exchanged via secure streams to guarantee privacy and integrity of the exchanged data. Pilot 2 does not (seek to) collect any sensitive data.

WHAT WILL HAPPEN IF YOU DECIDE TO TAKE PART IN THIS RESEARCH STUDY? With this pilot study (LUMINOUS Pilot 2), we intend to make further progress in providing and sharing the benefits of cutting-edge technologies in the training sector for industry.



This project has received funding from the European Union's HORIZON research and innovation program under grant agreement No 101135724. Content provided and information within this document is the sole responsibility of the LUMINOUS Consortium and does not necessarily represent the views expressed by the European Commission or its services.



WHAT WILL HAPPEN IF YOU DECIDE TO TAKE PART IN THIS RESEARCH STUDY? With this pilot study (LUMINOUS Pilot 3), we seek to enable architecture and interior design firms to carry out in-field tests on the use of the platform within a professional environment.

The consortium confirms that designers will have been provided with information on all recipients of their data in advance of any processing of their personal data.

HOW WILL YOUR PRIVACY BE PROTECTED? Designers consent forms will be collected and stored by MINDESK. The LUMINOUS consortium will follow the GDPR rules and inform the participants how their data will be used.

WHAT ARE THE RISKS OF TAKING PART IN THIS RESEARCH STUDY? There is minimal risk to participants in taking part in this research project. The LUMINOUS project follows the high ethical guidelines and standards required for EU HORIZON-CL4-2023-HUMAN-01-21 — Next Generation Extended Reality (RIA) Project.

CAN YOU CHANGE YOUR MIND AT ANY STAGE AND WITHDRAW FROM THE STUDY? Yes, if you decide that you do not wish to participate, you may withdraw at any time, and you do not need to provide a reason and with no disadvantage. Just please inform MINDESK of your decision. All data linked to your participation will then be immediately destroyed.

HOW WILL YOU FIND OUT ABOUT THE OUTCOMES OF THIS PROJECT? Once the project is completed and the results have been published, the information will be uploaded onto the LUMINOUS website.

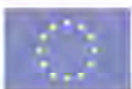
CONTACT DETAILS FOR FURTHER INFORMATION: For more information on this project please visit [our project website](#) If you feel that your private data or your rights were infringed under the GDPR, you have the right to make an official complaint to the data protection authorities in your country or the data protection authority where the infringement occurred https://edpb.europa.eu/about-edpb/aboutedpb/members_en.

DESIGNER CONSENT FORM

LUMINOUS Pilot 3: BIM & Architecture Design Review– Evaluating the integrated language-augmented multimodal platform.

Note: All personal identifiable data collected in this form will be collected by and remain in the possession of MINDESK and **will** be exclusively shared with the members of the Luminous project team. Please refer to the privacy section in the Information handout for further details.

- I have read and understood the Designer information leaflet for the LUMINOUS Pilot 3 study.
- I understand what the study is about and what my results will be used for.
- I have had time to consider whether to take part in the study.
- I understand that my personal information will not appear on any research data from this pilot study and any audio/video recordings will be deleted permanently once information for the project is collected and will be exclusively shared with the members of the Luminous project team.
- I am aware of the procedures involving my participation and of possible risks and benefits associated with the study.
- I understand that my **participation is voluntary** (choice under free will) and that I am free to withdraw from the research study at any time without disadvantage and without giving any reason. Therefore, **I agree to take part in this research** (please tick the box):





LUMINOUS

Name of Participant (in block letters): _____

Signature: _____ Date: _____

Please return this form to: info@vection-technologies.com

CONTACT DETAILS FOR FURTHER INFORMATION:

For more information on this project please visit our project website, or email didier.stricker@dfki.de.

If you have any questions about the protection of your personal data or if you wish to exercise your rights under the GDPR to access, rectify or to erase any personal data relating to you or restrict the processing of your personal data, you may contact us at didier.stricker@dfki.de.

If you feel that your private data or your rights were infringed under the GDPR, you have the right to make an official complaint to the data protection authorities in your country or the data protection authority where the infringement occurred:

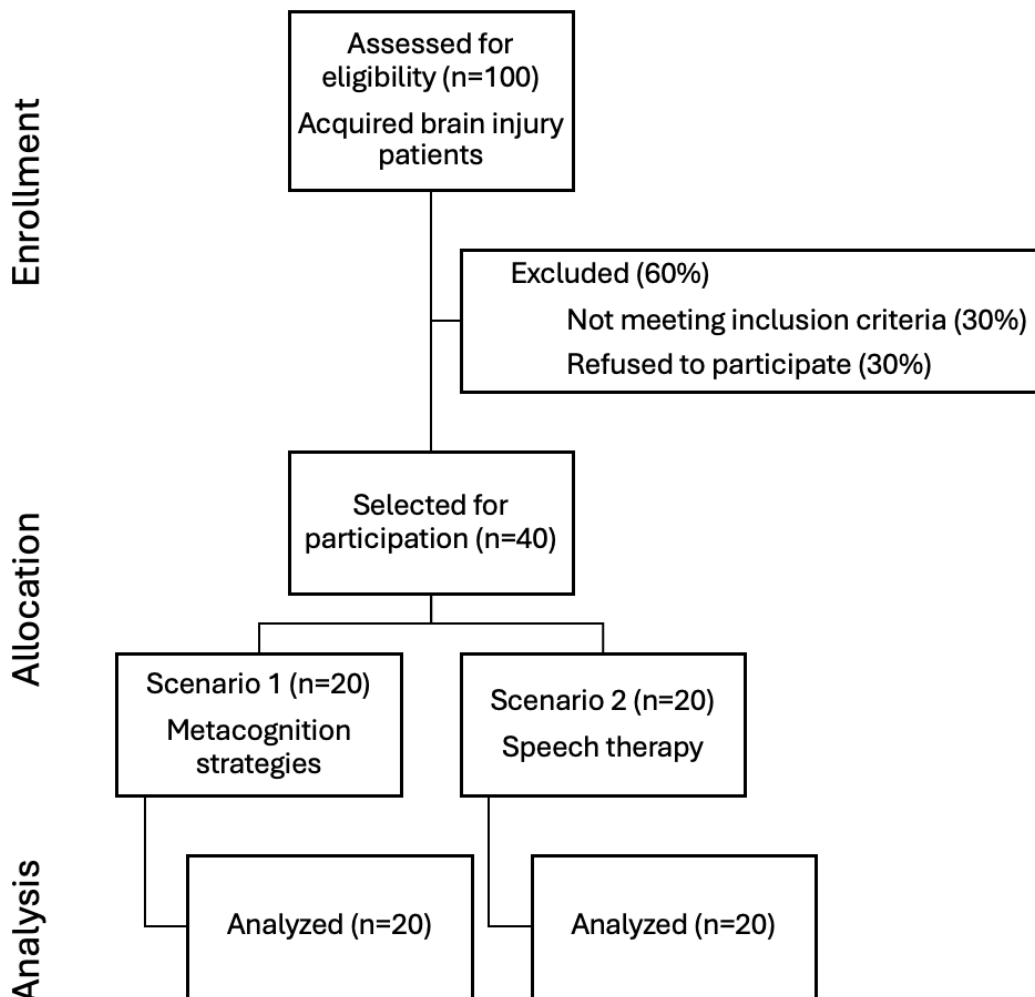


11.4 Annex 4 – LUMINOUS Pilots Consort Diagrams

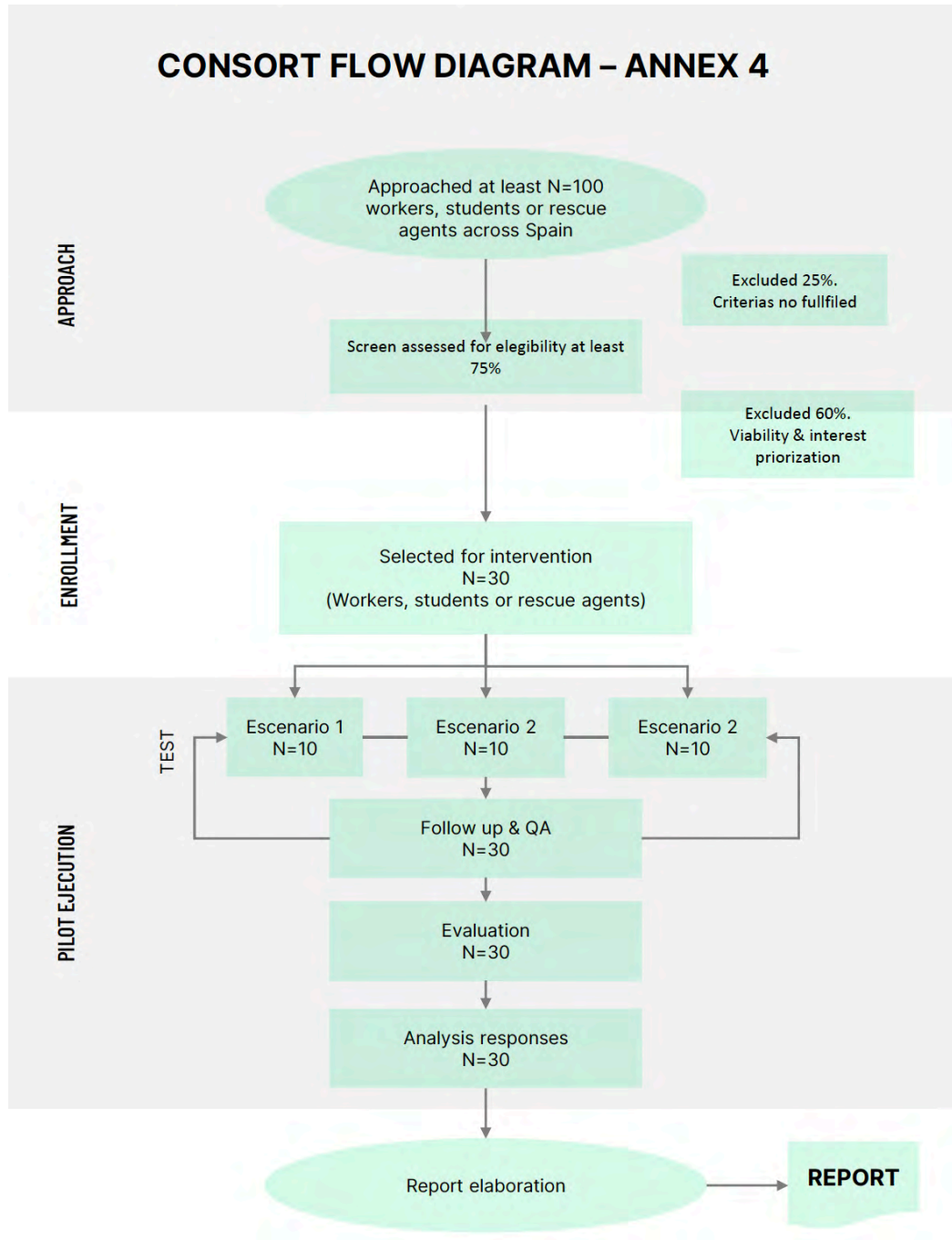
11.4.1 Pilot 1 Consort Diagram TBC

CONSORT Diagram – Pilot 1 (NeuroRehab)

Participants projection

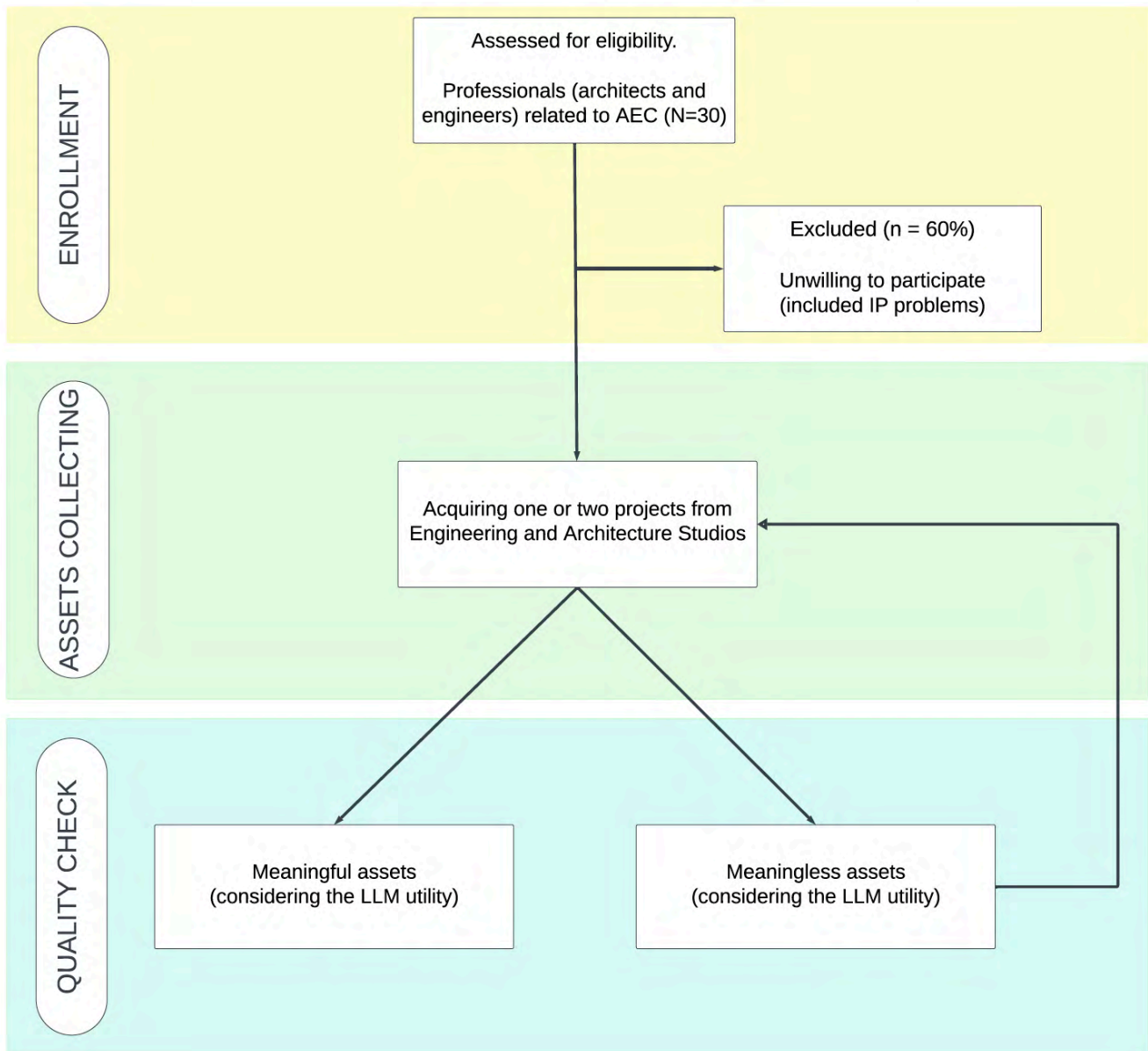


11.4.2 Pilot 2



11.4.3 Pilot 3

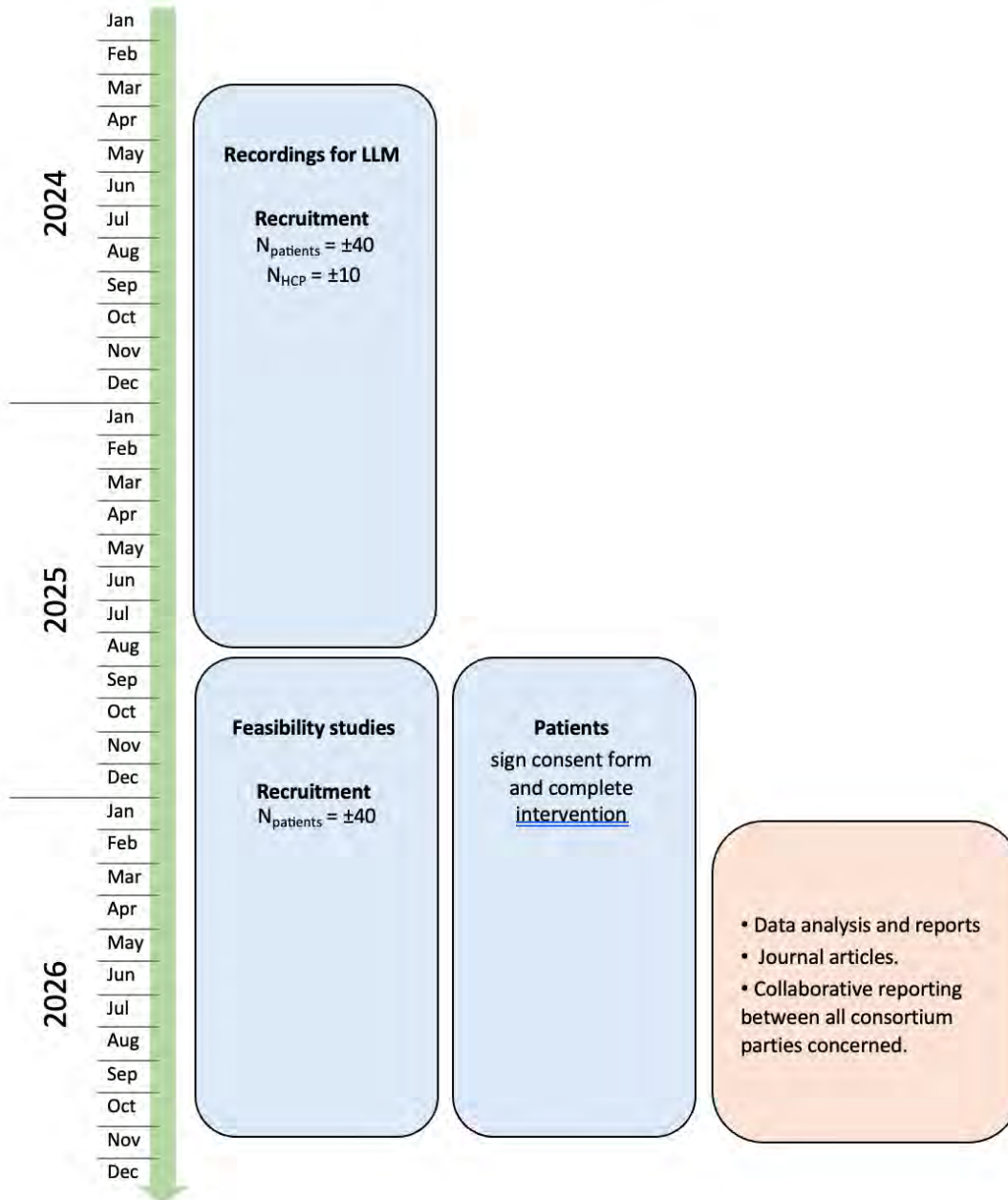
CONSORT DIAGRAM - ANNEX 4



11.5 Annex 5 – LUMINOUS Pilots Intervention Strategy

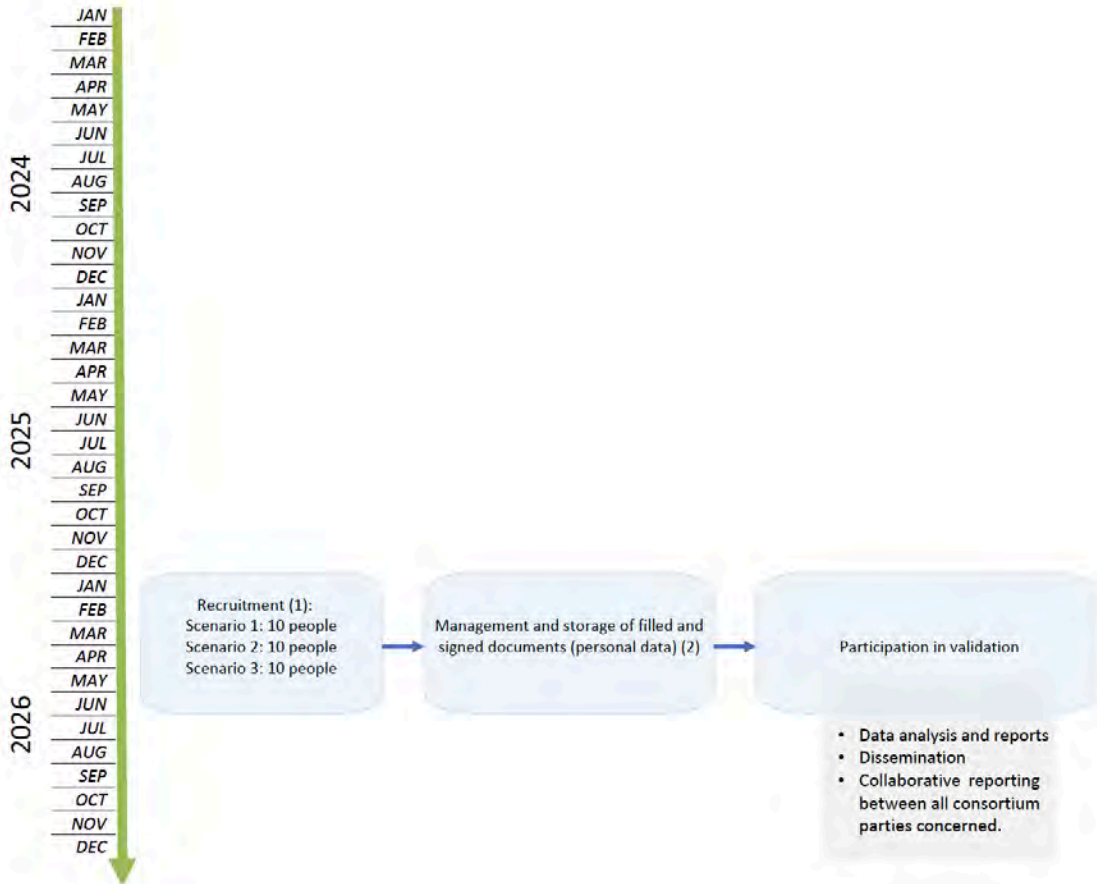
11.5.1 Pilot 1 Intervention Strategy

LUMINOUS Pilot 1 • Intervention Strategy



11.5.2 Pilot 2 Intervention Strategy TBC

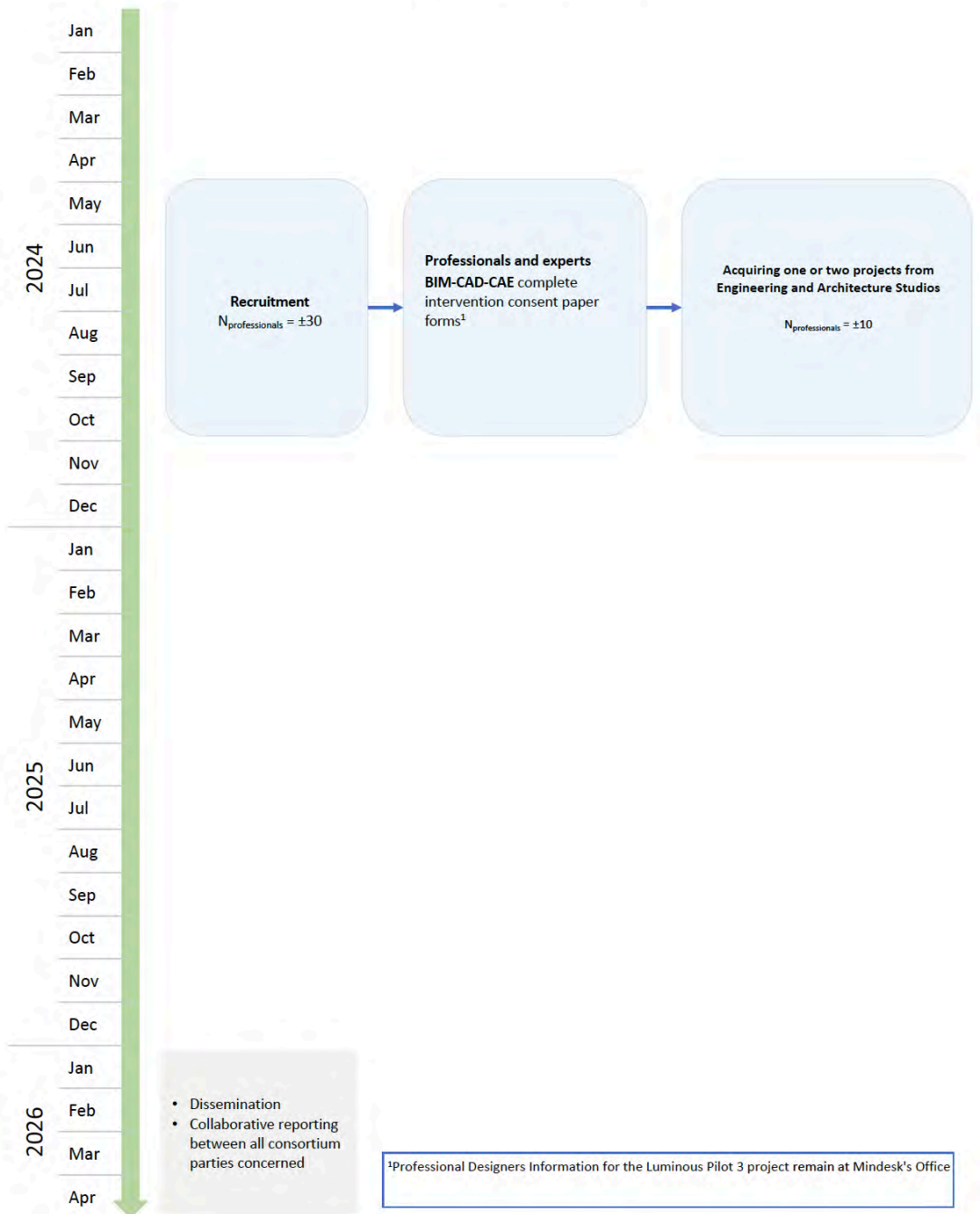
LUMINOUS Pilot 2 · Intervention Strategy · 01/02/2024,
LUDUS TECH S.L.



(1) Worker, students, Rescue agents, ...
 (2) According to national law and ISO 27001

11.5.3 Pilot 3 Intervention Strategy TBC

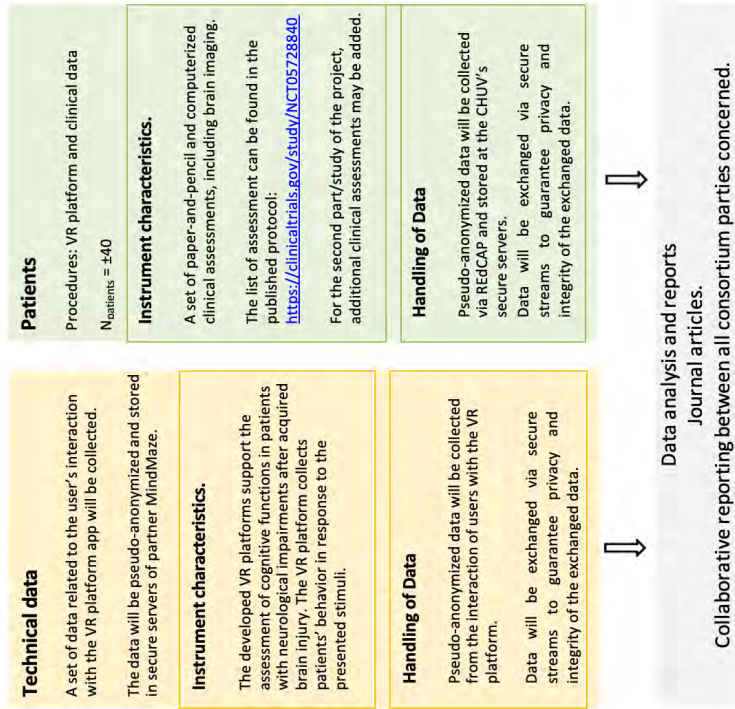
LUMINOUS Pilot 3 · Intervention Strategy · 29/01/2024, Mindesk Srl



11.6 Annex 6 – LUMINOUS Pilots Assessment Strategy

11.6.1 Pilot 1 Assessment Strategy

LUMINOUS Pilot 1 • Assessment Strategy
Research Question: How can LLM be purposefully integrated into neurorehabilitation strategies for training cognitive deficits after acquired brain injury?



11.6.2 Pilot 2 Assessment Strategy

LUMINOUS Pilot 2 Assessment Strategy
 Research Question: How does the LLM + avatar system improve the experience of HSE training in VR?



11.6.3 Pilot 3 Assessment Strategy

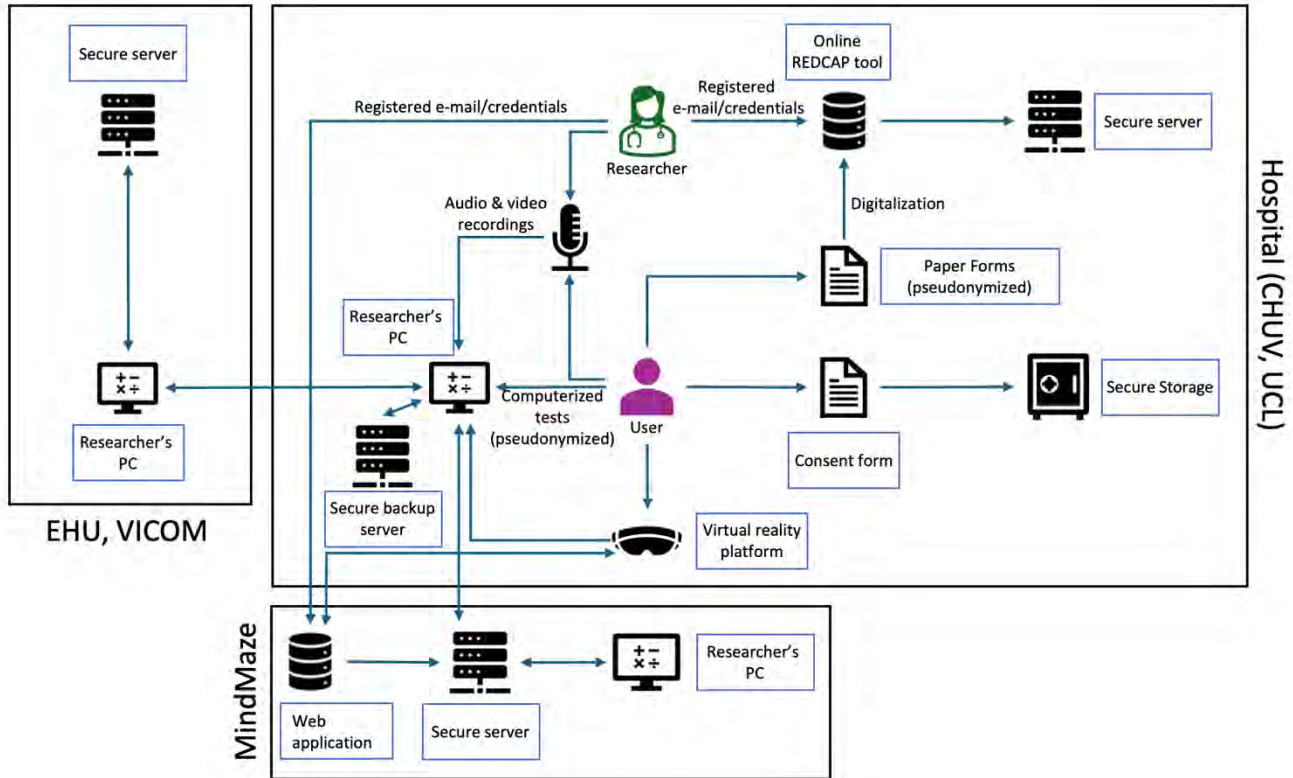
LUMINOUS Pilot 3 Assessment Strategy

Research Question: How does the project impact on professionals designers' activity?



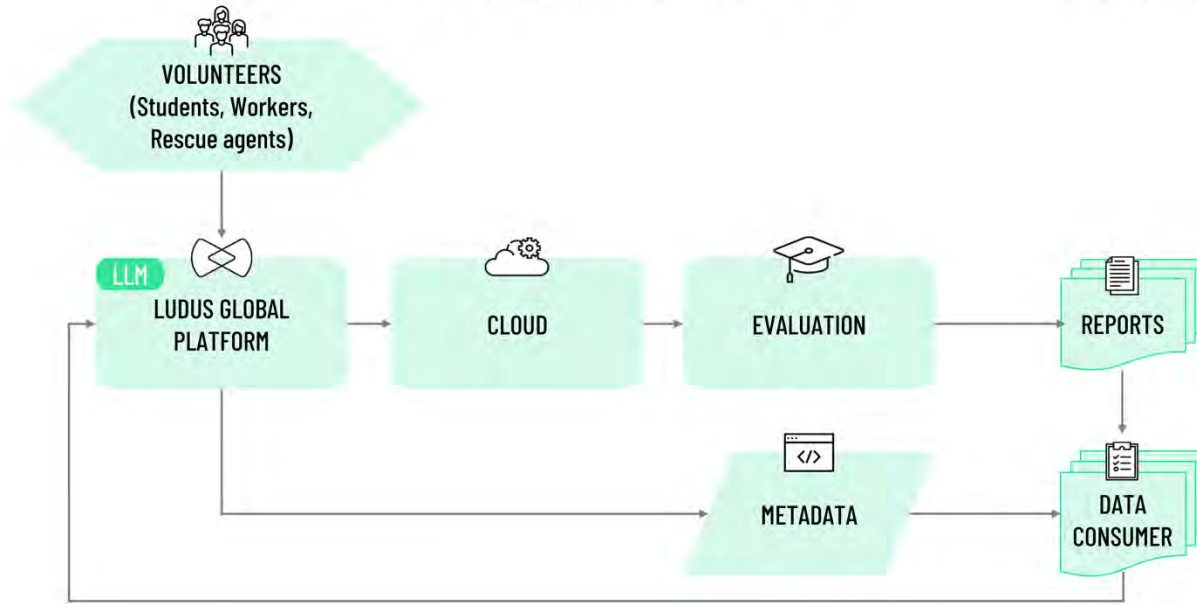
11.7 Annex 7 – LUMINOUS Pilots Data Flow Diagrams

11.7.1 Pilot 1 Data Flow Diagram



11.7.2 Pilot 2 Data Flow Diagram

DATA FLOW DIAGRAM_ ANNEX 7



11.7.3 Pilot 3 Data Flow Diagram

DATA FLOW DIAGRAM - ANNEX 7

