POLICY BRIEF

SOCIAL EUROPE AND WELL-BEING PROGRAMME

14 JANUARY 2026

Translating digital and AI advances into brain health outcomes

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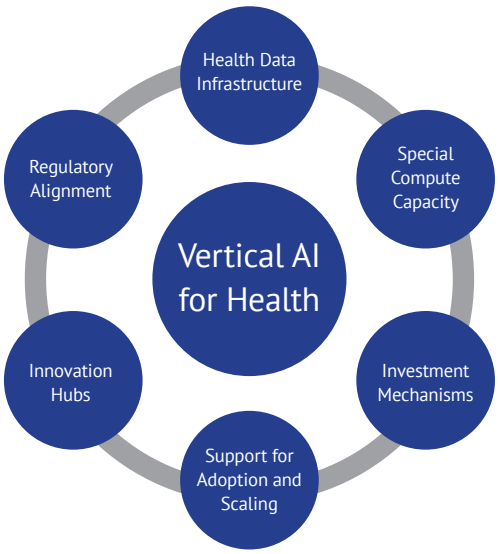
INTRODUCTION

Data and Artificial Intelligence (AI) underpin every dimension of modern brain research and brain health. Given the complexity and heterogeneity of brain disorders, the potential for digital tools and AI to accelerate prevention, diagnosis and treatment cannot be overstated. **Rapid progress in AI-enabled drug discovery is also reshaping global competitiveness.** As recent data demonstrates, there is a significant shift in global biomedical research activity. In 2024, China registered more clinical trials than the United States, approximately 7,100 versus 6,000, signalling a wider reconfiguration of the innovation landscape.[1]

Figure 1

COMPONENTS OF THE AI FOR HEALTH ECOSYSTEM



Source: The authors

A focused effort to build a **vertical AI for health plan**, as recommended by Mario Draghi in his report on European competitiveness,[2] is emerging as a major strategic priority for Europe. It would amount to a sector-specific ecosystem encompassing data, infrastructure, regulation, talent and investment to enable the development, testing and large-scale deployment of AI solutions. Its focus should be on mission-driven, real-world applications where Europe can build a competitive advantage.

Recent policy activity in the EU demonstrates significant political momentum, reflected in the Apply AI Strategy, the Life Sciences Strategy's substantial AI dimension, the European Health Data Space, and the Biotech Act. The urgency of delivering on these commitments is reinforced by **Europe's ambition to become the world's most attractive region for life sciences and AI by 2030**. With 2030 now only four years away, the timeline for achieving these objectives is exceptionally tight.

Brain research and brain health are areas in which an AI-driven transformation is urgently needed, making them **important testbeds for the use of vertical AI in health**. Brain diseases involve high heterogeneity, multi-dimensional symptoms and fragmented clinical pathways. They expose systemic barriers that vertical AI aims to solve in terms of fragmentation across EU member states, slow translation from research to clinical practice and uneven adoption of digital and AI tools in clinical settings. There are numerous examples where AI is already making an important contribution, whether it is early detection of Alzheimer's Disease, automated Multiple Sclerosis lesion quantification, digital biomarkers in depression and movement disorders, speech-based detection of cognitive decline, or virtual brain models.

In this context, brain health could serve as a pilot for Europe's AI-for-health ecosystem. It can be used to test and refine end-to-end approaches from multimodal data, validation pathways, governance and real-world clinical integration before broader deployment.

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BACKGROUND

1. Advances in data and compute infrastructure

In recent years, substantial progress has been achieved in building data infrastructure. However, Europe's AI factories, designed to pool compute power, data and talent to create cutting-edge AI models and applications, **lack the regulatory authorisations required to process sensitive clinical data**.[3]

Nevertheless, the EU's investment in 19 AI Factories, with 15 identifying health and life sciences as priority sectors, is **a major step toward aligning computation with data**. The upcoming legislation under the Data Union Strategy is expected to include data labs within these AI Factories, enabling researchers to access cleaned, high-quality datasets directly where computational resources reside. The expectation is that these infrastructures will progressively meet the requirements needed to handle sensitive health data securely and at scale. Complementary, member state–driven initiatives such as the 1+ Million Genomes (1+MG) Initiative can help strengthen Europe's large-scale genomic data foundations, supporting future health data labs and real-world evidence generation.

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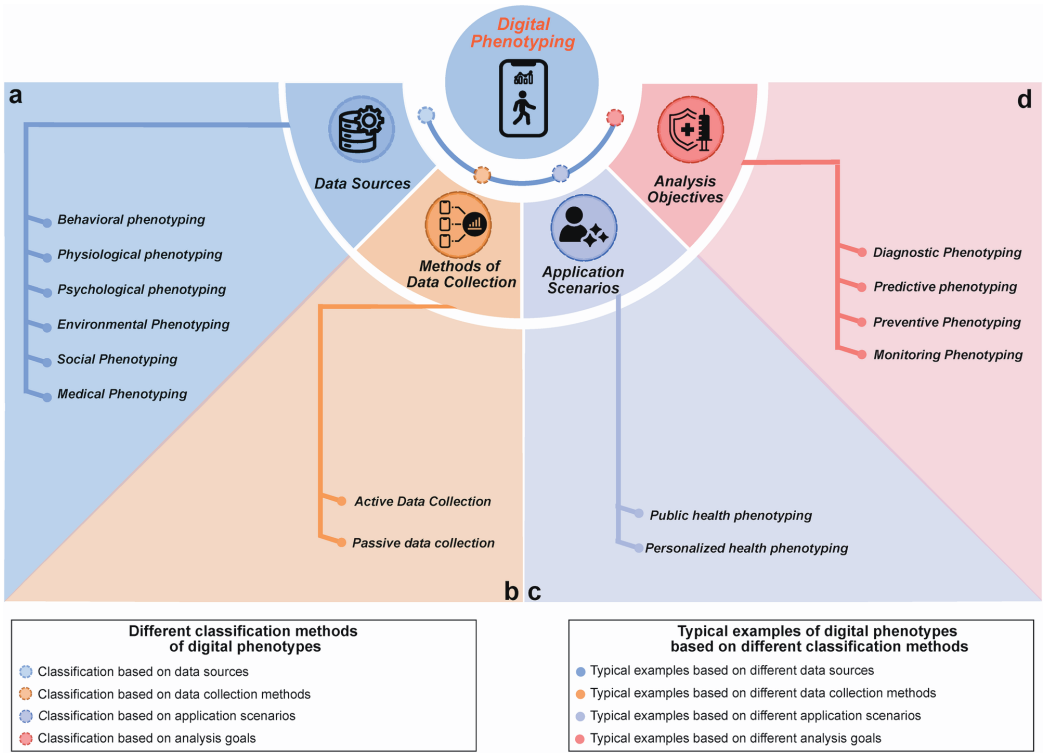
Figure 2

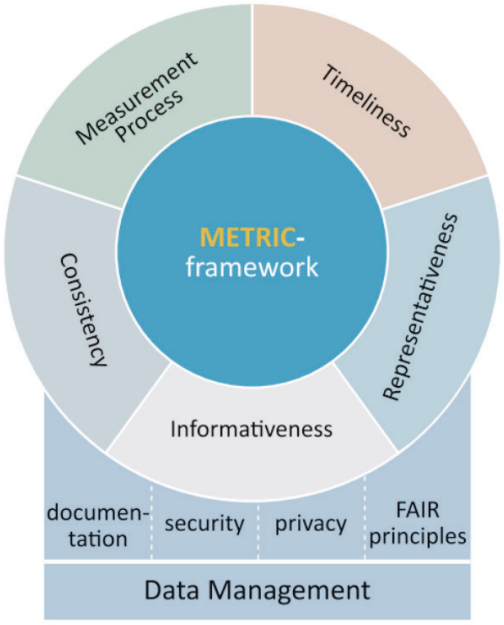
CLASSIFICATION OF DIGITAL PHENOTYPING BASED ON A) DATA SOURCES, B) DATA COLLECTION METHODS, C) ANALYSIS GOALS AND D) APPLICATION SCENARIOS



Source: Zhang, Yingbo et al (2025), "The comprehensive clinical benefits of digital phenotyping: from broad adoption to full impact", *npj Digital Medicine* vol 8, no. 196.

Figure 3

THE WHEEL OF DATA QUALITY FROM THE METRIC FRAMEWORK EVALUATES THE QUALITY OF MEDICAL TRAINING DATA



Source: Schwabe, Daniel et al (2024), "The METRIC-framework for assessing data quality for trustworthy AI in medicine: a systematic review", *npj Digital Medicine*, vol 7, no 203.

1.1. From access to actionable insights

Although access to data has improved substantially, it has not yet been matched by improvements in the quality of insights generated. Bridging this gap requires progress along critical axes of data integration: deep phenotyping, longitudinal data collection, multimodal integration, and the harmonisation, standardisation and interoperability required to support robust analysis. There are always trade-offs between sample size, duration of follow-up and the depth and granularity of phenotyping.

Patient and clinician advisory groups are essential partners in the design of realistic, digital and AI-enabled solutions.

Digital phenotyping offers one pathway to address these constraints by enabling more targeted interventions **tailored to an individual's unique brain profile, lifestyle and biology**. It also holds promise for identifying early disease markers, potentially years before clinical symptoms emerge. Digital readouts can include voice patterns, social media behaviour, and other behavioural markers – domains in which changes can be observed over clinically meaningful timeframes.

A fundamental precondition for making the axes of big data deliver is **data quality**. No AI system can compensate for poor-quality, fragmented or inconsistently recorded data. At present, data registries in Europe are very heterogenous, which hinders the generation of clear and robust real-world evidence. The **EU must build more robust real-world evidence infrastructures** to better define post-market surveillance frameworks.

Patient and clinician advisory groups are essential partners in the design of realistic, digital and AI-enabled solutions. In brain health, there are often substantial gaps between what individuals believe, report or intend to do and their actual behaviour. This discrepancy makes brain health a particularly promising domain for AI, which can identify real-world behavioural patterns that are difficult to capture in traditional clinical assessments.

Patient and clinician advisory groups are essential partners in the design of realistic, digital and AI-enabled solutions.

1.2. Making prospective data the norm

Crucially, many datasets deposited in public repositories are not reproducible.[4] Multi-omics data are typically not derived from the same individuals, meaning they cannot be functionally interlinked. As a result, when AI builds a knowledge graph from inconsistent data, it will not detect that the underlying correlations are biologically meaningless. For this reason, **prospective, deeply phenotyped cohorts, in which all data modalities are collected from the same patient over the same period, are essential**.

Data must be generated, curated and harmonised in a way that enables its use within the parameters of regulatory evaluation and decision-making. Fragmentation in data collection and care pathways is only expected to increase as health systems produce ever more digital information without unified structures to interpret and act on it. There often exists **a tension between the ideal of high-quality, standardised data and the realities of clinical workflows**.

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1.3. Encoding trust in responsible AI

Europe cannot remain constrained by a mindset that defaults to mistrust. While safeguards are essential, **an excessive focus on risk avoidance can unintentionally limit translation of research into clinical benefits**. Other regions are increasingly adopting approaches that build trust through clearly articulated societal value propositions. Trust in AI systems cannot be achieved through restriction alone, but through transparency, validation, protection of confidential information, governance and demonstrable impact on patient outcomes.

The EU's AI Act is designed precisely to build trust, by ensuring robust safeguards and predictable certification pathways. Trust also depends on empowering healthcare professionals, who often act as 'champions' driving adoption within their institutions, and providing networks where early adopters can share experience. Evidence form patient-driven initiatives suggests that **trust can be effectively encoded through governance models that place patients at the centre**. A data-sharing project Barcoding MS, led by the Italian MS Society – a patients' association – shows how strong societal value propositions and patient stewardship can enable broad participation and sustained engagement.

BARCODING MULTIPLE SCLEROSIS (MS)

Barcoding MS is project of the Italian Multiple Sclerosis Society and its Foundation, a patient organisation, which has spent four decades aligning clinical practice across Italy's MS centres. This long-term coordination has resulted in one of the most comprehensive disease registries in Europe: the Italian MS Registry currently contains clinical data on around 90,000 patients in a country with approximately 140,000 people living with MS. Building on this foundation, efforts are underway to make these clinical data interoperable with additional data layers. Italy is part of the International MS Genetics Consortium and has substantial genetic datasets on Italian patients. The Italian MS Society also leads the Innovative Neuroimaging Initiative, which hosts non-conventional MRI scans, alongside initiatives capturing patient-reported outcomes. Barcoding MS brings these elements together and makes them interoperable.

STATE OF PLAY

2. AI in next generation clinical trials and predictive modelling

Propelled by advances in image recognition, deep learning already played an important role in drug design in the 2010s. Generative AI has brought new hopes and expectations. There is practically no aspect of clinical trials in which AI cannot play a significant role.

In the context of rising research costs, **ensuring the efficiency of trial design and execution is crucial to therapeutic progress**.

2.1. Harmonised AI-based digital endpoints for clinical development

AI-based tools can enable the development of validated **digital clinical development endpoints, applicable across disorders**. Establishing such endpoints in a harmonised, multi-centre framework can meaningfully accelerate clinical trials and lower barriers to reimbursement and adoption. The prerequisite is the stratification of patients into subgroups based on treatment response and identification of digital predictors of therapeutic success.

This is a prime area for public–private collaboration, as **improved endpoint methodologies benefit entire therapeutic portfolios**, not just individual companies. Advances in imaging and other technologies are likely to shape the next generation of endpoints.

2.2. Improving recruitment efficiency through AI

Given the resource-intensive nature of clinical trials, **AI can meaningfully support patient recruitment and stratification**. Traditional approaches to matching patient characteristics with inclusion and exclusion criteria often run into a 'chicken-and-egg' problem: without prior patient consent, data cannot be legally used for trial selection; yet without access to those data, it is difficult to identify which patients should be approached for consent in the first place.

Under the framework proposed by the health-tech company Clininote,[5] AI agents analyse clinical notes in real time during patient visits and **flag potential eligibility signals based on primary clinical information**. The system does not access sensitive data that would require prior consent. Instead, it notifies clinicians that a relevant trial exists, allowing them to discuss participation directly with the patient. This preserves legal safeguards while enabling trial-matching.

AI can meaningfully support patient recruitment and stratification.

If implemented at scale, such a model could provide access to clinical trials across Europe by embedding matching into routine care rather than relying on informal networks or chance. It would also support high-quality, harmonised data generation, since the same AI-assisted processes could be applied across countries, languages and healthcare systems.

2.3. Biomarkers and beyond: Virtual twins for predicting disease progression

Despite significant advances, biomarkers alone cannot reliably predict progression in conditions such as Mild Cognitive Disorder (MCI). Digital biomarkers are therefore needed alongside biological ones to increase predictive accuracy. **Virtual twin models have a significant role to play, simulating disease trajectories and treatment responses in silico.** Multimodal prognostic modelling of individual cognitive trajectories can substantially improve efficiency in prevention trials with a significant reduction of required sample sizes. EU-funded work on Virtual Human Twins (including EDITH) combines imaging, genetic and behavioural data to support prediction and validate digital biomarkers, where traditional single-marker approaches have proven insufficient in brain health.

Virtual twin models are routine in regulated industries such as aerospace or oil and gas, yet they remain rare in European research projects, despite being essential for the regulatory approval of AI-based tools. **In the absence of regulatory-compliant validation datasets, even highly promising AI models require the collection of new data.** This results in delays of several years and extending time-to-impact to a decade or more – in some cases up to 20 years.

3. Improving adoption and implementation in health systems

Unlocking the full potential of digital and AI-driven innovation in healthcare will depend on the ability to integrate these solutions seamlessly into clinical practice. A key bottleneck concerns the path to clinical use and reimbursement of digital biomarkers, particularly in brain health. While the US and several Asian countries have begun integrating such tools into standard care, Europe continues to lag behind.

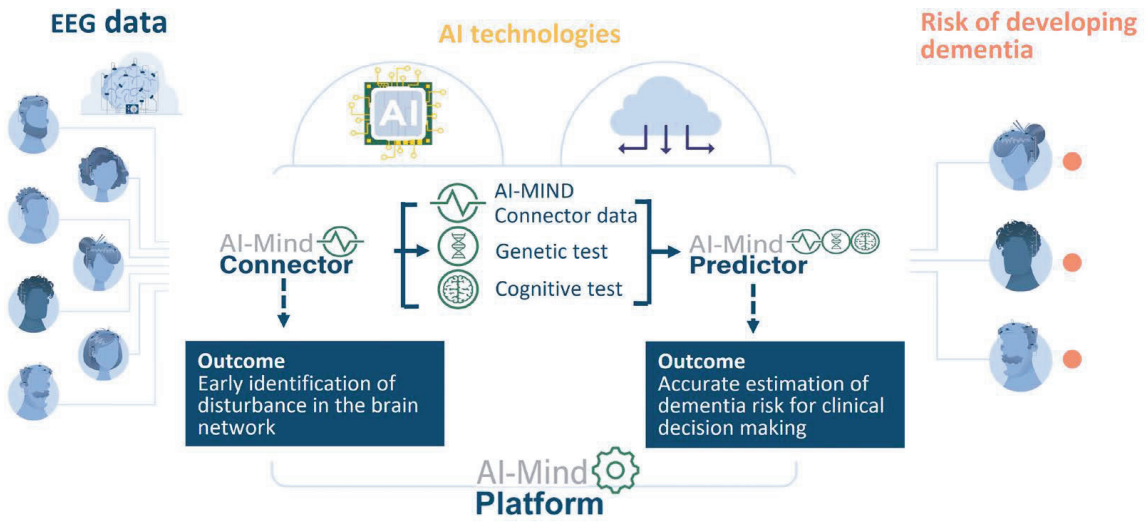
The European Commission has recently published its Apply AI Strategy, aimed at accelerating the uptake of AI solutions in key sectors, including healthcare.[6] The strategy's flagship initiative is the creation of a network of AI-powered advanced screenings centres designed to connect hospitals across Europe that are ready and willing to deploy AI in prevention, diagnostics and early detection.

The goal is to generate evidence on how AI solutions are used in real clinical workflows: how they perform in practice, and how this experience can be shared among leading centres while supporting hospitals that are not yet at the cutting edge.

At present, the focus is on cancer and cardiovascular disease, where significant EU funding is already in place. The goal is to generate evidence on how AI solutions are used in real clinical workflows: how they perform in

Figure 4

THE AI-MIND CONCEPT



Source: Alzheimer Europe (2025), AI-Mind: Artificial intelligence-based tools for screening of brain connectivity and dementia risk estimation, *Dementia in Europe*, Special Supplement Issue 48.

practice, and how this experience can be shared among leading centres while supporting hospitals that are not yet at the cutting edge. The Commission also aims to develop deployment playbooks to prevent different regions from 'reinventing the wheel' and to support innovators who struggle to persuade hospitals to adopt new tools. Looking ahead, the Commission's Digital Decade policy programme 2030 may also include an indicator on an AI uptake in healthcare.

Adoption by clinicians, particularly neurologists, remains a critical issue. New digital solutions are often met with reluctance and a strong perception of risk, while processes and rules vary widely across hospitals and healthcare systems. Importantly, adoption should be measured in terms of impact, not screen time. Digital and AI tools should enhance clinician–patient interaction, not displace it.

Large-scale transformations in data practices must work with, rather than around, Europe's institutional complexity.

In this context, the recently launched EU-funded Compass-AI project plays an important role.[7] It brings together hospitals, clinicians, managers, industry, economists and ethicists to develop deployment guidelines, best practices, educational programmes and practical playbooks for AI implementation across Europe.

Large-scale transformations in data practices must work with, rather than around, Europe's institutional complexity. A committed coalition of innovators can help build the technological layer needed to drive widespread adoption across clinical settings. In this context, adding an intelligent layer on top of existing hospital information systems, rather than attempting wholesale replacement, makes more sense; replacing foundational IT systems across thousands of hospitals would be prohibitively difficult.

AI copilots and agent-based systems can instead operate above existing infrastructures. By interpreting clinical documentation as it is created, they can transform unstructured text into structured, interoperable, high-quality data. Such tools could bridge the widening gap between routine care documentation and the stringent data requirements of clinical research and clinical trials.

PROSPECTS

Recommendations

Although digital and AI-based tools are gaining significant traction in both research and clinical practice, a step-change is required to ensure that their real-world impact is commensurate with their technological potential. This will require moving beyond isolated pilots and proof-of-concept studies toward scalable, interoperable and clinically validated solutions that are embedded in routine care and research workflows.

► Breakthrough improvements in data quality

Europe should reconsider its heavy investment in legacy registries and instead redirect resources to new, harmonised prospective datasets built on shared standards. These should include common metadata descriptions, ISO-aligned processes and regulatory-grade data splits.

The European Health Data Space (EHDS) represents a major opportunity for European industry, given that a large number of public organisations will need to procure solutions for the primary and secondary use of health data. **Brain health is well placed to play a decisive role in making the EHDS fully operational** and fit for advanced data research.

A unified, AI-enhanced prospective data layer – first validated in clinical trials and later extended to routine care – could become one of Europe's strongest levers to improve competitiveness, accelerate research and deliver better patient outcomes.

Europe should reconsider its heavy investment in legacy registries and instead redirect resources to new, harmonised prospective datasets built on shared standards.

► Trust as the cornerstone of data-sharing

High levels of public trust and digital literacy, combined with robust governance mechanisms, are necessary for extensive data use and for scaling digital health technologies. In major data-sharing initiatives, **involving patient organisations in a leadership or core role can be a major asset**. Such organisations can act as trusted intermediaries, reassure clinicians and facilitate collaboration.

Given the higher expectations placed on AI systems, **transparency in model development and protection of legitimate confidential information are essential**. Systems deployed in clinical or regulatory settings must be interpretable, auditable, explainable and aligned with established standards of evidence. They should also incorporate mechanisms that actively build trust, including clear governance structures and feedback loops.

► A health innovation system that moves at the speed of AI

AI is advancing far more rapidly than Europe's traditional innovation cycle, from early ideation to funding, validation and adoption. To capture the full value of these technologies, AI-enabled approaches must be integrated more quickly into both clinical trials and healthcare delivery. This requires regulators and policy institutions to be involved from the outset through pathfinder projects, allowing them to learn in real time, shape guidance and co-evolve regulatory frameworks as technologies mature.

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The foundation of any innovation ecosystem is the capacity to take, manage and regulate risk. In health AI, data quality, access, governance and long-term custodianship form the essential infrastructure. Without clarity in these areas, private investment will remain hesitant. Regulation should serve as a balancing mechanism – mitigating ethical and safety concerns while enabling innovation. Too often, Europe risks becoming bogged down in granular regulatory detail, refining marginal points while neglecting the broader enabling environment innovators need.

A recurring structural dilemma for European innovators is that regulation may not explicitly block innovation, but rarely encourages it. Europe's capabilities in AI and virtual-twin technologies are strong, but insufficiently integrated. Ensuring that leading European centres are actively involved, and that European analytics providers and industry profit from these investments, is necessary.

The EU should therefore develop clear tools and 'landing zones' to translate advanced research outputs into broader application. This is directly relevant to the new competitiveness instruments under development. Health and digital technologies are two of the four pillars of the proposed European Competitiveness Fund in the next Multiannual Financial Framework. Close coordination is needed to ensure that AI for health is not lost between thematic funding silos.

► Prioritising adoption in clinical settings

Practical barriers to AI adoption in hospitals centre standardisation, both technical and procedural.

Clinicians are unlikely to change established workflows unless AI tools seamlessly integrate with existing systems, including cloud architecture that remain difficult to implement in many hospitals. Streamlining certification pathways for AI-enabled medical devices is important in view of clinical uptake.

Reimbursement frameworks are another critical enabler. In this respect, the US model of temporary CPT-III reimbursement codes, used to support early deployment while generating real-world evidence before the transition to permanent CPT-I codes, offers a potential reference point for Europe.

► Driving transformational change in clinical trials

Clinical trials are one domain where AI-enabled innovation could be particularly transformative. European regulators and policymakers should support the development and large-scale deployment of AI-enabled patient–trial matching tools that operate within clinical encounters and without accessing sensitive data prior to consent.

Today's trial recruitment processes are manual, fragmented and inefficient. These should be replaced with AI-supported models embedded directly into routine care. Hospitals would need to enable AI agents to analyse clinical notes during patient visits to identify potential eligibility signals based solely on primary clinical data and alert clinicians when a relevant trial exists.

European regulators and policymakers should support the development and large-scale deployment of AI-enabled patient–trial matching tools that operate within clinical encounters.

Clinicians, not algorithms, would initiate conversations with patients, ensuring that legal and ethical safeguards are upheld. Such an approach would create fair and systematic access to clinical trials across countries, improve data quality and harmonisation, and accelerate trial activation and recruitment – reducing one of the most persistent bottlenecks in clinical research.

CONCLUSIONS

Europe must treat AI and digital technology as its potential 'coal and steel moment', a foundational opportunity capable of reshaping not only its economic future, but also the sustainability and effectiveness of health systems. Realising this goal in brain health will require embedding AI tools into clinical practice wherever they demonstrably improve care and outcomes.

Europe must evolve towards a health innovation system that moves at the speed of AI, aligning incentives, regulation and infrastructure to support rapid learning while preserving safety and accountability. Finally, transformative change in clinical trials through AI-enabled recruitment, stratification, digital endpoints and in-silico modelling will be essential to accelerate evidence generation and translate scientific advances into meaningful brain health outcomes for patients and society.

Europe must evolve towards a health innovation system that moves at the speed of AI.

This Policy Brief draws on discussions that took place at the European Policy Centre–NeuroCentury–Brain Capital Alliance Round Table held in Brussels on 13 November 2025. The authors are grateful for participants' invaluable insights, particularly those of: Niklas Blomberg, Executive Director, Innovative Health Initiative; Rachel Fellner, Health Policy Researcher, OECD; Ira Haraldsen, Oslo University Hospital, Coordinator of AI-Mind; Robert Ługowski, CEO, Clininote; Ulf Nehrbass, CEO, Luxembourg Institute of Health; Emre Ozcan, Senior Vice-President, Global Head of Digital Health & Devices, Merck Healthcare; Marco Salvetti, Head of the Department of Neurosciences, Sapienza University; Anca Scortariu, Deputy Head of Unit, AI in Health and Life Sciences, AI Office, European Commission; and Rym Ayadi, President, Euro-Mediterranean Economists' Association, Co-Founder, Brain Capital Alliance.

This project has been financially supported by Merck.

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1 Ostertag, Meghan (2025), "Fact of the Week: China has surpassed the US in the number of drug clinical trials, with 1,100 more trials listed", WHO's International Clinical Trials Registry Platform cited by the Information Technology and Innovation Foundation Information Technology and Innovation Foundation, 9 June 2025.

2 Draghi, Mario (2024), *The Future of European Competitiveness*, Part B, Brussels: European Commission, pp. 83.

3 European Commission, "AI Factories", Shaping Europe's digital future, accessed 5 January 2026.

4 Scott, Marek et al. (2022), "Reproducible brain-wide association studies require thousands of individuals", *Nature*, vol 603, pp. 654–660.

5 CliniNote, "CliniNote", accessed 5 January 2026.

6 European Commission, "Apply AI Strategy", Shaping Europe's digital future, accessed 5 January 2026.

7 European Institute for Biomedical Imaging Research, "Compass-AI", accessed 5 January 2026.

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Co-funded by the European Union