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AI-Mind

Artificial intelligence-based tools for screening of brain connectivity and dementia risk estimation

17
partners

8
countries

5
years

AI-Mind

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AI-Mind project coordinator Ira Haraldsen presenting at the 34th Alzheimer Europe Conference (Geneva, Switzerland, October 2024)

Front cover photo:
AI-Mind Consortium members at the General Assembly Meeting (Bodø, Norway, May 2025)

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Foreword

Jean Georges

> “Artificial Intelligence (AI) in this field is still relatively new, but rapidly evolving. This research can greatly benefit from the involvement of the general public, people with an interest in the topic and those experiencing cognitive problems. I am very proud of how Alzheimer Europe was able to include its views through its work on the ethical reflection on the use of AI-based dementia risk prediction in the clinical setting.” – Jean Georges

I am very pleased to welcome the readers of our Dementia in Europe magazine to this special supplement dedicated to the AI-Mind project, which is an initiative funded by the European Union’s Horizon 2020 research and innovation programme.

At the heart of the AI-Mind project is the development of innovative Artificial Intelligence (AI)-based tools designed to screen brain connectivity and estimate dementia risk. These tools are designed to assist healthcare professionals in diagnosing dementia, ultimately enabling timely interventions for patients.

Currently, there is an ongoing AI revolution that is transforming the health sector, reshaping how diseases are diagnosed and managed, thus offering potential opportunities for personalised care and improved patient outcomes. The European Commission has emphasised “how AI and supercomputing offer new opportunities to transform healthcare” in the EU White paper on Artificial Intelligence, published in February 2020. Recently, the Artificial Intelligence Act (AI Act) was published in the European Union Official Journal, laying down harmonised rules on AI. The AI Act is part of a wider package of policy measures to support the development of trustworthy AI and represents the first-ever comprehensive legal framework on AI worldwide.

The AI-Mind project is a five-year research and innovation programme that has been growing since its launch in March 2021, expanding from 15 to 17 partners across eight European countries. AI-Mind brings together professionals from multiple sectors, including academic institutions, medical centres, small and medium-sized enterprises, spin-off companies and patient associations, with a common goal of providing future patients with a better and personalised diagnosis.

This supplement begins with a general description of the project and I would like to thank Ira Haraldsen, the project leader, for sharing her vision and enthusiasm for this important topic. Following this, you will find an overview of the AI-Mind study, a key part of the project aiming to enrol 1,000 participants with mild cognitive impairment (MCI) aged 60-80 across five clinical centres. The collected data will help develop and validate the AI-Mind tools that predict who is at risk of developing dementia. The AI-Mind tools, namely the AI-Mind Connector and the AI-Mind Predictor, will be integrated into a cloud-based diagnostic platform. Details of collected data and how the AI-Mind tools are designed are also covered in the supplement.

AI in this field is still relatively new, but rapidly evolving. This research can greatly benefit from the involvement of the general public, people with an interest in the topic and those experiencing cognitive problems. I am particularly proud of Alzheimer Europe’s contribution to the ethical reflection on the use of AI-based dementia risk prediction in the clinical setting.

In addition to this, the supplement also includes a Health Technology Assessment, which explores the implementation of AI-Mind tools and the potential health impact of these innovations. Finally, you will be able to read more about the innovation and exploitation aspects of the project.

I hope you will find this special supplement on the AI-Mind project informative and inspiring and that you will share our interest in the important topic of AI for dementia prevention.

Jean Georges
Executive Director, Alzheimer Europe

The AI-Mind vision

The AI-Mind project aims to develop novel Artificial Intelligence (AI)-based tools for screening brain connectivity and estimating dementia risk, ultimately supporting healthcare professionals in providing accurate diagnoses and timely interventions for patients. Project Coordinator Ira Haraldsen shares the motivation behind the project, as well as the key achievements to date.

Ira Haraldsen

The rationale behind the AI-Mind project

According to the World Health Organization (WHO), dementia affects more than 55 million people worldwide. Estimates suggest that, globally, nearly 10 million people develop dementia every year, which translates into one new case every three seconds. Dementia is currently the seventh leading cause of death and one of the major causes of disability and dependency among older people globally.

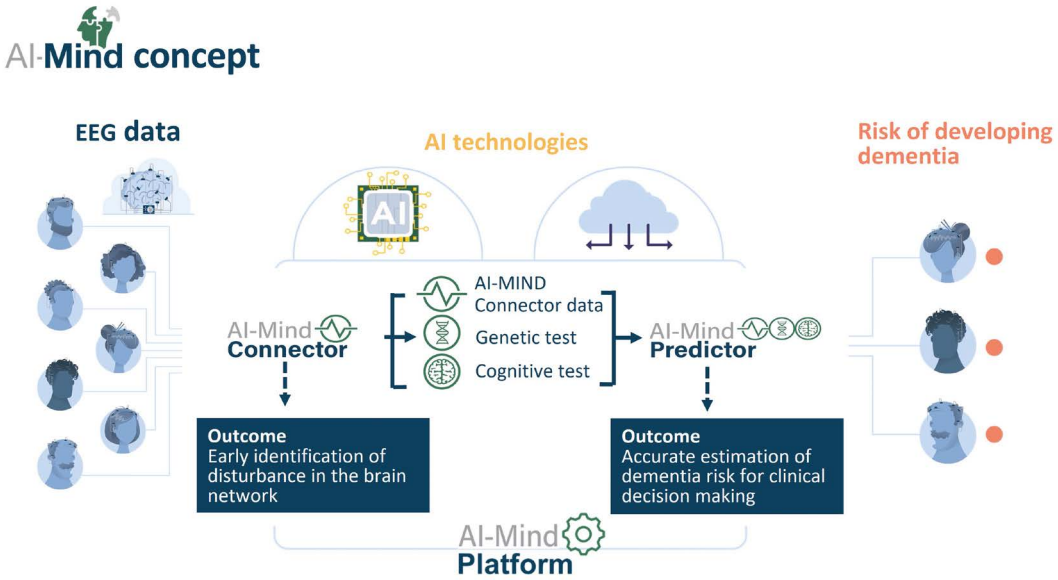
Dementia results from a variety of diseases and injuries that affect the brain and as such, it takes different forms. Alzheimer's dementia is the most common form of dementia, thought to account for over 50% of cases. Like all other types of dementia, Alzheimer's dementia is progressive, with symptoms worsening over time. These figures highlight the urgent need for timely diagnosis and intervention in dementia care.

Mild Cognitive Impairment (MCI) is often considered as the stage between the expected cognitive decline of normal ageing and the more significant decline of dementia. While not all individuals with MCI progress to dementia, those diagnosed with it have a higher risk. Current practice lacks the necessary screening tools to identify people at risk of developing dementia in the future. Timely detection of risk factors and the identification of potential brain connectivity dysfunctions could help healthcare professionals offer more personalised and effective interventions. This is where AI-Mind steps in.

The AI-Mind solution

The patient's journey towards a conclusive dementia diagnosis often takes many years, involving inefficient clinical follow-ups. AI-Mind aims to radically shorten this journey through a digital platform service that can be easily integrated into existing clinical practices. AI-Mind is developing two AI-based tools: the AI-Mind Connector and the AI-Mind Predictor.

The AI-Mind Connector focuses on identifying dysfunctional brain networks, while the AI-Mind Predictor assesses the risk of dementia by analysing data from the Connector, enriched with information collected through the clinical study (i.e. cognitive tests, genetic biomarkers). The AI-Mind Predictor will provide an early marker



of risk for dementia in people with MCI with high sensitivity and specificity (>95%). These two tools will be integrated into a cloud-based diagnostic platform, the AI-Mind Platform, and will be validated across five European clinical centres.

One of the most ground-breaking features of AI-Mind is the establishment of an early population-based and cost-efficient screening method for synaptic pathology. By integrating electroencephalography (EEG) with more advanced magnetoencephalography (MEG), AI-Mind aims to enhance the diagnostic potential of these technologies. Both EEG and MEG provide a non-invasive measure of electrical activity in the brain with millisecond temporal resolution. AI-Mind researchers are collecting a broad range of prospective data from participants with MCI, consisting of demographic, neuropsychological, genetic, blood biomarkers and M/EEG data. All the data will be securely uploaded to a central server in Norway, ensuring data privacy and integrity.

Achievements to date

The project has already achieved significant milestones. The project has successfully enrolled over 1,000 research participants in its clinical study, reaching its target. Significant work has been done to develop AI algorithms for the AI-Mind tools, including the AI-Mind Connector and AI-Mind Predictor, as well as the interactive visualisation tools. Ethical considerations related to the use of AI in clinical diagnostics have been thoroughly examined to ensure that the development of AI-based diagnostic tools is done in an ethically responsible manner. Public outreach and engagement have been another key area of focus. AI-Mind is gaining visibility by publishing research papers and through participation at international conferences. Notably, AI-Mind has been invited to exhibit at the Nemo Museum in Amsterdam for the entirety of 2024. These advancements exceed the project's initial expectations and set the stage for the integration of AI-Mind tools into clinical practice. Additionally, AI-Mind has successfully been integrated into the EBRAINS infrastructure. This partnership fosters new opportunities for collaboration with other leading European research initiatives, ensuring that the AI-Mind project will continue to thrive well beyond its official end date.

> "Throughout the AI-Mind project, we have made significant strides in developing innovative AI-based tools to support healthcare professionals in their diagnosis and offering timely interventions to patients. This has been possible by uniting researchers and clinical experts to drive forward our shared vision for AI-enabled brain health solutions. The progress we have made so far is just the beginning, as we are laying the foundation for a future where AI-driven insights will support personalised and more effective interventions." - Ira Haraldsen

What's coming next?

As the AI-Mind project enters its final year, the focus is on refining the tools developed and testing them in clinical practice. The project aims to deliver a platform that will serve as a valuable resource for healthcare professionals in all EU member states, helping to enhance timely detection and intervention in dementia. Looking ahead, this platform has the potential to become a cornerstone of European big data on MCI, offering a wealth of information for population-based screening and research.

In addition to completing its objectives, the AI-Mind consortium is actively engaging in discussions to secure further funding through grant proposals. The insights and data gathered from the project will also be leveraged in other EU-funded initiatives, ensuring that the AI-Mind results will continue to contribute to advancements in dementia research and clinical practice well beyond its current scope.

> "Artificial intelligence has shown great results in its ability to parse large amounts of data and to solve complex problems not only in the technology sector, but also in the sciences and in medical research in particular. In AI-Mind, we deal with highly complex data of a variety of different types. This is where AI can truly shine in finding connections in the data that may be unintuitive, very difficult, or time-consuming to uncover by traditional means. As such, AI-Mind is well-poised to take full advantage of various AI techniques, making full use of the high-quality data we have painstakingly collected. The use of AI is also a highly delicate matter when it concerns people's sensitive information, such as medical data. This is a responsibility taken very seriously by AI-Mind and we therefore also welcome the growing awareness regarding this issue." - Ainar Drews, Technical Coordination Manager at AI-Mind and Senior Engineer at University of Oslo IT

The AI-Mind study

The AI-Mind clinical study is a key part of the AI-Mind project. With the ultimate goal of predicting who is at risk of developing dementia, the AI-Mind study has been set to recruit 1,000 participants and generate data that will be used to develop and validate two powerful AI tools: the AI-Mind Connector and the AI-Mind Predictor.

Clinical study design and sites

The AI-Mind study is the largest European study focused on MCI, involving five clinical centres across four countries: Norway, Italy, Finland and Spain:

- Department of Neurology, Oslo University Hospital (OUS, Norway)
- Memory Clinic at the Catholic University of the Sacred Heart (UCSC, Rome, Italy)
- IRCCS San Raffaele (IRCCS, Rome, Italy)
- Helsinki University Hospital (HUS, Finland)
- Universidad Complutense de Madrid (UCM, Madrid, Spain).

The AI-Mind study is aligned with national state-of-the-art (SOA) procedures for MCI and progressive dementia diagnostics, ensuring its integration with current best practices. It is also important to note that the study does not involve any new pharmacological treatments.

The study follows a structured design, consisting of a clinical assessment for inclusion, a baseline visit and three subsequent follow-up visits, each separated by eight months over a two-year follow-up period. Throughout the study, a range of data is collected, including clinical, neuropsychological, high-density EEG and ApoE/pTau blood biomarker samples. This data is crucial in developing and validating the AI-Mind Connector and AI-Mind Predictor tools. The clinical assessment is repeated at the last follow-up visit to assess changes over time.

Paolo Rossini from IRCCS emphasises the importance of data collection:

"MCI represents a population of huge interest for many reasons: 1) It is the 'basin' from which new dementia cases are deriving every year; 2) People with MCI are not yet 'patients' since only 30 to 50% of them (according to different studies) progress to dementia, while the remainder will never progress to dementia and may even revert to 'normality'; 3) The MCI condition allows complete autonomy in daily life activities including high cognitive ones. 4) Disease-modifying drugs - if efficacious - in the MCI-prodromal-to-dementia condition might therefore maintain people in complete autonomy forever or at least for longer; 5) It would be extremely useful to focus methods for an early distinction between MCI at high-risk of developing dementia from those at low-risk on the former preventive, therapeutic (including those with expensive and side-effects provoking drugs) or rehabilitative procedures. AI-Mind aims to create an easy-to-use, non-invasive and low-cost instrument allowing such a timely distinction. To reach this goal, a large sample population has been recruited across Europe. The integration of diverse datasets across multiple clinical sites is essential for developing tools that are both robust and adaptable to different populations and healthcare settings. Moreover, differences in diagnostic/prognostic procedures across Europe can be harmonised".

For further information about the clinical study, you can read the protocol published in the journal Frontiers in Neurorobotics (doi: https://doi.org/10.3389/fnbot.2023.1289406)

Participants and recruitment

The AI-Mind study successfully reached its target of recruiting 1,000 participants with MCI, aged between 60 and 80 years. Eligible participants needed to meet specific criteria, including cognitive concerns (subjective complaints), objective cognitive impairment (beyond expected norms), preservation of functional independence and absence of dementia.

Efforts were made to ensure an equal distribution of participants across the four countries, although recruitment strategies were tailored to each country's healthcare system to ensure a diverse

Paolo Rossini

Joanna Plesniak

and representative sample. In Finland and Italy, participants were recruited directly from the hospitals' outpatient clinics. In Spain, participants were recruited from various neurological clinics in the proximity of Madrid and from community centres. In Norway, participant outreach was conducted through the online distribution of a self-assessment questionnaire on memory and other cognitive functions.

Patient recruitment remains a significant challenge in clinical trials, particularly for studies spanning multiple European countries. To address this, the AI-Mind partners implemented tailored strategies, combining clinical referrals with cross-media communication - including websites, social media, flyers, videos and study newsletters - to reach the recruitment goals.

"Reaching and engaging potential study participants, requires a people-centred approach, harmonised actions across countries, and communication that is both trustworthy and informative. Communication is a way to connect with people - to understand their needs and expectations and to find the best way to explain the benefits of science. In an age of increasing mistrust, we approached our task with the highest consideration, tailoring not only the language but all aspects of engagement - from the stories we shared to the words and even colours we used", said Joanna Plesniak from accelopment Schweiz AG. Local project web pages and the explanatory video developed in English while also being available in Italian, Spanish, Norwegian and Finnish, further supported accessibility.

Nonetheless, the success of the AI-Mind study depends on the rigorous monitoring of participant recruitment and follow-up to ensure that the collected data remains consistent and reliable across the five clinical sites. Regular meetings and continuous evaluations have been essential to harmonise procedures, track progress and address any challenges on the way.

Camillo Marra from UCSC explains:

"The progress of the entire AI-Mind study has required rigorous monitoring of the activities. It has, therefore, been necessary to hold regular meetings to ensure harmonisation of the procedures, both before the initiation of recruitment, as well as throughout the recruitment tracking and follow-up. This was particularly necessary considering the differences in patients' referral and neuropsychological procedures among the different countries. Furthermore, retention strategies were identified and definitions of drop-out subjects were clarified."

Camillo Marra

Fernando Maestú

Implementation and validation of the AI-Mind tools

The AI-Mind Connector and AI-Mind Predictor, the two key tools developed as part of the AI-Mind project, will be trained and validated using the data collected from the AI-Mind clinical centres. These tools are designed to analyse cognitive and neuroimaging data, identify early signs of dementia and predict which individuals with MCI are most likely to develop dementia. Additionally, they undergo health technology assessments to evaluate their trustworthiness and user compliance in real-world healthcare settings.

Fernando Maestú from UCM, discussed the technical aspects of the AI-Mind Connector: *"We have identified several potential M/EEG data features to be tested in the AI-Mind Connector and their technical implementation is currently in progress by the project partner sites. As a requirement for efficient feature extraction, the critical next step will focus on refining the automatisation of the EEG artefact removal process. This process is likely to attract a lot of interest, not just within the project, but also from outside."*

Insight from a research participant

To provide a deeper understanding of the AI-Mind study, we spoke to one of the study participants, who shared her thoughts on being involved.

"Participating in the AI-Mind study has been a wholly positive experience. It is reassuring to know that research is being conducted on Alzheimer's disease and it feels good to contribute. The examinations themselves have also been good experiences. In every way, I have felt well taken care of on the days I participated in the study. It is also rewarding to think that you are contributing to research that could have a significant impact on the next generation. That is something I both hope for and believe in", said Gunn, a research participant from Norway.

Data management and feature extraction

Hanna Renvall

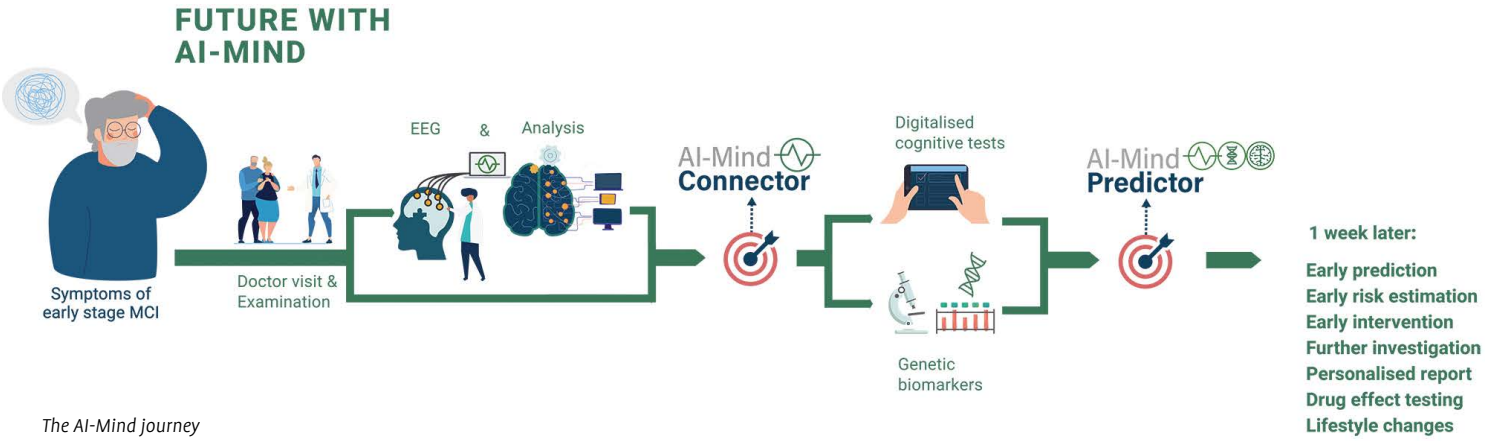
Effective data management and feature extraction are central to the success of the AI-Mind platform and for use in the development of the AI-Mind Predictor and Connector solutions. In this article, Hanna Renvall from Helsinki University Hospital explores the best practices for data collection and integration, as well as the importance of their standardisation for developing the innovative AI-Mind tools.

Data collection and integration

The AI Mind project mainly handles data which has been collected in the AI-Mind study at five sites in four countries. Retrospective open-access datasets (acquired earlier for other clinical and scientific purposes) have also been utilised in testing analysis pipelines and their validation.

To guarantee high-quality data, it is crucial to establish best practices for data collection and harmonise them across AI-Mind's partner sites. First, the technical requirements and methods for standardised data collection were defined (electroencephalography (EEG) and magnetoencephalography (MEG), digital cognitive testing, blood sampling, textual data) which were then used by the AI-Mind clinical partners for obtaining comparable and high-quality clinical data.

This process contributed to the creation of a robust cloud storage database, to ensure persistence, consistency, concurrency, integrity and security across all AI-Mind applications and processes. The implementation of this database, hosted on the TSD platform (Tjenester/ services for Sensitive Data), was conducted in line with the AI-Mind Data Governance Plan. All the AI-Mind data, consisting of demographic, neuropsychological, genetic, blood biomarkers, and M/EEG data, are securely uploaded to this central server located in Norway, ensuring data privacy and integrity. The AI-Mind platform relies on each clinical site to legally collect and pseudonymise participant data, which is then periodically uploaded to the platform, in accordance with the Data Transfer Agreement established between partners.



The AI-Mind journey

Overview of the prospective data

The AI-Mind participants with MCI in Finland, Italy, Norway and Spain were addressed with 20-minute resting-state EEG measurements and comprehensive neuropsychological testing, combined with blood biomarkers and APOE ε4 status, as early as possible along the disease trajectory. The collected data serves to find features which are crucial for predicting participants' dementia risk.

Each participant is addressed with EEG and cognitive measures four times at eight-month intervals (0, 8, 16 and 24 months). In addition to the EEG data, the Finnish cohort was addressed with simultaneous MEG measurements, twice (at 0 and 24 months). The neuropsychological performance of the participants was assessed twice (0 and 24 months) in four cognitive domains (verbal and visual memory, language functions, attention/executive functions, visual–constructive abilities). A set of the Cambridge Neuropsychological Test Automated Battery (CANTAB®; Cambridge Cognition Ltd) tests was administered at each research visit in conjunction with the M/EEG recordings. The CANTAB® is a cloud-based system for operator-independent cognitive testing that is conducted on a tablet. Finally, the participants are clinically followed for a minimum of five years to establish the eventual progression status (conversion or not to dementia stage).

> "In a project like AI-Mind, where data comes from different clinical centres, it's essential to standardise the collection process to ensure consistency" - Hanna Renvall

Extraction on brain imaging data for feeding into the AI-classified models

All the data collected in our clinical study is currently addressed with AI-based analyses developed and tested within the project group. Our first goal is to identify the M/EEG data features, or their combination that best describe the network-level changes related to cognitive decline. To this end, we are utilising the existing knowledge at each partner site for testing and validating different candidate measures. Subsequently, we bring the M/EEG features together with the other data modalities, to predict the overall disease trajectory at the individual level. This ambitious project thus aims to develop a screening method that would be cost-effective, widely available and highly reliable at the same time.

A few words about Electroencephalography and Magnetoencephalography

EEG and MEG play a pivotal role in advancing our understanding of Alzheimer's disease through non-invasive monitoring of brain activity. As Fabrizio Vecchio (Neuroconnect) notes, EEG is a non-invasive diagnostic tool that records electrical activity on the scalp, providing critical insights into alterations in brain network dynamics and connectivity in individuals with cognitive impairment. Similarly, MEG measures the magnetic fields generated by neural currents, offering high spatial and temporal resolution that complements EEG findings. This dual approach not only enhances the detection of subtle neurophysiological changes but also provides a comprehensive view of the underlying brain mechanisms affected in Alzheimer's disease.

"Recent studies have demonstrated that the application of graph theory —and, in particular, small-world network analysis— enables high levels of accuracy in distinguishing between converted and stable cases of MCI, thereby improving the prediction of conversion to Alzheimer's disease. By leveraging these advanced neuroimaging techniques, AI-Mind's data collection process extracts detailed functional brain network data that can be analysed using AI algorithms. The integration of these datasets facilitates the identification of early biomarkers and patterns indicative of dementia risk, significantly advancing predictive models beyond traditional methods. Furthermore, by combining EEG/MEG data with other clinical and imaging information, researchers can develop robust predictive models that detect dementia at much earlier stages, paving the way for early intervention and personalised treatment strategies in Alzheimer's disease management", Fabrizio Vecchio added.

Fabrizio Vecchio

Development of AI-based digital tools

This article from Anis Yazidi, Pedro Lind, Asma Belhadi (OsloMet) and Ersin Yılmaz (AALTO) sheds light on the machine learning methods employed for the development of the two AI-based tools, aiming at assessing and predicting functional brain network disturbances and the individual's risk of developing dementia.

AI modelling

Deep learning (DL) is a branch of AI that enables computers to learn complex patterns directly from raw data, much like the human brain does. Inspired by the remarkable success of DL in computer vision—where models learn to identify objects and scenes from images—our approach applies similar principles to analyse brain activity data. In this analogy, just as a computer distinguishes a cat from a dog by studying many images, models developed within AI-Mind differentiate between normal and altered brain activity by analysing extensive EEG recordings. This method eliminates the need for manually designing specific features and lets the system discover the most relevant information autonomously, ultimately supporting clinicians in identifying early signs of cognitive decline more reliably and consistently.

In the AI-Mind project, similarly to many scientific domains, a key challenge is extracting insights from high-dimensional, noisy EEG data where traditional statistics struggle to isolate weak signals amid individual variability. To address this, probabilistic machine learning (ML) models are being developed and implemented. These models employ sophisticated probabilistic techniques that transform complex EEG data into concise, low-dimensional neural fingerprints, capturing both shared patterns and unique subject-specific traits. By leveraging a multi-view approach across various EEG frequency bands and providing estimates of the respective uncertainty, these models enhance the detection of consistent trends and eventually support timely, personalised interventions for neurodegenerative diseases. The overall AI-Mind model, using such ML probabilistic techniques has two major components: the AI-Mind Connector and the AI-Mind Predictor – two AI-based tools.

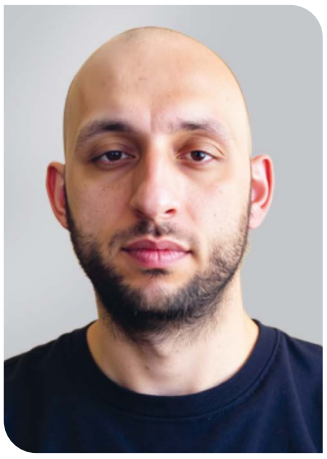
The AI-Mind Connector

The AI-Mind Connector leverages brain images derived from EEG data to evaluate the intricate interactions between different brain regions. By examining these functional connections, the system identifies subtle disturbances in the brain network—potential early indicators of cognitive change.

Developed with cutting-edge DL techniques and probabilistic modelling techniques, the Connector automatically extracts and identifies critical features from raw EEG recordings to distinguish subpopulations of individuals with MCI. A key component of this framework is the EEG-JEPA model, which operates in a self-supervised manner by predicting missing EEG signal segments—a concept inspired by modern computer vision methods. Similar to how Transformers allow ChatGPT to capture long-term dependencies in language, our Transformer-based architecture segments EEG recordings into small patches to capture long-range relationships in brain activity.

Pedro Lind

Anis Yazidi



Ersin Yılmaz

Asma Belhadi

AI-Mind Connector

To improve robustness and interpretability, the model incorporates Bayesian techniques, enabling the integration of prior knowledge and uncertainty estimation. The framework has been refined using preliminary and publicly available datasets that include biomarkers like p-tau values and cognitive scores, which provide critical indicators of disease progression. By integrating these insights, the AI-Mind Connector can better detect early markers of synaptic dysfunction and connectivity loss, improving its accuracy and reliability for clinical use.

The AI-Mind Predictor

Building on the capabilities of the AI-Mind Connector, the AI-Mind Predictor analyses EEG-derived brain images to map interactions between brain regions and detect early disturbances in functional networks. Beyond these neural fingerprints, the Predictor incorporates a range of data—including genetic profiles, blood-based biomarkers (such as p-tau levels), cognitive assessments, and demographic information—to refine its risk predictions. This comprehensive, cost-effective approach ensures broad clinical applicability. By combining classical and probabilistic ML techniques with advanced DL architectures, the AI-Mind models achieve high explainability (through methods like Support Vector Machines) and robust detection of complex spatial and temporal patterns in EEG signals. The Predictor also employs graph neural networks and self-similarity models to identify diagnostically relevant features, ensuring traceability back to functional brain networks.

Ultimately, the Predictor is designed to deliver timely, precise, and interpretable insights into dementia risk, paving the way for more effective prevention strategies and personalised interventions. DL models, such as convolutional or recurrent ones, analyse raw EEG signals without manual input and, in some instances, can integrate additional data like age or health markers, to enhance prediction accuracy. Trained on labelled examples, the model refines itself to identify brain states or disease risks, delivering clear, tailored insights into brain activity for applications such as timely disease detection.

AI-Mind Predictor

Testing and evaluating AI-Mind algorithms: ensuring reliability and reducing bias

Testing and evaluating our AI-Mind algorithms is a critical part of our development process. Rigorous strategies—such as cross-validation and bootstrap methods— are employed to systematically assess performance across multiple data splits, reducing overfitting and providing robust estimates of predictive accuracy. Uncertainty analyses, both epistemic (arising from limited data) and aleatory (stemming from inherent randomness), help quantify the confidence of each prediction. Ensemble methods in DL further capture the range of possible outcomes, offering a more complete picture of prediction uncertainty. A key focus of our evaluation is bias mitigation. Comprehensive data harmonisation ensures consistency across diverse data sources, while probabilistic ML methods (including Bayesian approaches) improve reliability and support the detection and reduction of bias.

Moreover, our commitment to explainability ensures that our algorithms provide clear, interpretable insights into their decision-making processes. Techniques are applied that highlight the contribution of critical features—ranging from neural fingerprints and biomarkers to cognitive scores—thereby making our models transparent and accessible to clinicians. This transparency is essential for building trust and facilitating the integration of AI-driven insights into clinical decision-making.

Through these multifaceted testing and evaluation strategies, the AI-Mind project is dedicated to delivering tools that not only achieve high predictive accuracy but also uphold the highest standards of fairness, reliability, and transparency in clinical applications.

Machine learning and deep learning

Machine learning (ML) refers to a set of computational methods that allow computers to learn patterns from data and make decisions or predictions without explicit programming. These models range from simple regression or decision trees to more sophisticated ensemble methods, all relying on statistical principles to improve over time.

Deep learning (DL), a subset of ML, utilises neural networks with multiple layers to automatically learn hierarchical representations from high-dimensional, unstructured data such as images, audio, and text. In the AI-Mind project, DL methods enable the extraction of complex features from EEG data, driving more accurate predictions in assessing dementia risk.

The AI-Mind digital platform

The AI-Mind digital platform, which includes the AI-Mind Connector and Predictor, stands out as a trustworthy platform designed to assist clinicians in analysing complete datasets and identifying patterns to assess the risk of dementia in people with MCI. In this article, Luis Peña from Lurtis provides an overview on the substantial progress made on delivering this interactive platform.

Luis Peña

Software architecture design and development

As an AI software solution, the aim of AI-Mind is to enable researchers and clinicians to conduct an early assessment of the risk of developing dementia for people with MCI using AI technology. For a solution like this, four main components are needed: (1) clinical data, (2) a computing platform, (3) AI algorithms and (4) data analysis tools.

To facilitate this, the AI-Mind digital platform was developed and hosted on the TSD (Tjenester for Sensitive Data) platform, ensuring the secure processing of clinical data. In collaboration with other teams, Lurtis designed, developed, tested and deployed this fundamental part of the AI-Mind project that will significantly help researchers and clinicians to evaluate the two AI-Mind models: the Connector and Predictor AI-tools.

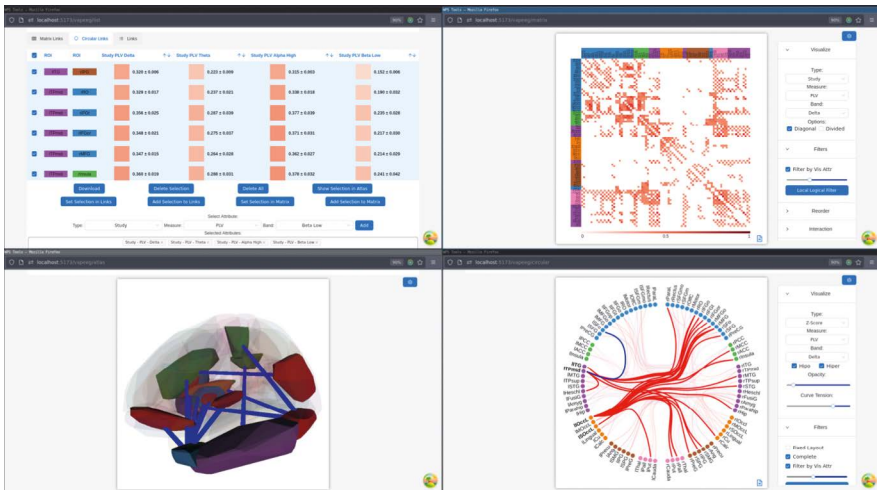
In addition to the software design, a crucial element of the AI-Mind platform's success lies in its ability to fulfil the project's requirements and handle the vast amounts of clinical data while maintaining high standards of quality and security. This platform not only ensures data quality but also supports the project's requirements for data governance, quality control and privacy, which are critical for biomedical applications.

In the early stages of development, architectural design ideas were outlined, including the data pipeline and main data transformations. Next, the preliminary designs of the platform's visualisation tool were developed, which were subsequently refined and improved upon, based on continuous user feedback. The platform underwent rigorous testing, both inside and outside of TSD, revealing software issues that were identified and resolved to enhance functionality and reliability. With each release, new components were added based on the feedback of the end users.

User interface

A critical aspect of the AI-Mind platform's development was ensuring that the interface met the needs of its end users, clinicians and researchers. Early in the development process, the team collaborated with scientists and clinical researchers to understand their expectations through interviews and meetings. It was important to consider their views and place them at the centre of the planning process, allowing them to guide the development of the AI-Mind platform. The feedback was used to create platform-user personas, use-case scenarios and journey maps, which guided the design process. The main persona was the clinical researcher, i.e. the main user of the AI-Mind platform, whose needs were prioritised during the design process.

This user-centred design approach allowed us to develop best practices, which not only improved the user interface, but also ensured that the platform would truly assist clinicians in their work.



Main views of the connectivity visualisation components. These views display the connectivity of populations and allow for one-to-one comparisons between populations, thus helping users identify significant connectivity differences

For further information, you can access the AI-Mind Share on AI technology and engineering, containing the public deliverable on UI/UX (user interface / user experience) design and guidelines.

Integration, testing and validation

Once the development of the AI-Mind Connector and AI-Mind Predictor framework was completed, the integration and testing phases began. During this stage, the framework of the tools was integrated into the AI-Mind data processing platform, ensuring smooth interoperability. A series of security, integration and usability tests were conducted to identify and resolve any issues, ensuring that the platform functions optimally in a real-world clinical setting. After this testing, the two AI-tools now await the integration of the AI-models that are under development. These will be trained on the AI-Mind data, some of which is still being collected during the ongoing clinical study. The individual AI-models are the "engines" of the two AI-tools and will provide the actual scientific, diagnostic and predictive outputs that the two AI-tools will present to the end-users. Once the individual AI-models are integrated, the AI-Mind Connector and AI-Mind Predictor can undergo final testing.

The AI-Mind Connector and Predictor frameworks are currently deployed in the Testing Environment hosted on the TSD platform and have undergone intensive testing. The deployment phase will mark the final step in the process, during which the tools will move from a development, testing and staging environment to the live production environment. The goal of this phase will be to ensure a smooth transition from development to production, to minimise downtime and ensure that the AI-Mind platform and its features are stable and functional for end users.

Corresponding software documentation was also generated. Finally, a starter kit will be developed (i.e. user guidelines, training exercises, general information on risk assessment and early intervention in dementia) to support clinicians and health-professionals in using the AI-Mind AI-tools in their appropriate settings, for research and in a clinical setting.

Interactive diagnosis data visualisation tools

A dedicated task within the AI-Mind project was focused on developing interactive visualisation tools, resulting in two key outputs: the AI-Mind EEG Visualisation tool and the AI-Mind CANTAB Visualisation tool. These tools are also currently deployed in the Testing Environment hosted on TSD, together with the rest of the AI-Mind Platform, before they will be deployed to the live production environment together.

The AI-Mind EEG Visualisation tool facilitates the exploration and analysis of brain connectivity data at the population level. It offers four core views: an adjacency matrix, a circular node-link diagram, a 3D atlas and a link list. These views empower clinical researchers to compare connectivity patterns between populations, identify significant differences and navigate the data in an interactive, user-friendly manner. Designed to enhance the interpretability of AI model results, the tool enables researchers to pinpoint where and to what extent connectivity differences occur between high- and low-risk populations.

The AI-Mind CANTAB Visualisation tool enables the interactive exploration of cognitive data from CANTAB (Cambridge Neuropsychological Test Automated Battery) tests. This tool effectively manages the high complexity of the data through

Jorge Acosta

an interactive hierarchy that allows users to aggregate and filter variables. These variables are displayed in a global overview in the form of a table, enabling interactive navigation of observations. Selections made in this table can then be analysed using specialised components designed for specific analytical tasks, such as comparison analysis, evolution analysis and correlation analysis. This structured approach provides researchers with a flexible and intuitive way to explore and interpret complex datasets, enhancing their ability to derive actionable insights.

> "The interactive data visualisation tool plays a pivotal role in enabling clinicians to understand the insights generated by AI models. Its integration into the AI-Mind platform marks a significant step towards transforming complex data into actionable information"
> - Jorge Acosta from Universidad Politécnica de Madrid

Innovative practice guidelines for AI-Mind diagnostics tools

Daniel Irabien

Sonia Sousa

Daniel Irabien and Sonia Sousa from Tallinn University share an update on the complexities and evolution of the development of the practice guidelines for AI-Mind diagnostic tools. This overview chronicles the process from the initial definition of the task, the reflective process based on consultations with our partners, as well as the literature to refine and adapt this future document to a continuously evolving project while ensuring its usefulness and relevance.

Innovative practices

Interdisciplinary and future-oriented projects like AI-Mind are, at the same time, vital for our societies and complex to implement, requiring the collaboration of a large number of stakeholders. The AI-Mind diagnostic tools require an extra level of care and rigour when offering guidelines to future stakeholders. This requires not only building a document for the tools as they are now, but also for the future of these tools, which implies an interdisciplinary effort to build a useful yet accessible document.

One of our initial efforts was to align the differing perspectives between the fields of medicine and engineering on the concept of “best practices”. To support this, the evolution and evidence gathered throughout the AI-Mind project timeline have been mapped. Given the novel nature of the system under development, the approach was reframed and the document was treated as a living resource. Rather than adhering strictly to traditional best practices, alignment was made with the concept of “innovative practices”, deemed more appropriate for emerging technologies. To ensure the document reflects real-world needs and experiences, user-centred design methodologies were adopted to gather insights and recommendations that will form the foundation of the final version.

The importance of a common language

In parallel, to ensure clear communication across all stakeholders, the AI-Mind team is also compiling a glossary of key terms related to AI diagnostics, regulatory frameworks and best practices. This glossary will serve as a valuable reference helping stakeholders stay aligned throughout the development process. By standardising terminology, the aim is to avoid misunderstandings and ensure that all parties involved have a shared understanding of the concepts being discussed and implemented.

Looking ahead

By the end of the AI-Mind project, the team will finalise a comprehensive report outlining these best practice guidelines. The final guidelines will ensure that AI-Mind tools are implemented in ways that are ethically sound, legally compliant and scientifically robust. As the AI-Mind project continues to evolve, these best practice guidelines will play an essential role in shaping the future of AI in dementia diagnosis.

Concept governance and requirements

The AI-Mind project aims to reduce the disease burden by developing novel AI-based tools that support healthcare professionals for the diagnosis and offer timely interventions to patients. As part of this innovative approach, the AI-Mind team first focused on investigating the existing legal frameworks and associated clinical guidelines across Europe related to medical device development. This effort was critical for understanding the current landscape of legislation that governs the use of medical tools and technologies, particularly in the context of AI. By reviewing these frameworks, the team aimed to summarise the current understanding of relevant legislation and enable data sharing between clinical centres, all while facilitating the creation of the AI-Mind diagnostic tools. A Data Governance Plan was developed, ensuring the categorisation and protection of data, the legal basis for processing of data and the legal requirements related to obtaining consent for participation and processing. In parallel, the team has taken into consideration a wide range of factors that may influence the development of these tools, including ethical, economic, scientific and societal implications, keeping in mind the broader implications of AI-based diagnostics.

For further information, watch the webinars on our YouTube channel, delivered by our partner Det Norske Veritas® (DNV), outlining all the types of data, as well as the considerations around how to handle this data when it comes to data collection, data preparation, modelling, evaluation and deployment. You can also access the AI-Mind Share on Data governance, containing all the public deliverables such as the governance plan.

Public Involvement and stakeholder consultation

In this article, Dianne Gove from Alzheimer Europe presents the Public and Stakeholder Involvement work conducted in the AI-Mind project.

The importance of Public and Stakeholder Involvement work

Whilst AI is increasingly being used in many areas of people's everyday lives, its successful application in the medical field, especially for dementia diagnosis and risk prediction, depends heavily on the trust and willingness of both patients and healthcare professionals to use and understand it. It is essential that this new AI-based technology aligns with the needs and values of patients, clinicians and other key stakeholders.

In collaboration with other AI-Mind partners, Alzheimer Europe conducted a rapid review of ethical issues followed by Public Involvement (PI) and stakeholder consultation work to better understand the perceptions and needs of patients, general practitioners (GPs) and specialised clinicians regarding the use of AI in dementia risk prediction for people with MCI. This work aimed to ensure that the development of AI-based diagnostic tools reflects the concerns and interests of all affected parties.

Rapid review

The aim of the rapid review of existing literature was to identify criteria that should be met or addressed for an AI-based risk prediction tool to be considered trustworthy and for the risk to be considered as having been ethically communicated. The goal was to explore, characterise and summarise arguments, experiences and discourses surrounding the use of AI-based dementia risk prediction amongst people with MCI in the clinical setting. The findings of the review highlighted many issues that are common to predictive testing for dementia (e.g. related to understanding risk, data protection issues and premature labelling as being "ill") and a few that are more specific to the use of AI (e.g. whether additional consent is needed, the "black box" issue, liability, bias, inequity, the impact and potential resistance in the context of clinical practice and the broader implications of the use of resources in other areas of health care).

Public and Stakeholder Involvement work

The Public and Stakeholder Involvement was conducted alongside the literature review and involved people with no cognitive impairment, people with MCI, people with dementia and clinicians, including GPs as well as different specialists (e.g. neurologists and geriatricians). Various methods and approaches were used to involve these different groups, including one-to-one interviews, focus group discussions and a short, open-ended survey. This work aimed to help ensure that the various ethical, societal and practical issues considered reflect the views, beliefs, assumptions and possible concerns of lay people from some of the groups affected by the use of these tools, and of clinicians, in addition to those of published scholars and AI specialists. This approach thereby helps ensure that moral norms are established through a fair dialogue in which everyone's perspectives and viewpoints are heard and taken into account. The PI and Stakeholder Involvement provided valuable insight into how members of the general public and clinicians feel about AI (in general), the extent to which they are familiar with AI as a concept and in their daily lives, and the prospect of AI-based dementia risk prediction tools being used in clinical practice.

Strategy for the ethical and trustworthy communication of AI-based dementia risk prediction

The review and series of consultations, organised in the framework of the AI-Mind project, led to the development of a comprehensive strategy for the ethical and trustworthy communication of AI-based dementia risk prediction to people with MCI in the clinical setting. In concrete terms, key outcomes of this strategy include tentative guidance and topics for further reflection on how to broach the topic of AI and risk prediction, using AI-based risk prediction tools in clinical practice, issues related to informed consent, the promotion of supported decision making, the trustworthy development of AI-based risk prediction, communication of AI-based risk predictions and broader ethical issues related to justice, equity and fairness, as well as the balance between the interests of society and those of the individual. This strategy, which was developed together with people with MCI and people with dementia, is targeted at clinicians who might eventually be using AI-based dementia risk prediction tools (e.g. the AI-Mind platform) and the broader healthcare structure. It can be freely downloaded on the AI-Mind website.

> "The successful implementation of AI-based dementia risk prediction tools is highly dependent on all those affected finding them trustworthy and valuable. The PI work and stakeholder consultation helped ensure that the various ethical and societal issues addressed reflected their views, beliefs and priorities and not solely those of a limited number of published scholars and AI experts." - Dianne Gove

How and why Health Technology Assessment demonstrates the value of the AI-Mind tools

Rossella Di Bidino

The integration of AI in healthcare has immense potential to revolutionise patient diagnosis and care. Health Technology Assessment (HTA) plays a critical role in facilitating this process, particularly in the context of AI-based tools. Rossella Di Bidino from Università Cattolica del Sacro Cuore, explains how HTA can support the development and implementation of the AI-Mind tools and model their potential health impacts.

Understanding Health Technology Assessment

In a nutshell, HTA evaluates the benefits, risks, cost-effectiveness, organisational impact and implications for patients, that are associated with health technologies such as drugs, medical devices and care pathways. It aims to support informed decision-making to enhance both efficiency and patient outcomes, and supports the sustainable integration of innovations. HTA thus plays a crucial role in implementing new technologies.

The HTA involvement spans the entire journey of health technology, from its initial development to post-market assessment and even disinvestment. In particular, Early HTA is crucial for developers and policy-makers evaluating feasibility, potential impact and innovation direction before market entry.

Often described as a bridge between science and policy, HTA connects evidence with healthcare needs. A successful HTA influences policy decisions making them based on robust evidence, societal values and ethical principles, such as equity, patient autonomy, and access to care.

Role of HTA in demonstrating the implications of the AI-Mind tools

Any technology is not inherently beneficial even if it is innovative. It should be seen as a part of the healthcare system and society. It is crucial to assess the effectiveness of the AI-Mind tools in real-world settings, their cost-effectiveness, and their overall impact on patients' health and quality of life. The multidisciplinary approach of HTA addresses these needs.

Available evidence shows that the global societal cost of dementia surged from USD 604 billion in 2010 to USD 1.3 trillion in 2019, with an estimated annual increase in costs of 6.5% since 2017. Taking into account all the potential implications of dementia on the economy and the healthcare system, projections estimate a macroeconomic burden of USD 14.5 trillion by 2050.

Dementia is often associated with other comorbidities. However, analyses have reported higher total costs for people with dementia compared to those without dementia who have similar comorbidities.

Additionally, a strong correlation between healthcare costs and dementia severity has been demonstrated. Studies have shown that excess healthcare costs in people with dementia begin to rise as early as ten years before a formal diagnosis, while simulation studies demonstrated that treatments capable of delaying the progression from MCI to dementia can significantly reduce the economic burden. Therefore, early detection of dementia risk has implications not only from a clinical perspective but also in terms of economic sustainability.

HTA aims to demonstrate the value of the AI-Mind tools by evaluating their potential impact on patients and caregivers, and their role in ensuring the long-term sustainability of the National Health Service (NHS).

Equally importantly, HTA examines the organisational impact of adopting the AI-Mind tools and exploring how care pathways should be adapted to integrate them effectively.

Development of an HTA framework for AI-Mind

At the beginning of the project, the main challenges from an HTA perspective were: the lack of a dedicated framework capable of capturing the peculiarities of AI, the absence of models to guide the assessment based on the technology's stage of development, and uncertainties regarding the availability and quality of evidence.

Due to the lack of a standardised framework for evaluating AI-based technologies according to HTA principles, a panel of 46 international

experts was involved in a three-round Delphi survey. The research included patient representatives, technical experts (e.g. data programmer/engineer and cybersecurity specialist), AI developers, industry representatives, clinicians, ethicists/bioethicists, health economists, policy makers and HTA experts. The majority of them (65%) had already been involved in the implementation of AI-based technologies in the healthcare sector.

Any HTA framework is structured in domains, with each domain being divided into topics, and each topic further subdivided into several issues. A list of potentially relevant HTA topics was suggested to experts, who were asked to grade their relevance. 48 out of the 65 proposed topics emerged as critical and needing to be assessed. Furthermore, 14 of the 20 additional topics, currently not included in the traditional HTA frameworks such as the EUnetHTA (European network for Health Technology Assessment) Core Model, emerged as crucial.

The most important topics that emerged were: the accuracy of the AI model, patient safety and benefit-harm balance evaluated from an ethical and clinical standpoint, bias in data, target condition, technology features and risk management.

The current AI-Mind HTA framework is structured into 12 domains:

1. Health problems and current use of technology
2. Description and technical characteristics
3. Safety
4. Data related aspects
5. Clinical effectiveness
6. Cost and economic evaluation
7. Ethical analysis
8. Organisation aspects
9. Patients and social aspects
10. Legal aspects
11. Trustworthiness
12. Transferability.

While developing the HTA frameworks, it was confirmed that there was a need to adapt the assessment to the Technology Readiness Level (TRL) of the AI-based tool. To address this, the Early HTA decision model (https://ai-mind.shinyapps.io/earlyHTA/) was elaborated. This model allows a comparison between current practices in MCI diagnosis and dementia prognosis and a scenario where the AI-Mind tools are used in practice from the early stages of its development. The model is flexible, allowing for modifications to inputs and customisation to specific scenarios and models of care for MCI and dementia. The Early HTA model estimates the health outcomes and cost-effectiveness of the AI-Mind tools. It can be further refined based on clinicians' input, patient age groups, and expected severity levels. The Early HTA dynamic framework is accessible via a dashboard.

HTA, as a bridge between science and policy, is strongly based on available evidence. Therefore, while developing the AI-Mind tools, all stakeholders must be aware of the evidence they need to collect and provide to assessors and decision-makers. Continuous monitoring of available and validated AI-reported guidelines is ongoing. Their goal is to enhance the transparency and interpretability of data in AI applications in medicine, from the development phase of AI algorithms to the trials conducted to demonstrate their clinical impact. The focus on reporting guidelines aims to guide AI-Mind developers and clinicians in the collection of the data.

The framework defined for the AI-Mind project represents a significant advancement in the HTA ecosystem. It was built upon existing models to avoid duplication and was further refined through consensus building with all relevant stakeholders. Additionally, it was widely disseminated at national and international events, including training programmes, gathering valuable feedback for continuous improvement and to support its optimal application.

Looking ahead

The goal of the HTA framework developed for AI-Mind is to facilitate the advancement of the AI-Mind tools and to ensure transparency for all stakeholders, including policymakers, by clearly defining the evidence required to demonstrate its overall value.

The AI-Mind partners fully recognise that HTA is a multidisciplinary process that spans the entire lifecycle of health technologies. Therefore, further refinements to the methods and tools adopted are anticipated, along with an increasing ability to address all the topics covered by the HTA framework.

The AI-Mind HTA framework and Early HTA model received the award in the category 'Methods and Experiences in Health Technology Assessment' during the XXIV AIIC National Conference in Rome (May 2024)

Innovation and implementation: a strategic path-to-market

Innovation is at the heart of progress and in today's rapidly evolving technological landscape, it is essential for AI-Mind to effectively manage its innovation processes.

Jeanette Muller

Erik Christensen

By leveraging its AI-driven tools, the AI-Mind consortium is poised to address both healthcare industry needs and policy-level advancements, ensuring that its solutions transition into standard medical practice. To capitalise on these innovations, it was crucial to develop an exploitation strategy that maximises the impact of the AI-Mind results across different sectors, including the commercial, regulatory and education sectors.

Collection of potential exploitable results

The innovations coming from AI-Mind have the potential to affect the project but may also impact the entire European healthcare system on a superordinate scale. With an active innovation management approach, Swiss company accelopment Schweiz AG has developed accelINNO® - an innovation management support toolkit tailored to EU-funded projects. It helps identify exploitable results and supports project partners throughout the entire innovation process from the collection of exploitable results, through their assessment and planning of future commercial and non-commercial exploitation.

To date, more than two dozen innovative outcomes have been reported, with three already progressing towards exploitation.

"Thanks to newly-generated knowledge and technologies as well as strategic partnerships with key players in the Alzheimer's diagnostics market, AI-Mind is well positioned to deliver innovative clinical tools for the early detection and prevention of Alzheimer's disease", said Jeanette Muller, founder and CEO of accelopment Schweiz AG.

AI-Mind's innovation potential has already been recognised beyond the consortium, with the FluiDx-AD "spin-off" project, funded under Horizon Europe. This new initiative represents an example of how the results of the AI-Mind project are already having an impact. In the final months of AI-Mind, further opportunities for joint actions will be explored to maximise the impact of its innovations and ensure sustainability.

Path-to-market strategy

The AI-Mind project has led to several exploitable outcomes, particularly the AI-Mind Platform. This platform will support healthcare professionals in the analysis of brain connectivity and the prediction of dementia risk to improve timely diagnosis and treatment.

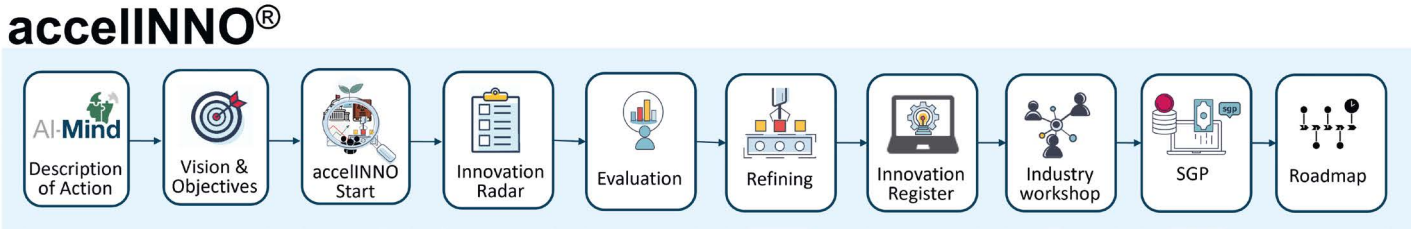
The development of the AI-Mind Connector and Predictor has also opened up several innovative avenues, each of which has the potential to be exploited (commercially or not) in different contexts, further broadening their potential impact. To guide these innovations, the AI-Mind consortium has developed a strategic path-to-market approach, which includes a market assessment and an exploitation roadmap. This strategy serves to evaluate the transferability of the project's results to the market, addressing both the risks on the market and the opportunities arising.

"Early risk identification supports dementia prevention, which is key for a higher quality of life for many people and AI-Mind is working to tackle this great objective and bring solutions to the market", said Alejandro Sánchez-Rico, senior consultant at Lurtis.

Expansion of the consortium

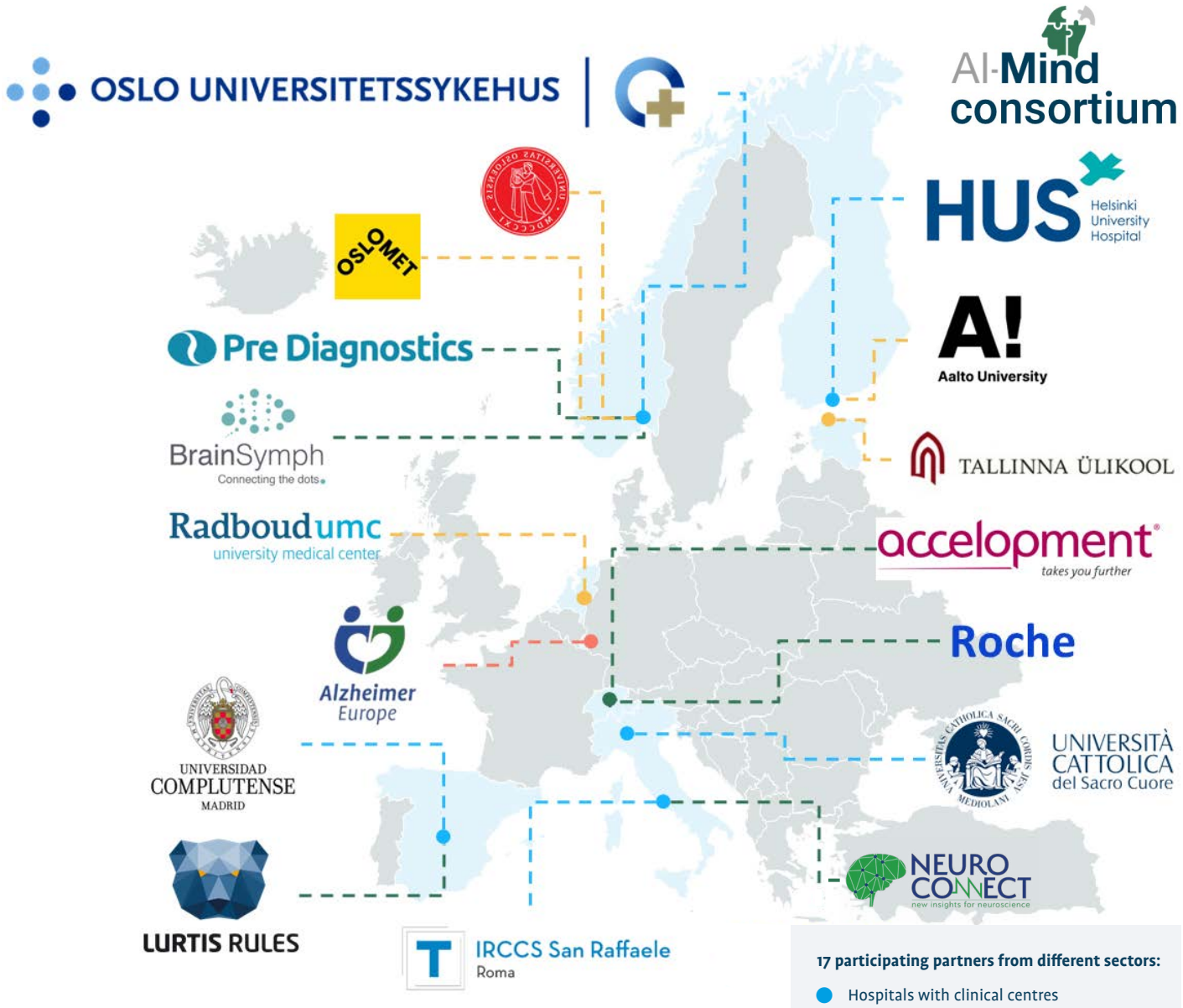
The consortium believes that the restructuring of its partners is a logical step towards improving the diagnostics journey of people affected by MCI. In 2023/2024 AI-Mind welcomed new industrial partners, namely PreDiagnostics and Roche. The addition of these key players is strategically important, positioning the AI-Mind project for greater success in the exploitation of its results towards industry.

"The AI-Mind partnership will facilitate further development and validation of our innovative services, such as fluid biomarkers for AD diagnosis and monitoring as well as biomarkers to predict personalised response to new disease-modifying therapies for Alzheimer's disease", said Erik Christensen, Chief Medical Officer and co-founder of PreDiagnostics.



The AI-Mind partners

The AI-Mind consortium brings together a multi-disciplinary, interdisciplinary and multi-national network including academic institutions, medical centres, small and medium-sized enterprises, spin-off companies and patient associations.



DNV

Disclaimer: Please note that DNV was a partner in the consortium from the outset but withdrew from the project as of 31 December 2023.

Collaboration

EBRAINS HDC HealthDataCloud Human Brain Project

AI-Mind

For more information on the AI-MIND project,
please visit our website: https://www.ai-mind.eu

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Alzheimer Europe