

From Brain Science to Trusted Digital Health Services

Positioning Europe's brain modelling platform for sustainable impact

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

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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