From Brain Science to Trusted Digital Health Services

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Executive Summary

Neurodegenerative diseases such as Alzheimer's and related diseases constitute one of the most pressing healthcare challenges due to their complexity, multifactorial nature, and difficulty of early diagnosis, being the leading cause of disability worldwide and making new and integrative approaches imperative. The central digital platform **EBRAINS** was established to address the necessity for a collaborative European **Research Infrastructure** which responds to this **urgent public health and research need**, by connecting leading organisations and researchers across disciplines. The **eBRAIN-Health project** addresses this need by bridging the gap across basic research and applied healthcare solutions, ultimately driving the creation of deployable digital health services.

The project is strategically anchored in two complementary pillars. First, the **Health Data Cloud** offers a secure and federated ecosystem that allows cross-institutional integration and analysis of sensitive data. Built under Findable, Accessible, Interoperable, Reusable **(FAIR) principles** and **General Data Protection Regulation**, the Health Data Cloud combines harmonised datasets, interoperable tools, and scalable workflows within a Virtual Research Environment, laying the groundwork for collaborative research, advanced brain modelling, and development of **digital brain twins**.

The eBRAIN-Health project is grounded in a **solid scientific foundation** that leverages validated approaches such as whole-brain modelling, multiscale simulation of brain activity, and machine learning using multimodal datasets, to translate them into **accessible formats** of digital brain twins that clinicians, patients and caregivers can use in their daily life. Examples of this include **The Virtual Brain**, a simulation platform for personalised brain models, the **Brain Atlas Web Visualizer**, that provides an accessible, interactive, and scientifically accurate platform for exploring human brain anatomy and function, or the "**EEG and The**

Virtual Brain" online course, expanding the educational component of these activities.

The second key outcome of the project is a portfolio of **near-market solutions** that transform cutting-edge methods into tangible value for prevention and healthcare for stakeholders. Examples of these innovations include **BrainSymph**, which facilitates the early detection and risk assessment of cognitive decline through the integration of multimodal data and artificial intelligence (AI)-driven predictive analytics, and **Neuro-PsychoMMSig**, a privacy preserving platform to identify meaningful biological patterns from multi-omics data. These capabilities are further strengthened by **iMapper**, which supports the harmonisation and integration of complex datasets, and **KG-Orchestra**, which expands and enriches existing knowledge graphs with additional, evidence-based insights. Complementing these data-driven approaches, **Eodyne**'s end-to-end neurorehabilitation platform is designed to support patients throughout the entire care process by incorporating game-based therapy and data-driven insights for personalised intervention. Similarly, the **SmartMe&You-TELEMAIA** platform in the CINECA cloud infrastructure enables ongoing home-based daily assessment of sedentariness, chronic cardiovascular stress, sleep quality, and training of cognitive and motor functions in people at risk of or living with neurodegenerative conditions.
All together, these innovations represent a new category of **open** and **advanced scientific tools** and, most importantly, are conceived to be interoperable and aligned with European regulatory frameworks, ensuring their readiness for validation and deployment within **Testing and Experimentation Facility for Health (TEF-Health)** environments. The **TEF-Health** project offers potential access to testing infrastructure, data and evaluation resources to facilitate market access for trustworthy health AI and robotics.

As neurological disorders represent a major and growing global health burden, this has led to coordinated **international** and **European initiatives** to improve prevention, treatment, and brain research. The Human Brain Project (2013-2023) laid the foundation for **EBRAINS**, integrating neuroscience data, tools, and services. EBRAINS acts as a trusted European **Research Infrastructure**, a provider of interoperable and certified health data ecosystems, and a catalyser for the digital health transformation. Building on this, the **eBRAIN-Health project** (Horizon Europe) provides a protected, cloud-based environment for sensitive clinical data and supports multiscale brain research. EBRAINS Research Infrastructure is part of the **European Strategy Forum on Research Infrastructures roadmap** and

leverages synergies with major European Research Infrastructures in the Health domain to connect data, preclinical models, and clinical and therapeutic research. At policy level, it aligns with international and European organisations and supports the establishment of a **European Coordination Plan for the Brain**. It also contributes to major partnerships such as the **European Partnership on Brain Health**, to strengthen collaboration and investment in neuroscience. EBRAINS plans to apply for a **European Digital Infrastructure Consortium** legal status by 2027-2028 that will create a **European Brain Data Space** linked to the European Health Data Space. Establishing a **TEF-Health EDIC** is also highly recommended. This pathway could ensure long-term sustainable shared investments, scalability to Europe-wide deployment and coordinated cross-border governance.

The development of digital neuroscience platforms requires strong **compliance** with European legal and ethical frameworks, particularly for sensitive health data. EBRAINS and eBRAIN-Health implement **FAIR data principles**, ensuring data usability and reproducibility through standardisation, metadata, and traceability. The **Virtual Research Environment** and **Health Data Cloud** support compliant data processing and sharing. The **European Health Data Space** Regulation (March 2025) established a common framework for the **primary and secondary use** of health data. The eBRAIN-Health project aligns with EHDS by enabling structured access to large-scale health data, and high-quality datasets, while supporting interoperability with EHDS data records across Europe. The platform ensures compliance with **General Data Protection Regulation** through data **pseudonymisation**, **secure processing** environments, **encryption**, strict **access control**, and **accountability**, supported by Data Protection Impact Assessments for high-risk data. The **AI Act** introduces a risk-based legal framework for **trustworthy AI**. AI tools used in the eBRAIN-Health project (e.g., neuroimaging analysis, diagnostics) are classified as high-risk category, requiring regulation compliance and registration. **AI regulatory sandboxes** provide controlled frameworks for testing innovative systems under regulatory supervision, enabling to support eBRAIN-Health with early alignment with AI Act obligations and high-risk compliance expectations.

All project's results align with European policy targets. EBRAINS supports the **European Research Area** objective of a unified research space by providing an open, distributed infrastructure. The eBRAIN-Health project extends this into clinical area through a **cloud-based protected platform** and **digital brain twins** for research and innovation. The eBRAIN-Health project contributes to strengthening Europe's leadership in AI through the development of an ecosystem of **health data**

modelling and **simulation platforms.** The project aligns with the expanding **Horizon Europe** initiatives to apply AI digital technology in health. The collaboration between eBRAIN-Health and **TEF-Health** bridges research and clinical application by **validating and scaling** AI-driven neurotechnology, facilitating safe and compliant **market entry**.

EBRAINS demonstrates that large-scale digital Research Infrastructure can bridge the gap between neuroscience research and clinical application while maintaining both **data sharing** and **privacy protection**. Key lessons highlight the importance of **integrated infrastructures** such as EBRAINS for translating research into real-world impact; the interoperable datasets and tools; the need for sustainable governance models such as EBRAINS EDIC. The eBRAIN-Health project illustrates how the **Health Data Cloud** can generate lasting value through FAIR-compliant infrastructure, reusable datasets and workflows, community building and long-term accessibility. TEF-Health is identified as a critical pathway for **scaling AI and digital twin tools** by providing testing infrastructure, data and evaluation resources, facilitating their validation and certification, and accelerating safe market access of trustworthy innovation.

eBRAIN-Health consortium

CHARITE – Universitaetsmedizin Berlin, Germany / EBRAINS, Belgium / Forschungszentrum Juelich GmbH, Germany / Stichting Radboud Universiteit, Netherlands / Universidad Pompeu Fabra, Spain / OSLO Universitetssykehus HF, Norway / tp21 GMBH, Germany / Fraunhofer Gesellschaft zur Foerderung der Angewandten Forschung eV, Germany / INDOC RESEARCH EUROPE gGmbH, Germany / Universitaet Wien, Austria / Universidad Complutense de Madrid, Spain / EODYNE Systems SL, Spain / ATHENA – Research and Innovation Center, Greece / University of Oslo, Norway / Stichting Amsterdam UMC / Universita degli Studi di Roma la Sapienza, Italy / Alzheimer Europe, Luxembourg / Institute National de Recherche en Informatique et Automatique, France / Centre Hospitalier Universitaire Vaudois, Switzerland / The University Court of the University of St Andrews, United Kingdom / Eidgenössische Technische Hochschule Zürich, Switzerland

List of Abbreviations

AD	Alzheimer's Disease
ADMCI	Alzheimer's Disease with Mild Cognitive Deficit
AI	Artificial Intelligence
AISBL	International non-profit association (*association internationale sans but lucratif*)
BBMRI	Biobanking and Biomolecular resources Research Infrastructure
CDM	Common Data Model
DALY	Disability-Adjusted Life Years
DIGITAL	Digital Europe Programme
DPIA	Data Protection Impact Assessment
EAN	European Academy of Neurology
EATRIS	European Infrastructure for Translational Medicine
EBC	European Brain Council
EBRAINS	European Brain Research Infrastructures
EC	European Commission
ECRIN	European Clinical Research Infrastructure Network
EDIC	European Digital Infrastructure Consortium
EEG	Electroencephalogram
EFNA	European Federation of Neurological Associations
EHDS	European Health Data Space
EHR	Electronic Health Record
EP	European Partnership
EPA	European Psychiatric Association
EPF	European Patients' Forum
EPRS	European Parliamentary Research Service
ERA	European Research Area
ERDERA	European Rare Diseases Research Alliance
ESFRI	European Strategy Forum on Research Infrastructures
EU	European Union
EUFAMI	European Federation of Associations of Families of People with Mental Illness
FAIR	Findable, Accessible, Interoperable, and Reusable
FENS	Federation of Neuroscience Societies
FET	Future and Emerging Technologies
GAMIAN	Global Alliance of Mental Illness Advocacy Networks
GDPR	General Data Protection Regulation
HBP	Human Brain Project
HDC	Health Data Cloud
HPC	High Performance Computing
IBRO	International Brain Research Organization
ICT	Information and Communication Tools

IGAP	Intersectoral Global Action Plan
IHI JU	Innovative Health Initiative Joint Undertaking
INCF	International Neuroinformatics Coordinating Facility
KG	Knowledge Graph
MCI	Mild Cognitive Deficit
MEG	Magnetoencephalogram
MIMS	Medical Information Management System
MRI	Magnetic Resonance Imaging
NS	Nervous System
RGS	Rehabilitation Gaming System
RI	Research Infrastructure
rsEEG	Resting-state Electroencephalogram
TEF	Testing and Experimentation Facility
TEF-Health	Testing and Experimentation Facility for health
VBT	Virtual Brain Twin
VHT	Virtual Human Twin
VRE	Virtual Research Environment
WHO	World Health Organization

Scientific & Innovation Module

Why eBRAIN-Health is Needed

In an increasingly ageing population, neurodegenerative diseases such as Alzheimer's and related diseases belonging to dementia are emerging as **relevant healthcare challenges**. Those diseases lead to a progressive, severe deterioration of cognitive functions (e.g., memory, executive functions, etc.), identity, and autonomy, affecting not only patients but also the lives of their families and caregivers.

Unlike diseases driven by a single biological mechanism, those neurodegenerative diseases in the pathological brain ageing are inherently **multiscale** and **multifactorial**. This complexity makes it difficult to study using isolated datasets or single artificial intelligence (AI) models. Furthermore, its progression is often slow and changes in the brain can appear long before symptoms do, making **early diagnosis** and monitoring a major hurdle.

Addressing such complex conditions requires new, **integrative, multimodal approaches** based on precision medicine. Large, curated multimodal datasets combining lifestyle (to derive risk factors), clinical, imaging, electroencephalographic (EEG), and genetic data are essential to capture the full disease picture and develop appropriate pharmacological and nonpharmacological (e.g., non-invasive brain stimulation and brain cognitive training) interventions. Significant progress depends on combining these rich datasets with cutting-edge approaches, including mechanistic brain models that go beyond purely statistical AI to simulate the complex pathoneurobiological and pathophysiological phenomena underpinning Alzheimer's and related diseases that can be harnessed by research communities. At the same time, the development of secure environments that protect privacy for processing sensitive health data is essential to foster international collaboration and maintain trust and compliance within an open science context.

Building on these needs, the **eBRAIN-Health project** emerges as a **key translational bridge**, connecting basic research with clinical application and, ultimately, with deployable digital health services. Its ambition is to move beyond fragmented scientific knowledge and facilitate its integration into real-world

healthcare solutions, particularly in areas such as neurodegenerative diseases along pathological brain ageing.

At its core, eBRAIN-Health provides a **distributed European research platform** where sensitive brain data from multiple sources can be processed, modelled, and simulated. This platform makes it available to researchers thousands of multi-level digital brain twins from both patients with neurodegenerative diseases and older cognitively unimpaired people at risk of those diseases, opening new opportunities for research and innovation in the study of brain diseases and clinical services. One of the project's main goals is to build interdisciplinary **digital brain twins** from multiscale data on brain status for an advanced assessment of older people at risk of or with cognitive deficits due to Alzheimer's and related neurodegenerative diseases. In other words, a virtual companion to the patient's brain that continuously evolves as new information is added. By integrating various data sources, from clinical, EEG-magnetoencephalography (EEG-MEG), and neuroimaging data to genetic and behavioural information, these models have the potential to revolutionise healthcare by transforming how neurological diseases are understood, predicted, prevented, and treated, paving the way for more **precise** and **personalised healthcare**.

This initiative backs on a certified and federated framework, with EBRAINS as the underlying infrastructure and eBRAIN-Health as the research layer expanding its reach into health applications. Developed as part of the Human Brain Project, the **EBRAINS Research Infrastructure (RI)** provides Europe's digital platform for brain research, offering advanced tools, computing power, and interoperable services. The eBRAIN-Health project leverages and expands this ecosystem to the healthcare sector, while maintaining rigorous standards for data security and interoperability.

The eBRAIN-Health project stands out as an **international** and **interdisciplinary** joint effort. Given the complexity of the brain, no single laboratory or discipline can address these challenges alone; the project brings together expertise from neuroscience, medicine, data science, and engineering to enable truly integrative solutions.

Within this framework, the impact of eBRAIN-Health is strategically anchored in two complementary pillars. First, the **Health Data Cloud (HDC)** provides a secure, federated environment, serving as an enabling layer to support the workflows and sensitive data handling needed to create thousands of digital brain twins. Second,

the project translates the foundational scientific research behind the scenes into tangible value through a **set of scientifically grounded innovations** to deliver actionable tools for improved diagnosis, decision making, and patient care.

The Health Data Cloud (HDC)

Research data in patients with neurodegenerative diseases remain highly fragmented, scattered across institutions, and often inaccessible due to legal and ethical constraints, which limits the integration of multimodal data necessary to understand the mechanisms and tackle these complex conditions.

As one of the main pillars, the eBRAIN-Health project approaches this challenge with a secure federated research data ecosystem, interoperable with EBRAINS tools and services, enabling neuroscience research consortia across Europe and beyond to collect and analyse sensitive data. The EBRAINS Health Data Cloud builds on an existing **GDPR-compliant Virtual Research Environment (VRE)** developed at Charité for the secure management of sensitive data (Schirner & Ritter, 2024). Its **federated architecture** enables data to remain at source while being securely query able across institutions, thus preserving ownership and controlled access. The HDC ensures alignment with FAIR principles, making data findable, accessible, interoperable, and reusable within a regulated framework.

Offering **end-to-end services** for personalised complex brain modelling and simulation, HDC stands out for its capacity to integrate large-scale, carefully curated multimodal datasets into harmonised standards. Unlike other conventional platforms, it offers a unified digital environment where researchers from different disciplines can store, share and analyse large multidisciplinary health datasets within a single ecosystem, with **data protection by design** and **by default**.

The HDC has been validated through reproducible and scalable workflows, further supported by demonstrations and clinical use cases, such as research on neurodegenerative diseases, within its Virtual Research Environment (Patow et al., 2023; Schirner et al., 2023; Kashyap et al., 2025), highlighting secure data access and advanced analysis in practice.

The HDC represents a fundamental shift in the way brain research and digital health innovation are conducted in Europe. By bringing together integrated data sources and high-performance computing, it enables **digital brain twin approaches** and simulation-based research operational at scale. Crucially, it provides the secure

environment for testing and validating clinical AI, while laying the groundwork for future TEF (Testing and Experimentation Facility)-Health services.

Beyond this, the HDC positions eBRAIN-Health within a **sustainable**, federated European health data infrastructure aligned with the European Health Data Space, offering a next-generation clinical research environment and a secure, **open space** for innovation across academia and industry.

From Foundational Science to Innovation

Within the eBRAIN-Health project, innovations have emerged as a natural extension of long-standing, high-quality neuroscience research, rather than as an isolated engineering effort. The project builds on a scientifically mature understanding of brain function and dysfunction, in which **large-scale computational methods** have become well-established approaches for testing hypotheses on the principles of brain function (Schirner et al., 2023).

On this basis, mechanistic modelling, multiscale simulation, and connectome-based analysis have been established as robust and reusable approaches for studying the human brain. A key aspect of this continuum is the validation of **mechanistic whole-brain modelling** as a reliable scientific method for capturing large-scale brain functioning beyond purely correlational descriptions, helping explain more precisely the causes of different brain states across conditions (Kashyap et al., 2025; Schirner et al. 2023; Patow et al. 2023). Building on this foundation, **multiscale brain simulation** has shown that neuronal level processes and whole-brain dynamics can be coherently integrated within a single computational model (Meier et al., 2022). In parallel, connectome-based studies have shown how the brain's structural connectivity significantly influences large-scale brain activity patterns, including the way signals are transmitted and how brain rhythms are organised across different regions (Koller et al., 2024). These next-generation approaches also support applied developments, where brain simulations can provide digital markers (digital brain twins) to enhance **machine-learning-based** detection of patients with cognitive deficits due to Alzheimer's and related neurodegenerative diseases, emphasising the translational value of brain mechanistic models and multiscale simulation in the clinical landscape (Triebkorn et al., 2022). Importantly, most of this research has operated within the interoperable Virtual Research Environment of the Health Data Cloud, which provides a secure and standardised infrastructure for running and sharing analyses.

These validated insights directly inform applied tools developed as part of the eBRAIN-Health project, providing a scientifically grounded educational experience that transforms the complex research into accessible formats that clinicians, patients and caregivers can use in their daily life. An example of this is the **Brain Atlas Web Visualizer**, a significant advancement in the field of neuroeducation by providing an accessible, interactive, and scientifically accurate platform to explore the human brain anatomy and function. In addition, coupling the atlas with predictive models and simulation tools could provide novel ways for predicting changes in neurological health and tailoring educational content. In light of this, **The Virtual Brain platform** was used and further developed as an open-source simulation platform running within the EBRAINS ecosystem to create personalised computational brain models ("digital brain twins") by integrating large datasets, helping researchers to develop and test potential therapies and diagnostic approaches (Avila-Varela et al., 2024; Escrichs et al., 2024; Patow et al., 2023; Patow et al., 2024; Patow et al., 2025). To illustrate these capabilities, resting-state EEG (rsEEG) data have been used to generate subject-specific digital brain twins capable of identifying alterations in excitatory and inhibitory neuronal activity in patients with prodromal stages of Alzheimer's disease with mild cognitive deficits (ADMCI), supporting more personalised simulation-based diagnostics (Lopez et al., in preparation). In parallel, ongoing research tackles additional pathological dimensions of ADMCI status, improving the understanding of the cerebral glymphatic system in the accumulation of AD-related neuropathology in the brain, as well as the alteration of its intrinsic brain rhythms regulating the maintenance of vigilance, to develop a comprehensive neurobiological and neurophysiological AD model that can be translated into The Virtual Brain in the future (Lopez et al., 2026). The educational component of these activities is delivered through the **"EEG and The Virtual Brain" online course** designed to train professionals in advanced EEG analysis and its use in The Virtual Brain platform, ultimately empowering the transition toward precision and personalised medicine (free access to the course in the Educational PDWaves pages, https://www.pdwaves.eu/education/).

Within the eBRAIN-Health project, further activities have expanded the platform's capabilities. Specifically, **machine learning approaches** combined with individual rsEEG data have demonstrated their ability to reliably distinguish between Alzheimer's disease, Lewy body disease, and healthy older adults through non-invasive and cost-effective measurements (clinical EEG costs about 25 Euro in the Eurozone). These models not only provided clinically relevant discrimination but also identified disease-specific neurophysiological signatures (so-called "periodic"

rsEEG signatures for Alzheimer's patients and "aperiodic" rsEEG signatures for Lewy body disease patients), making it scalable to routine neurology clinics (Henao Isaza et al., in preparation). In addition, machine learning methods have been used to predict the cognitive decline at 1-year follow-ups in patients with ADMCI, using EEG and demographic data as input variables (Babiloni et al., 2026). By embracing advanced machine learning and deep learning tools, preliminary results have also demonstrated the potential of synthetic rsEEGs generated by deep learning models trained with true rsEEG data as a valuable tool for augmenting the rsEEG database and effectively training machine learning models used to detect patients with MCI (Upreti et al., 2026, in preparation).

Taken together, these developments position eBRAIN-Health as a translational initiative that connects foundational research and clinical applications with real-world, deployable digital health services for digital brain twins, ensuring they are built on scientifically grounded, reusable, and well-accepted methods rather than experimental assumptions.

Innovations for Clinical and Market Uptake

Within this translational landscape, a set of key innovations has emerged, converting the scientific advances into practical, near-market solutions. These innovations bridge the gap between basic research and real-world practice, transforming sophisticated methods into user-friendly digital health technologies. Collectively, they represent the tangible value for patients, clinicians, and industry by optimising clinical workflows, empowering decision-making, and facilitating large-scale healthcare implementation.

BrainSymph platform

By translating research on brain connectivity into clinical practice, BrainSymph addresses a key gap in current healthcare, where brain health is often assessed after symptoms become apparent. **Early detection** is critical, as research has proven that early intervention can delay and slow down cognitive decline. In this context, BrainSymph emerges as an innovative digital health platform designed to **map brain health** and **estimate the risk of developing dementia** due to Alzheimer's and related neurodegenerative diseases by integrating multimodal data in a structured and efficient manner. Developed in collaboration with neurological research environments, BrainSymph is part of the EU-funded AI-Mind project, a core component of the wider eBRAIN-Health infrastructure supporting multimodal

brain modelling and clinical translation. It combines state-of-the-art methods with biomarkers and AI-driven predictive analytics to provide a comprehensive assessment of brain function and disease risk.

The BrainSymph platform enables the systematic collection of individual brain-related data, including EEG recordings, cognitive performance measures, and any other relevant clinical information. These inputs are processed using AI models and brain network representations to evaluate an individual's brain health profile and estimate the risk of cognitive decline. The resulting outputs support both **clinical decision-making** and **self-monitoring**, enabling earlier and more informed intervention.

BrainSymph has been applied across different real-world scenarios. In clinical settings such as hospitals and primary care, it supports early detection and more personalised treatment planning. The integration of biomarkers, cognitive tests, and AI, facilitates healthcare professionals to identify cognitive decline early, which directly translates into **improved patient care**. By leveraging the platform, businesses can gain access to **early-stage diagnostics** for brain health, equipping employees with the tools to manage and prevent cognitive decline before it impacts productivity. From the patient perspective, the platform provides a personal evaluation report that helps individuals understand their risk of cognitive decline or brain-related diseases, offering accessible insights to **guide lifestyle decisions**.

The BrainSymph platform makes brain health mapping easy, systematic, and efficient at scale. It generates personalised brain health reports that help users and clinicians understand risk trajectories before clear symptoms emerge.

Eodyne platform

The Rehabilitation Gaming System (RGS) is Eodyne's end-to-end neurorehabilitation platform designed to support patients across the full **continuum of care**, from admission and hospital treatment to home-based recovery. It integrates game-based therapy, clinical management tools, and data-driven insights for personalised intervention.

This continuum starts at the clinical setting, where **RGSclinic** delivers AI-based virtual reality exercises that adjust in real-time to each patient's motor and cognitive profile, enabling therapists to maximise recovery while reducing hands-on time and equipment. Once the patient is discharged, the same therapy can continue at home through **RGS+**, a cross-device display (smartphone, tablet, laptop or

smart-TV) that serves augmented reality exercises for upper- and lower-limb training, along with cognitive tasks. Importantly for patient engagement, these tasks adapt in real-time to each patient's performance using AI-driven algorithms, maintaining an optimal level of challenge to maximise motivation and recovery outcomes. Both components transmit the pseudonymised data to **RGS-Medical Information Management System (MIMS)**, a web-based management system for professionals to support therapy planning, remote monitoring, and data-driven decision-making through progress tracking. All information handled by MIMS is stored securely in the cloud, so no local installation or manual data-transfer step is required.

By pairing RGS+ on the patient side with MIMS on the clinical side, the eBRAIN-Health platform offers a continuous workflow in which healthcare professionals configure and monitor therapy in MIMS, while patients complete the exercises on their own devices via RGS+, with performance data feeding back to clinicians for evidence-based follow-up.

RGS has been extensively validated in real-world neurorehabilitation contexts, particularly in stroke recovery, where it has been used with thousands of patients across acute, subacute, and chronic phases. Clinical studies have demonstrated improvements in motor function, sustained recovery outcomes, and enhanced effectiveness compared to standard therapy. Within the eBRAIN-Health context, the system has been extended to support patients with mild cognitive deficits (MCI) and dementia, further broadening its applicability.

Ultimately, Eodyne seeks to help and empower all patients in need of rehabilitation to achieve the best possible recovery, while also reducing the burden on healthcare centers and workers, and lowering healthcare costs.

SmartMe&You-TELEMAIA platform

Sleep duration and quality, chronic cardiovascular issues due to autonomic nervous system dysfunctions, fluctuation of cognitive performances, and sedentariness are increasingly recognised as early detectable and potentially alterable factors associated with the risk of and progression of cognitive and motor deficits due to Alzheimer's and related diseases (Livingstone et al., 2024). Based on this notion, the **SmartMe&You-TELEMAIA** platform was designed to enable ongoing home-based telemonitoring for one week of step counts, heart rate variability, sleep duration and quality, and assessment and training of cognitive and motor functions in older adults at risk of or living with conditions such as Alzheimer's,

Parkinson's, and Lewy body diseases. Developed and clinically validated within the eBRAIN-Health project, the SmartMe&You-TELEMAIA platform is operative on the **cloud-based CINECA** infrastructure, integrated within the CINECA digital ecosystem, and allows to log in, collect, store, visualise, and analyse those telemonitored and clinical data with machine learning tools to predict the cognitive status of the user.

To be scalable, the telemonitoring procedure implemented in the SmartMe&You-TELEMAIA platform was enacted by commercial devices. Data from both older adults with intact cognition and patients with cognitive decline due to neurodegenerative diseases is collected through home telemonitoring over a one-week period. A consumer smartwatch continuously monitors **key dementia risk factors**, which includes sedentariness/physical activity, sleep-wake cycle, night-time sleep quality and efficiency, and heart rate and pulse over 24 hours. At the same time, a common tablet offers a suite of **serious video games** designed for both the monitoring and training of cognitive functions such as vigilance, visuospatial attention, and executive functioning. Importantly, all performance data from these serious games are pseudo-anonymised to ensure protection of user's identity, according to GDPR-compliant CINECA rules.

Data collected from these devices is automatically transmitted to the **SmartMe&You-TELEMAIA platform**, where it is also integrated with clinical and neuroimaging registries derived from the patient's hospital records. On this platform, **machine learning models** trained on these multimodal datasets can be used to predict the cognitive status with clinically relevant accuracy, supporting early detection and continuous monitoring.

The usability, acceptability, and validity of the SmartMe&You platform have been successfully evaluated as part of the eBRAIN-Health activities in both healthy individuals and patients with cognitive deficits due to Alzheimer's and Parkinson's diseases (see an overview of the results presently under evaluation in scientific journals of clinical neurosciences). The results demonstrated high usability and strong alignment with established standard clinical and instrumental (e.g., rsEEG) measures, supporting its validity as remote (telemonitoring) dementia risk factors and cognitive assessment tool.

Overall, the SmartMe&You-TELEMAIA platform is active in the CINECA infrastructure with the potential to be interoperated with all assets of EBRAINS-Italy and with the other eBRAIN-Health computational and data services,

facilitating interoperable research that complies with the FAIR principles. This platform enables **low-cost**, **scalable**, and environmentally sustainable home telemonitoring of dementia risk factors and cognitive status, opening new pathways for telemedicine applications, supporting earlier diagnosis, remote evaluation of those risk factors and cognitive status, thus improving disease prevention in older people at risk and the management of patients with Alzheimer's and related diseases. This is promising for mitigating well-established dementia risk factors and to make possible cognitive brain training with the serious video games to enhance their quality of life and health status.

iMapper platform

Biomedical datasets are often fragmented, stored with inconsistent structures and variable names, making it difficult to harmonise across studies. Mapping datasets to Common Data Models (CDM) is therefore a critical but highly manual and time-consuming task. In this context, iMapper was conceived as an interactive platform for **semantic mapping** and **data harmonisation**, designed to integrate heterogeneous datasets and facilitate interoperability across systems. Although these functions are used within the eBRAIN-Health project, their capabilities can be expanded to any field.

In brief, iMapper provides AI-assisted harmonisation workflows that support multiple mapping scenarios, including aligning datasets to CDM and mapping dataset features to knowledge graphs (KG) or biomedical bases. The **CDM mapping workflow** enables harmonisation across multiple datasets, making it easier to integrate, compare, and reuse data in downstream analysis and machine learning pipelines. In parallel, the **KG mapping component** connects dataset features to structured knowledge and evidence bases, helping AI models to provide context and support clearer interpretation of results, which ultimately help researchers understand the potential mechanisms and evidence behind model predictions. Importantly, the platform combines different matching approaches to generate mapping suggestions, while keeping human validation at the centre to ensure transparency and trust.

The platform can be deployed locally or used online, including in **federated** and **privacy-sensitive environments** where institutions can validate data structures without sharing sensitive information. By reducing manual effort and enabling reusable mappings, iMapper supports **scalable**, **interoperable**, and **explainable biomedical AI** and data integration workflows.

KG-Orchestra

Biomedical discovery depends on knowledge that is not only vast, but accurate, clear, and well-grounded. In line with this need, KG-Orchestra emerges as an open-source multi-agent framework that **enriches existing biomedical KGs** with cause-and-effect precision, bridging the gap between the scalability of automated systems and the level of detail traditionally achieved through manual curation. Within eBRAIN-Health, these enriched KGs support the inference of pathological mechanisms and provide recommendations on early and late neurodegenerative disease factors for patients, clinicians, and the general public.

The framework orchestrates specialised AI agents across two coordinated processes: one that autonomously acquires and filters relevant evidence from PubMed and PMC, and another that builds, aligns, and validates new knowledge relationships through iterative refinement. Importantly, every result can be traced back to its source, ensuring transparency.

Validated across real-world biomedical contexts, KG-Orchestra has demonstrated its ability to expand and enrich existing KGs by incorporating large amounts of scientific evidence while maintaining a high level of reliability. It also increases the coverage of concepts and relationships, strengthening the overall knowledge base.

KG-Orchestra supports use-cases such as drug repurposing, pathway completion, and evidence review. It can be deployed in different computing environments and represents a step forward in how specialised biomedical knowledge is built, validated, and used.

Neuro-PsychoMMSig

A common limitation in research on neurodegenerative and psychiatric disorders is the use of unimodal approaches, which often fail to capture the full biological complexity of the disease. MMSig is a web-based platform that combines **multi-omics datasets** with **disease-specific knowledge graphs** to identify mechanistic signatures. As an open-source platform, MMSig enables the analysis of sensitive patient data while maintaining privacy, supporting applications in disease stratification and *in silico* drug discovery within the eBRAIN-Health project.

The platform is built on manually curated KGs covering a range of diseases, including Alzheimer's disease, Parkinson's disease, and schizophrenia. These graphs can be explored interactively by researchers using biomarkers such as genes, proteins, pathways, and phenotypes, to identify shared or distinct

mechanisms across diseases. In addition, MMSig applies a set of network-based algorithms to user-provided genomic or transcriptomic data, using the KGs as prior knowledge to identify key changes, underscore dysregulated pathways, and generate meaningful patient-level insights.

When applied to public Alzheimer's datasets, MMSig has identified **novel dysregulated biological processes** and has demonstrated the ability to **stratify mild cognitive impaired patients** into distinct molecular subgroups. On post-mortem brain samples from schizophrenia patients, it has also confirmed trends **consistent with existing research**, supporting its reliability.

Beyond patient stratification, MMSig supports biomarker discovery by helping identify relevant biological mechanisms linked to specific patient groups, allowing researchers gain insight into the underlying pathology before conventional clinical evaluation.

AI-mind

AI-Mind is a **European clinical AI platform** developed for the early prediction and prevention of dementia risk in individuals with mild cognitive impairment (MCI). The platform integrates advanced EEG-based brain network biomarkers, blood biomarkers, digital cognitive assessments, comorbid organ information as heart and metabolism and machine learning models within a regulatory-aware, GDPR-compliant framework.

Built on a prospective multinational cohort, AI-Mind demonstrates how multimodal data can be transformed into clinically actionable stratifying risk predictions, supporting the transition from reactive care to precision prevention in brain health. As a scalable digital health asset, AI-Mind contributes to the vision of data-driven, personalized neurology and future virtual human twin applications.

Stakeholder Value & Service Categorisation

These innovations are part of an integrated eBRAIN-Health ecosystem that connects research-driven methods with clinically deployable and market-oriented digital health solutions, representing a new category of **open** and **advanced scientific services**. They function as interoperable components across the full continuum, from data acquisition and modelling to clinical decision support and patient-facing deliveries.

Recognising the challenges posed by the adoption of smart neurotechnologies among older adults with cognitive impairment, the eBRAIN-Health project has been

carefully designed to address barriers related to the digital divide, usability, and data security. For the implementation to be successful, simple, user-centred designs, strong support for both caregivers and patients, and the building of trust through rigorous privacy protection are essential components (Lizio et al., in progress).

Importantly, these innovations have been designed with clear exploitation perspective, intended to interface with TEF-Health services for independent validation, certification, and large-scale European deployment.

Scientific Readiness for TEF-Health and Sustainability

EBRAIN-Health Outputs as a Basis for TEF-Health Services

In the fast-evolving field of digital health, ensuring that innovations successfully reach patients requires rigorous compliance with regulatory and data protection frameworks, which remains a major bottleneck for many emerging applications. The eBRAIN-Health project addresses this obstacle by ensuring compliance, interoperability, and reproducibility at the core of its scientific and technological developments.

The project provides a solid basis for TEF-Health services via a federated, GDPR-compliant Virtual Research Environment-Health Data Cloud (VRE-HDC), along with curated, harmonised, and FAIR datasets ready for modelling and simulation. Reproducible workflows delivered through the EBRAINS digital infrastructure guarantee traceability and standardisation, bringing these outputs to a **pre-certification maturity stage**.

A clear **bidirectional value** exists between eBRAIN-Health and TEF-Health. On one hand, key outputs such as the HDC can evolve into TEF-Health services offered to companies for product testing and validation. On the other, eBRAIN-Health innovations can leverage TEF-Health services to achieve certification and progress toward market readiness.

Continuity and Scaling Potential

The eBRAIN-Health innovations are strategically placed for immediate testing and validation within TEF-Health, facilitating their journey toward **regulatory certification** (i.e., GDPR compliance) and deployment. Their outputs are fully aligned with TEF infrastructures, enabling seamless **integration into TEF testing environments**. This paves the way for scaling from research to practical

application, helping to advance solutions by providing access to larger datasets, testing environments, and collaboration with industry partners.

Overall, EBRAINS and TEF-Health are complementary infrastructures that support the entire **AI digital health lifecycle**. EBRAINS provides the digital infrastructure needed for collaborative, high-impact research, while TEF-Health offers the validation and certification channels required for market entry.

Taken together, these sustainable infrastructures are essential to both healthcare and the European economy. Their ongoing development will support member states accelerate innovation in the field of brain disorders, such as dementia, and will help ensure that research rapidly and reliably reaches the people who need it.

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Policy Module

Landscape of European Initiatives

EBRAINS Research Infrastructure

Brain diseases (such as Alzheimer's and Parkinson's) often affect patients over long periods and represent one of the highest long-term disability burdens. In 2021, **43.1% of the global population** had nervous system health loss, emphasising the significant public health impact of these conditions. Given the very high disability-adjusted life years (DALYs), there is an urgency of improving **prevention**, **treatments** and **rehabilitation strategies** (Steinmetz et al, 2024). Neurological conditions are now the leading cause of poor health and disability worldwide, with the overall amount of disability, illness and premature death rising by 18% since 1990. In response to the **growing burden of nervous system disorders** worldwide, the World Health Assembly adopted the Intersectoral Global Action Plan on epilepsy and other neurological disorders 2022–2031 (IGAP) to set out strategic objectives and targets to **improve access** to treatment, care and support for people with neurological disorders; implement strategies for brain health promotion and disease prevention; strengthen research and data; and emphasize a public health approach to the neurological disorders. (WHO, 2024; Steinmetz et al, 2024).

The European Commission (EC) funded the Future and Emerging Technologies (FET) Flagship **Human Brain Project (HBP)** from 2013 to 2023. The ultimate objective of the HBP funding was to achieve an integrated, multi-level understanding of the structure and function of the brain, and to contribute to the development of new treatments for brain diseases through the development and use of information and communication (ICT) tools. This objective is realised through the creation of an ICT platform that integrates data, technologies, and services to support the scientific community in the long term, extending beyond the duration of the HBP project. This integrated digital platform of the HBP, designed to advance and accelerate progress in neuroscience and brain health, was officially launched in 2019 and is named "**EBRAINS**" (European Brain ReseArch INfraStructure) (EBRAINS, 2024). EBRAINS is positioned as the **central platform to integrate brain related data sets of sensitive and non-sensitive nature, and to provide the necessary tools and base infrastructure to integrate, process, and analyse these**

data. EBRAINS was established to address the necessity for a collaborative European **research infrastructure (RI)** which responds to this **urgent public health and research need**, by connecting leading organisations and researchers across disciplines. The EBRAINS RI is coordinated by the EBRAINS AISBL, a non-profit legal entity located in Brussels.

EBRAINS has a key role in brain research and medicine in Europe thanks to its leading position as:

- the European **RI** in neuroscience and neurotechnology
- the single networked **access provider** to interoperable, certified **health data** ecosystems
- the catalyser for the EU **digital health** transformation in brain science

eBRAIN-Health, a four-year, €13 million **Horizon Europe** project, focused on neurodegenerative disorders, builds on the foundational neuroscience data, and tools provided in EBRAINS. eBRAIN-Health complements EBRAINS by providing a protected environment for sensitive medical data that interoperates with EBRAINS' already vast data collections (eBRAIN-Health, 2026). It enables multiscale brain research—from molecular and cellular levels to the whole organ—and provides tools for brain atlases, medical analytics, modelling, FAIR data (findable, accessible, interoperable, and reusable), and computing.

The **EBRAINS 2.0** project is established for three years and receives funding from the European Union's Research and Innovation Programme Horizon Europe[1]. The overarching goals are to further consolidate the Research Platform, to foster a deeper understanding of brain structure and function with dedicated and mature software tools, and to facilitate the development of more effective treatments, new drugs, diagnostics, and preventive measures for neuro-psychiatric disorders (EBRAINS RI, 2026 (a)).

The EU-funded "**Virtual Brain Twin (VBT)** for personalised treatment of psychiatric disorders" project is a four-year project coordinated by EBRAINS AISBL (international non-profit association). It introduces an innovative approach to psychiatric care with modelling the interactions of nervous system activity and simulation tools embedded within the EBRAINS digital neuroscience research infrastructure (EBRAINS VBT, 2023).

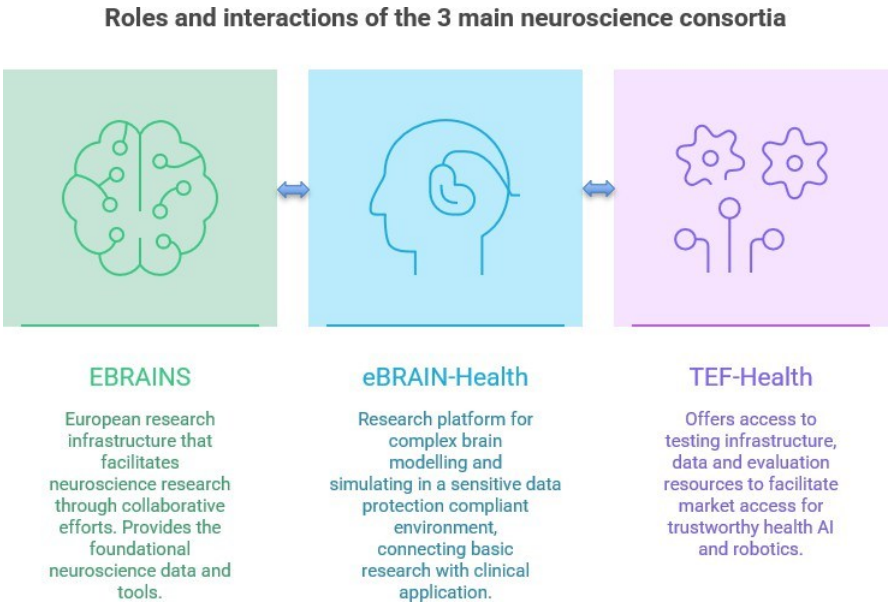
[1] under Grant Agreement No. 101147319 (HORIZON-INFRA-2022-SERV-B-01)

The **Testing and Experimentation Facility for Health (TEF-Health)** project, partner of EBRAINS, offers potential access to testing infrastructure, data and evaluation resources to facilitate market access for trustworthy health AI and robotics.

EBRAINS is expected to transition in the next few years into a **European Digital Infrastructure Consortium (EDIC)** legal status to consolidate, extend its core services, and provide a sustainable platform. While the EBRAINS EDIC will be focused on providing services of a digital nature, the broader EBRAINS community offers critical complementary capabilities for other types of services.

EBRAINS supports an international public TEF-Health event in **June 2026 in Berlin**, with the aim to provide access to real-world test environments and position Europe as a leader in trusted AI and robotics innovation.

The diagram below describes the roles and interactions of the 3 main initiatives:



European Strategy Forum on Research Infrastructures

The EBRAINS RI has been included in the European Strategy Forum on Research Infrastructures (ESFRI) Roadmap since June 2021 with France being the lead country. It is operated by the EBRAINS AISBL and delivered through its National Nodes[2], offering an integrated portfolio of multi-scale brain atlases, curated and FAIR-compliant neuroscience data, modelling and simulation platforms, neuromorphic and high-performance computing, and federated services for

[2] https://ebrains.eu/about/regional-presence/national-nodes

sensitive clinical data. There are around 17,000 registered users from 95 countries that are supported by EBRAINS services and tools (EBRAINS (b), 2026).

EBRAINS has created strong links with other ESFRI RIs in the Health and Food thematic domain such as the **European Biobanking and BioMolecular resources Research Infrastructure (BBMRI)**, the **European infrastructure for translational medicine** (**EATRIS)**, the **European Clinical Research Infrastructure Network (ECRIN)**, the **Europe's distributed research infrastructure for life science data (ELIXIR)**, the **Euro-BioImaging**, **European research infrastructure for modelling human diseases (INFRAFrontier),** the **Integrated Structural biology infrastructure (INSTRUCT)** and the **European infrastructure of open screening platforms for chemical biology (OpenScreen)** (Hol et al, 2026). The following synergies have been identified between these RIs:

Data

ELIXIR's data standards and interoperability protocols have the potential to enhance **EBRAINS**' neuroscience data-sharing capabilities, enabling better integration across life sciences and cross-disciplinary research. **Euro-BioImaging**'s imaging capabilities can be used to generate high-quality brain imaging data for EBRAINS, which can then integrate this data into its modelling and analytics tools, advancing brain mapping and neuroimaging studies. **BBMRI**'s biobank data could be integrated into ELIXIR and EBRAINS' data management systems, leveraging their standards for broader accessibility and interoperability. **INSTRUCT**'s focus on structural biology to understand biological processes at a molecular level can complement EBRAINS' focus on integrating structured data across different scales (from molecular level up to the whole brain). This can help create comprehensive datasets that combine genetic, clinical, and biomolecular information.

Preclinical studies and models

INFRAFRONTIER's animal models can benefit from **Euro-BioImaging**'s advanced imaging platforms and brain-specific modelling tools at **EBRAINS**, enhancing the phenotypic analysis of disease models. Together, they enable in-depth investigations at molecular, cellular, and systemic levels.

Clinical and therapeutic research

Complementary expertise specialisations of RIs such as **OPENSCREEN**, **EATRIS**, **EBRAINS**, **ECRIN**, and **INFRAFRONTIER** are beneficial for the development of biomarkers and new treatments. OPENSCREEN can contribute initial "hit" compounds, which EATRIS can further develop, validate, and take through

preclinical and early clinical stages, creating a seamless pipeline from discovery to validation. In addition, EATRIS can use INFRAFRONTIER's animal models to validate biomarkers or drug candidates *in vivo* before clinical trials, creating a pipeline from preclinical validation through early clinical development. BBMRI's biobanks can supply well-characterised biospecimens for ECRIN-supported clinical trials, while ECRIN's infrastructure enables these biospecimens to be tested across multiple countries in standardised and ethical ways. EBRAINS can provide neuroscience-specific tools and data that can be used in ECRIN -supported clinical trials focused on neurological conditions, enhancing the quality and depth of clinical research in brain sciences.

Non-profit organisations and non-governmental organisations:

International organisations in neuroscience have been established to facilitate discussions and work toward the development of **international data governance** framework that can provide solid ethical and legal guidelines to researchers as regulation tightens. The **International Brain Initiative** founded in 2017 serves as a coordinator for exchange across large-scale neuroscience initiatives, with the aim of creating impact that benefits neuroscience at an international scale (Eke et al, 2022; EBRAINS, 2021).

EBRAINS aligns with the policy actions developed by **non-profit**[3] and **patient organisations**[4] and advocates for the establishment of a comprehensive **European Coordination Plan for the Brain** to align with World Health Organization global targets by 2030-2031. This strategy emphasises that investment in brain research is not only a health priority but a necessity for Europe's future competitiveness, resilience, and economic prosperity.

European partnerships

EBRAINS joined the **European Partnership on Brain Health (EP BrainHealth)**, launched in January 2026. This is a ten-year partnership with a total planned budget of approximately €500 million. It is one of the largest collaborative efforts in

[3] Non-profit organisations and non-governmental organisations:
European Psychiatric Association (EPA) / European Academy of Neurology (EAN) / European Brain Council (EBC) / International Brain Research Organisation (IBRO) / Federation of Neuroscience Societies (FENS) / International Neuroinformatics Coordinating Facility (INCF)
[4] Patient organisations :
European Patients' Forum (EPF) / European Federation of Neurological Associations (EFNA) / European Global Alliance of Mental Illness Advocacy Networks (GAMIAN-Europe) / European Federation of Associations of Families of People with Mental Illness (EUFAMI)

brain research worldwide. It aims to strengthen transnational collaboration as well as increase and better align investments in brain-related research and innovation. Its mission is to promote the translation of research findings into tailored solutions for prevention, diagnosis, treatment and care, accessible to all (Hol et al, 2026).

In addition to **the EP BrainHealth,** there are other partnerships that have synergies with brain health such as the **European Partnership for Personalised Medicine (EP PerMed)**, the **European Rare Diseases Research Alliance (ERDERA)** and the **Innovative Health Initiative Joint Undertaking (IHI JU)**.

Additional initiatives

• The **Virtual Human Twin (VHT**) initiative for personalised medicine created by the EDITH project (coordination and support Action).

The VHT initiative is EC-funded independent initiative, as much as the VBT project, aimed at integrating patient-specific data (e.g., imaging, biology) into digital models to improve personalised medicine, both are aligned with EU strategies for AI and digital health. EBRAINS aligns with the broader multi-scale modelling efforts of the European VHT initiative.

• The **Copernicus Health Hub** brings together all Copernicus' environmental data and products pertinent to health, including those related to physical health, mental health, and well-being.

Legislative Framework

The increasing use of digital data requires the development of secure and **collaborative digital platforms** that ensure **data security**, **data protection**, and **compliance** within the applicable legal frameworks. eBRAIN-Health data and AI tools are intrinsically high-sensitivity domains, so **trust** is a prerequisite for secondary use of data (i.e., when health data is reused for research, innovation, public health, policy-making and personalised medicine), clinical translation and sustainable service provision. Trust must be demonstrated through compliant governance, robust technical and organisational measures, transparent access procedures and evidence-generating validation pathways.

FAIR data principles

The FAIR Data Principles, making data **Findable**, **Accessible**, **Interoperable**, and **Reusable**, are a widely accepted set of guidelines formally introduced in 2016 for scientific data management that aim to maximise the usability of data for a more

open and efficient research environment (Wilkinson et al, 2016). The principles refer to three types of entities: data (or any digital object), metadata (information about that digital object), and infrastructure (FAIR principles, 2022). HBP created the resources to help facilitate meeting these requirements, which are now implemented in the digital EBRAINS RI (Amunts et al, 2024). EBRAINS is sharing data and information in an integrated platform.

The Virtual Research Environment (VRE) forms the basis of the Health Data Cloud (HDC) and is the digital research platform providing researchers with flexibility to implement their own workflows, including experimental processing methods. VRE/HDC supports researchers in complying with FAIR principles through its tools for recording digital provenance, data standardisation, and versioning, with the aim of improving reproducibility. User-friendly interfaces help trace the origin and processing path of data to enable transparent and comprehensible research practices. **Datasets** can be structured and validated against predefined formats and annotated with **metadata** using standardised or user-defined machine-readable schemas (Schirner and Ritter, 2024). Existing metadata can also be imported into the EBRAINS Knowledge Graph to improve visibility, discoverability, and reuse (Amunts et al, 2024; EBRAINS Knowledge Graph, 2026).

European Health Data Space

The **European Health Data Space (EHDS)** Regulation, which entered into force in March 2025, aims to establish a common framework for the use and exchange of electronic health data across the EU. It enhances individuals' access to and control over their personal electronic health data (**primary use**), while also enabling certain data to be reused (**secondary use**) for public interest, policy support, and scientific research purposes. It seeks to foster a health-specific data environment that supports a single market for digital health services and products by harmonising legal and technical requirements for **electronic health record (EHR)** systems, fostering interoperability, innovation, and the smooth functioning of the internal market. This will enable the EU to benefit from the full potential offered by a safe and secure exchange and, use and reuse of health data to benefit patients, health professionals, researchers, regulators, and innovators. With this new regulation, the European Union intends to initiate a fundamental transformation of the health data governance framework (EHDS, March 2025; Regulation (EU) 2025/327 (EHDS)).

eBRAIN-Health aligns with the main targets of EHDS for researchers: the possibility to have access to **large-scale health data** for scientific research and **a clear and**

structured system to discover which **datasets** are available, where they are located, and what is their quality. To this effect, eBRAIN-Health focusses on proposing a more personalised approach to prevention of **dementia and Alzheimer's**, due to high-quality data sets that are interoperable with EHDS data records across the EU and meet agreed data standards and meta-data tagging frameworks. It also aligns with the EHDS implementation timeline, specifically targeting the March 2029 deadline for the application of the secondary use rules for most data categories.

General Data Protection Regulation and data management compliance

The **General Data Protection Regulation (GDPR)** provides the EU-wide legal foundation for **processing personal data**, including special categories such as health data, while EHDS adds health-specific rules for primary and secondary use that complement and strengthen the rights already provided for by the GDPR. A trusted health research platform therefore needs to translate these legal principles into concrete safeguards, through **purpose limitation**, **data minimisation**, **access control** and **accountability**, that are consistently applied and evidenced (Regulation (EU) 2016/679 (GDPR); Schirner and Ritter, 2024).

In eBRAIN-Health, a large variety of data sources has been brought together in a GDPR-compliant research platform, to support the development of digital representations of the brain (digital twins). The platform ensures that sensitive brain data is pseudonymised and stored in a way that respects **confidentiality**, with data processed at local nodes. The project aligns with GDPR Article 6(1)(f) (legitimate interests) and Article 6(1)(a) (consent) for managing user data and communications (Regulation (EU) 2016/679 (GDPR)).

Because health data often retains a personal reference – and personalisation is often the explicit goal of research – processing must follow "data protection by design and by default" (GDPR Article 25). The VRE/HDC aligns with the principles of the EHDS and the GDPR to **protect personal data**. The digital platform places strong emphasis on confidentiality, integrity, and availability of research data through **encryption**, **access control**, **anonymisation** techniques, and comprehensive **logging** to support lawful processing and **accountability**. This offers a secure, scalable and collaborative environment in which sensitive data are processed inside controlled virtual machines and containers, with segregated data zones, strict access interfaces, data encryption, and logged transactions to

demonstrate compliance (Schirner and Ritter, 2024), satisfying the needs of **data sharing** and **privacy protection**.

Data protection impact assessments (DPIAs) (GDPR Article 35) prior to uploading sensitive health data are used as a control gate when processing is likely to result in high risk (Schirner and Ritter, 2024).

EU's Artificial Intelligence Act and its applications in medical devices

The EU approach to **artificial intelligence (AI)** emphasises excellence and trust - boosting research and industrial capacity while ensuring safety and fundamental rights. The **AI Act**, the worldwide first regional regulation enforcing **trustworthy AI**, establishes a risk-based legal framework (with four different levels of risk) for AI systems in the Union, intended to promote human-centric and trustworthy AI, ensuring a high level of protection of health and safety while supporting innovation.

The Commission is committed to a clear, simple and innovation-friendly implementation of the AI Act, as outlined in the AI Continent Action Plan and the Apply AI Strategy. On 19 November 2025, the EC proposed targeted amendments to the AI Act as part of the Digital Simplification Package. These efforts complement the actions already in progress by the Commission and its AI Office to provide clarity for businesses and national authorities (European approach to AI, 2026; Regulation (EU) 2024/1689 (AI Act), June 2024).

The AI tools used in the eBRAIN-health project, such as tools for diagnosing Alzheimer's, detecting seizures, or analysing neuroimaging, fall under the high-risk categories as defined in the AI Act for which obligations of compliance should be ensured. The **high-risk category** includes AI tools designed to be deployed in medical devices due to the potential high risk for human safety. These tools need to be registered in the EU database along with instructions for their use for deployers.

AI Regulatory sandboxes

The final version of the AI Act, adopted in 2024, defines an **AI regulatory sandbox** as "a controlled framework set up by a competent authority which offers providers or prospective providers of AI systems the possibility to develop, train, validate, and test, where appropriate in real-world conditions, an innovative AI system, pursuant to a sandbox plan for a limited time under regulatory supervision". A recent article by the European Parliamentary Research Service (EPRS) (Marcelin, 2026) highlights that Member States are obliged to establish or participate in at least one AI

regulatory sandbox and that researchers have identified design, fragmentation, and timing challenges to the implementation of AI regulatory sandboxes.

For eBRAIN-Health, the strategic implication is that AI-enabled **brain digital twins** and decision-support tools are likely to require early alignment with AI Act obligations, **high-risk compliance** expectations and would benefit from structured, supervised testing pathways.

European Policy Positioning

All project results are aligned with appropriate policy targets, described below.

European Research Area

The **European Research Area (ERA)**'s long-standing ambition is a single, borderless market for research, innovation, and technology with free movement of researchers, knowledge, and innovation, supported by ERA governance and policy agendas (ERA, 2026).

EBRAINS is an open, distributed RI, providing data, tools and services across brain-research scales, built by and for the community and supported through funding from EU and national nodes. eBRAIN-Health extends this RI paradigm into the clinically sensitive space by delivering a **cloud-based protected platform** and compliant health-data processing environments for accessing cohorts of multi-scale digital brain twins of patient brains and that acts as a tool for research, innovation, clinical decision making and patient support (Schirner and Ritter, 2024). Digital brain twins provide advanced modelling, simulation, and prediction capabilities to RI users and their research communities through a combined access to advanced digital technologies such as high-performance computing, complex simulation software, AI methods and big data analytics.

eHealth in Horizon Europe

Horizon Europe is the EU's key research and innovation funding programme (2021-2027), designed to strengthen the impact of **research and innovation** in support of EU policies and global challenges, and to optimise investment impact within a strengthened European Research Area (Horizon Europe programme, 2026).

Project's results align with the expanding Horizon Europe initiatives to apply AI digital technology in health, namely the European **VBT** Initiative[5]. This **open-access** and **open-source** four-year project stands at the forefront of personalised medicine in psychiatry and supports the emergence and adoption of the next generation of VHT solutions in health and care. The eBRAIN-Health project develops a protected platform with tools and patient data (e.g., lifestyle factors, neuropsychological testing, magnetic resonance imaging, and blood markers), creating digital **brain twins** for personalised modelling, early diagnosis and prediction of future disease. The EU funded EBRAINS 2.0 project furthers development and provision of the RI to the scientific community.

Digital Europe's Testing and Experimentation Facility for Health (TEF-Health)

Testing and Experimentation Facility (TEFs) under the Digital Europe Programme (DIGITAL) are EU-wide networks- that help bring trustworthy AI from the lab to the market by providing real-world testing, **validation,** and demonstration. As central tools, TEFs can also contribute to the **implementation of the AI Act** by supporting **regulatory sandboxes** in cooperation with competent national authorities for supervised testing and experimentation. TEFs will be an important part of building the AI ecosystem of excellence and trust to support Europe's strategic leadership in AI (TEFs, 2026).

The **TEF-Health** project, started in January 2023[6], is carried out by a consortium led by Charité University Medicine Berlin and includes 52 public and private organisations. Like other TEFs, TEF-Health offers potential clients access to a **testing infrastructure**, data and evaluation resources, and, considering regulatory requirements (e.g., certification, standardisation, and codes of conduct), to facilitate **market access** for trustworthy health AI and robotics. TEF-Health and sandbox-enabled testing can be positioned as de-risking instruments that connect research outputs to deployable, trustworthy services (TEF-Health project, 2026; TEF for health, 2022).

eBRAIN-Health's **synergies** with the **TEF-Health** project, involving nine European countries and financed by the Digital Europe Programme[7], target the validation,

[5] under Grant Agreement No. 101137289 (HORIZON-HLTH-2023-TOOL-05) - https://ebrains.eu/impact/projects/virtual-brain-twin
[6] with an expected cost of 60 M€ and a contribution from the EC of 30 M€ by December 2027
[7] Testing and Experimentation Facility for Health, European Commission (DIGITAL-2022-CLOUD-AI-02-TEF-HEALTH) - https://ec.europa.eu/info/funding-

certification, and market adoption of AI-driven neurotechnology and digital twin solutions in the health domain. By combining eBRAIN-Health's expertise in brain simulation and data with TEF-Health's testing infrastructure, the collaboration aims to bridge the gap between research (Horizon Europe's objectives) and clinical application (Digital Europe' objectives) in the treatment of brain health disorders.

This consortium ensures that AI systems are not only innovative, but also safe and compliant. By harnessing Articles 74 and 75 of the AI Act, this partnership provides the technical and scientific support required for notified bodies to certify high-risk AI, ensuring European innovations reach the market fast while maintaining Union values. This will be highlighted at the public event supported by EBRAINS, and co-organised by eBRAIN-Health and TEF-Health projects, on June 9th, 2026 in Berlin.

EDIC governance frameworks

eBRAIN-Health collaborates with both the EBRAINS RI and the TEF-Health Facility to guarantee sound governance for its data related and simulation output results. Both EBRAINS RI and TEF-Health have plans to apply to become an **EDIC**.

EDICs are a legal framework under the **Digital Decade Policy Programme 2030**, established by a Commission Decision, enabling participating European countries to speed up and simplify the set up and implementation of multi-country projects with shared governance, legal personality (recognised in all member states without requiring transposition in national law), and joint infrastructures and services. EDICs will enable the achievement of the Digital Decade general objectives and targets (EDIC, 2026).

For clinically sensitive digital infrastructures, sustainability requires predictable cross-border governance, shared investment, and clear access rules across countries — areas where EDICs are explicitly designed to help. A TEF-Health EDIC pathway could therefore support continuity beyond TEF-Health's project lifetime for validating clinical services supported by EBRAINS linked health data.

EBRAINS supports the development of **VBT** technology for health research and TEF-Health enables for its **accreditation** for clinical analysis support as it reaches a high Technology Readiness Level. At the data level, the sensitive datasets available to eBRAIN-Health are catalogued via the *EBRAINS openMINDS* framework, a community-driven metadata framework for neuroscience graph databases, and

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accessible via the *EBRAINS Knowledge Graph* in protected access mode (EBRAINS RI and data services, 2026 (c)).

EBRAINS is establishing an EDIC legal status as its long-term form of governance. EBRAINS EDIC is recognised in the Commission's catalogue of established and planned EDICs and will create a common European Brain Data Space linked to the EHDS. Its establishment is operationalised through the EBRAINS IMPLEMENT project, a Horizon Europe project starting in June 2026 that will develop the legal, financial and operational framework on which member states commitments will rest. Pre-submission engagement with the Commission's Multi-Country Project Accelerator is scheduled for late 2026, and the EDIC application is targeted for late 2027 or early 2028.

EU AI and digital industry strategy

Fostering excellence in AI will strengthen Europe's potential to compete globally. The Commission and member states agreed to boost excellence and trust in AI by joining forces on policy and investments. At the EU level, both the Horizon Europe and Digital Europe programmes will invest €1 billion per year in AI (TEFs, 2026).

The eBRAIN-Health strategy involving the application of **AI in Neuroscience** targets a better understanding of the mechanisms that characterise the healthy and the disease-affected brain, in a new era featuring large-scale data-driven clinical research and health care in the EU. The potential impact of eBRAIN-Health's disruptive technology on clinical practices as well as on the health industry emanates from the will to solve key hurdles for clinical research, namely regarding the lack of data integration and access. eBRAIN-Health acts as a catalyst for the development of an ecosystem of **health data modelling** and **simulation platforms** fostering the development of cross-domain data-driven precision medicine. Within this landscape, TEF-Health provides access for companies to health AI data and secure processing environments to test and validate their products and make them CE certification ready, facilitating market access for trustworthy technologies.

Policy Lessons Learned and Recommendations

If an initiative such as EBRAINS was not in place today, there would continue to be a gap between neuroscience research and its practical applications, preventing the translation of discoveries into concrete solutions for brain disorders, and a choice would have to be made between data sharing and privacy protection.

The EC has released a 10-year assessment of the HBP flagship that ended in 2023. The report, authored by a panel of independent scientific experts, highlights that the HBP "flagship is one of the most groundbreaking research and innovation initiatives undertaken by the EU" and that "the HBP succeeded in developing the unprecedented digital EBRAINS Research Infrastructure" (EBRAINS, 2024). Today, the value of **EBRAINS RI** is visible in projects such as **eBRAIN-Health**. eBRAIN-Health's curated multi-cohort datasets, reusable processing workflows, The Virtual Brain ontology for computational brain models, and proposed brain imaging data structure extension for brain simulation data interoperate with **EBRAINS tools and services** and are discoverable through the EBRAINS Knowledge Graph. eBRAIN-Health will leave a legacy of not only publications and a trained community, but also sustainable, **FAIR-compliant** infrastructure for **VBT** that remains discoverable and findable to the wider neuroscience and clinical research communities via the EBRAINS RI. EBRAINS and eBRAIN-Health demonstrate that Europe does not need to choose between **data sharing** and **privacy protection**.

EBRAINS is a crucial digital neuroscience infrastructure, supported by **integrated tools**, datasets, brain atlases, simulation platforms, and AI-based analysis. Included on the ESFRI's roadmap to become a strategic RI and funded with €38 million from the EC through 2026, it plays a key role in advancing brain research and will continue developing tools and services to serve the wider research communities in neurosciences, brain medicine, and brain-inspired technologies (EBRAINS, 2024). As **sustainability** requires predictable cross-border governance, shared investment, and clear access rules across countries, the **EDIC application** will support continuity beyond project funding for EBRAINS-linked health data and services.

TEF-Health can be positioned as the European pathway to validate and scale **AI and digital twin tools**. It can provide testing infrastructure, data, and evaluation resources to help trustworthy health AI and robotics reach the market faster, acting as a bridge between research and clinical application. In collaboration with eBRAIN-Health, it enables facilitating the **validation** and certification of AI-driven neurotechnology by combining testing capabilities with brain simulation expertise. This partnership helps ensure innovative AI systems are safe, **compliant**, and **market-ready**, accelerating their clinical use in brain health while aligning with the EU regulatory framework.

The need for a **legal entity** to take charge of TEF-Health's assets, the **public mission** of that entity, and the **multi-country** nature of its project, combine to make

EDIC an appropriate type of organisation to transform TEF Health into a permanent and strategically sustainable asset.

The planned **TEF-Health EDIC** (provisional name) will inherit the resources, infrastructure, expertise, and relationships built by the TEF-Health project. Contributions from participating European countries will be needed to make the transition from project to legal entity, develop the business, and set up its activities, making it possible for revenues from service delivery to gradually become the predominant source of income. The scope of the TEF-Health EDIC will cover all EU-27 countries. Its legal framework will be operationally supported by the foundations established through the TEF-Health project's activities.

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