

FROM FRAGMENTATION TO INTEGRATION

A European Strategy for Research, Innovation and Precision Mental Health

Policy Brief for the European Parliament - Draft for discussion

Brussels, 14 October 2026 | A United Europe for Psychiatry: From Research to Care

POLICY CASE

- Mental health conditions affect around one in six people in the WHO European Region. Europe also bears a major economic burden: mental disorders have been estimated to cost more than 4% of GDP across EU countries.
- Europe is not starting from zero: Healthier Together (2022-2027), the Comprehensive Approach to Mental Health, the European Partnership for Brain Health, the European Health Data Space and the ECNP Precision Psychiatry Roadmap, the EPA Action Plan already provide complementary policy, research and data frameworks.
- The priority is therefore not another standalone roadmap, but to connect these frameworks and accelerate cross-border validation, regulatory readiness, implementation and equitable access to precision approaches.

Foreword

Europe has shown that a coordinated political and scientific action can transform health outcomes through ambitious initiatives in areas such as cancer, rare diseases or genomics. Mental disorders warrant comparable strategic attention. Europe already has internationally recognised expertise in psychiatry, neuroscience, artificial intelligence, digital health, clinical research and patient-led innovation, as well as an increasingly structured European policy and research architecture.

This policy brief does not propose a new parallel roadmap. It sets out a targeted implementation agenda for Precision Mental Health within existing European frameworks. Precision Mental Health provides the broader policy frame, while precision psychiatry remains the scientific and clinical core for mental disorders. The shared objective is to turn research and innovation into validated, person-centred and equitable improvements in care.

Executive Summary

Mental health conditions affect around one in six people - approximately 140 million - in the WHO European Region. A substantial treatment gap persists, while mental ill-health imposes major healthcare, social and productivity costs. Across EU countries, these costs have been estimated at more than 4% of GDP. These figures underline the need to combine stronger services with sustained research, innovation and implementation.

At the same time, discoveries in genetics, neuroimaging, digital phenotyping, data science and artificial intelligence are creating new opportunities to improve prevention, stratification, diagnosis, treatment selection and monitoring. Realising this potential requires evidence generation at scale, multinational validation, secure and interoperable data, regulatory-ready development and meaningful involvement of patients and carers. It should also ensure that patient-reported outcomes and experiences are routinely captured and integrated into health data systems to help public policies to be ruled.

Europe already has complementary policy, research and data frameworks. The remaining challenge is to connect them and close the gap between discovery and routine care. European coordination can add value through cross-border demonstrators, multinational trials, shared evidence requirements, European Health Data Space-compatible research pathways, implementation science, workforce development and faster learning between health systems.

1. Mental Health: A Strategic Investment for Europe

Mental health is not solely a healthcare issue. It affects educational attainment, labour participation, social inclusion, resilience and productivity. Investing in prevention, earlier and more accurate diagnosis, effective treatment, implementation and recovery can improve outcomes for individuals while reducing avoidable long-term costs for health and social systems.

The concept of Brain Capital highlights the contribution of brain and mental health to skills, adaptability, innovation and economic prosperity. In this perspective, mental health research and innovation are both a public health imperative and a strategic investment in Europe's social and economic resilience.

2. Europe's Scientific Opportunity

Europe hosts world-leading universities, research institutes, clinical centres, patient organisations and collaborative programs. Horizon Europe, the European Research Area, the European Brain Council, The European College of Neuropsychopharmacology (ECNP), European Psychiatric Association (EPA), national programs and emerging European infrastructures provide a strong foundation. The principal challenge is no longer to design another roadmap, but to connect these assets and turn existing strategies into implementable pathways.

European coordination can create critical mass by connecting existing cohorts and biobanks, enabling secure and interoperable data use, supporting multinational validation and trials, and aligning evidence-generation and implementation priorities. It can also reduce duplication and make European research more attractive to public and private investment.

3. Building on a European Architecture Already Underway

Europe is not starting from zero. Healthier Together - the EU Non-Communicable Diseases Initiative (2022-2027) includes a mental health and neurological disorders strand focused on implementation, prevention, early detection, diagnosis, treatment management and quality of life. The Commission's 2023 Comprehensive Approach to Mental Health reinforced this work through 20 flagship initiatives and around EUR 1.3 billion in financing opportunities, including support for a joint ecosystem for brain research.

On the research side, the European Partnership for Brain Health, launched in January 2026 for 2026-2035, already has a Strategic Research and Innovation Agenda, a research-infrastructure landscape and a data roadmap. The European Health Data Space, in force since March 2025, is establishing the legal and technical framework for secure cross-border use and reuse of health data, with phased application from 2029.

In parallel, the ECNP-coordinated Precision Psychiatry Roadmap is a dynamic international framework to align stakeholders, harmonise methods and datasets, validate biomarkers and move towards biology-informed diagnostics and treatments; its 2027 meeting will focus on clinical trials and regulatory-ready pathways. A European Precision Mental Health agenda should therefore connect and operationalise these existing frameworks, not duplicate them.

4. Precision Psychiatry within a Broader Precision Mental Health Framework

Precision Mental Health provides the broader policy frame, spanning prevention, early detection, treatment and long-term care. Within it, precision psychiatry is the scientific and clinical core for people with mental disorders: enriching clinical information with biological, cognitive, environmental and digital data to improve stratification, diagnosis, treatment selection and monitoring. The aim is to

progressively add validated quantitative information where it improves clinical decisions and outcomes, while preserving clinical judgement and individual preferences.

Digital tools, artificial intelligence and other emerging technologies can substantially support research and care. Their deployment must, however, be clinically validated, transparent, secure and accountable. Meaningful human oversight is essential, and responsibility for medical decisions must remain with appropriately qualified healthcare professionals.

For AI-enabled mental health technologies, Europe should establish clear and coordinated pathways across the EU AI Act, Medical Devices Regulation/IVDR, the European Health Data Space and data-protection frameworks. Early and structured dialogue among developers, clinicians, patients, regulators, notified bodies and health technology assessment agencies should ensure that evidence generation supports clinical utility, safety, regulatory compliance and eventual adoption. These pathways should also consider general-purpose and consumer AI systems where their real-world use may have clinically relevant effects on mental health, even when they are not formally marketed as medical devices.

Key priorities include:

- Use and connect existing European cohorts, biobanks and clinical networks, rather than create parallel infrastructures.
- Make mental-health data and research workflows interoperable with the European Health Data Space and the EP BrainHealth data roadmap, while protecting individual rights.
- Build cross-border validation networks for biomarkers, digital measures and AI-enabled tools, using clinically meaningful outcomes.
- Establish independent European evaluation environments for mental-health AI, including assessment of clinical safety, robustness, equity, human-AI interaction and performance across languages, populations and health systems, with appropriate monitoring of performance after deployment.
- Enable multinational adaptive and stratified clinical trials aligned with the ECNP Precision Psychiatry Roadmap and regulatory evidence needs.
- Invest in implementation science, workforce capability and patient/carer involvement so validated innovations can be adopted safely and equitably.

5. Closing the European Implementation Gap

The remaining barriers are increasingly translational rather than conceptual: heterogeneous ethics and governance procedures; differing interpretations of data-protection requirements; uneven access to interoperable data; fragmented regulatory, health technology assessment and reimbursement pathways; and limited implementation capacity in health services. These barriers can prevent promising approaches from being validated and adopted at European scale.

European action should therefore focus on:

- Facilitating cross-border clinical research through proportionate, consistent governance and practical alignment with the European Health Data Space.
- Developing regulatory-ready evidence pathways for biomarkers, digital measures, artificial intelligence and adaptive or stratified trial designs.
- Develop proportionate post-deployment monitoring, safety surveillance and incident-reporting approaches for AI used in mental health, including generative and conversational systems, with clear human escalation pathways where systems interact with people experiencing significant clinical risk.
- Agreeing core patient-relevant outcomes and shared evidence-generation plans, with earlier dialogue among regulators, health technology assessment bodies, payers, clinicians, patients and developers.
- Supporting cross-border demonstrators that test not only efficacy but feasibility, workflow integration, acceptability, cost and equity in routine care.

- Connecting evidence generation to clinical guidance, professional training, organisational change and sustainable access.

6. European Added Value: Demonstrate, Learn, Scale

European coordination is particularly valuable as no single Member State can generate sufficient scale or diversity. A limited number of well-designed cross-border demonstrators could connect existing cohorts, research infrastructures and clinical networks, generate evidence in diverse populations and test how validated precision approaches perform in different health systems.

These demonstrators should:

- Address defined implementation gaps not already covered by EP BrainHealth or the ECNP Roadmap, and reuse existing infrastructures wherever possible.
- Generate comparable clinical, functional, quality-of-life, implementation and resource-use outcomes.
- Engage regulators, health technology assessment bodies and payers early so that evidence can support both authorisation and adoption.
- Produce reusable standards, implementation tools and lessons that can be transferred across Member States.

7. Securing European Leadership in AI for Mental Health

Artificial intelligence is becoming a strategic capability in health and the wider economy, with much of the current technological development concentrated in the United States and China. Europe has major strengths in mental-health research, clinical science, public healthcare systems, longitudinal cohorts, multilingual populations, regulatory science and responsible AI. However, these assets remain fragmented. Without coordinated investment and infrastructure, Europe risks becoming primarily an adopter and regulator of AI systems developed elsewhere rather than a leading developer of technologies shaped around European clinical needs, languages, health systems and values.

Europe should therefore build a coordinated AI-for-mental-health innovation capacity that connects leading research centres, clinical networks, patients and carers, secure data infrastructures, regulators, SMEs and industry across Member States. This should support access to appropriate computing infrastructure, high-quality and representative data, multilingual evaluation benchmarks, independent testing environments, cross-border clinical validation, and clear pathways for successful European innovations to move from research into health-system adoption and scale.

The objective should not be technological sovereignty for its own sake, but strategic capacity: ensuring that Europe can develop, evaluate and deploy high-quality AI for mental health on its own terms, compete internationally, reduce unnecessary dependence on external platforms, and translate its scientific strengths into better patient outcomes, economic value and globally influential standards for trustworthy mental-health AI.

8. From Existing Roadmaps to Implementation

The sequence should be aligned with existing policy, research, data and regulatory cycles rather than create a new standalone roadmap:

2026-2027 Connect and operationalise	Use the final phase of Healthier Together and the first years of EP BrainHealth to connect existing roadmaps, identify unmet implementation gaps, select cross-border demonstrators, agree shared evidence and
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	outcome requirements, and prepare EHDS-compatible research pathways and the post-2027 agenda.
2028-2030 Validate and scale	Use the next EU research framework program and EP BrainHealth to run multinational validation and trials, connect cohorts and infrastructures, compare implementation models, and strengthen regulatory, HTA, payer and workforce alignment.
2031-2034 Embed and evaluate	Integrate validated approaches in routine care where evidence supports their use; compare uptake and outcomes across health systems; monitor equity, clinical benefit and costs; and update shared standards as evidence evolves.

9. Patient and Carer Co-Creation

A credible European implementation agenda must place people with lived experience and carers at its core. Their involvement improves the relevance of research questions, feasibility of study design, interpretation of outcomes, acceptability of implementation and identification of unintended inequalities.

Patients and carers should be partners in:

- Setting research priorities and defining outcomes that matter to people and families.
- Study design, recruitment strategies and communication of results.
- Development of policy, regulatory and health technology assessment approaches.
- Evaluation of innovation, including effects on quality of life, functioning, autonomy and equity.
- Design of person-centered pathways for implementation in routine care.

Co-creation strengthens trust and can accelerate responsible adoption while helping ensure that precision approaches address real needs and do not widen inequalities.

10. Expected Impact

A coordinated implementation agenda could:

- Turn existing European mental health and brain-research investments into greater clinical, economic and societal impact.
- Increase the scale, representativeness and cross-border validity of evidence generated in Europe.
- Accelerate regulatory-ready validation and responsible implementation of effective innovations.
- Improve equity of access to research and, ultimately, to validated diagnostic and therapeutic advances across Member States.
- Reduce avoidable long-term healthcare and societal costs through earlier and more effective interventions where evidence supports them.
- Improve clinical, functional and quality-of-life outcomes for people living with mental disorders and their families.

Policy Recommendations

1. Ensure continuity beyond 2027 by maintaining mental health research, innovation and implementation as a strategic European priority after the current Healthier Together cycle.

- 2. Advance a European Precision Mental Health implementation agenda within existing structures**, explicitly building on the Comprehensive Approach to Mental Health, EP BrainHealth, the ECNP Precision Psychiatry Roadmap, the EPA Action Plan, and the European Health Data Space rather than creating parallel frameworks.
- 3. Fund a limited portfolio of cross-border demonstrators** that connect existing cohorts, biobanks, clinical networks and data infrastructures to validate precision approaches in representative populations.
- 4. Facilitate multinational adaptive and stratified clinical trials and regulatory qualification** of biomarkers, digital measures and AI-enabled tools through shared standards and early regulatory engagement.
- 5. Build a coordinated European AI-for-mental-health innovation capacity**, connecting research centres, clinical networks, patients and carers, secure data infrastructures, regulators and industry to support the development, independent evaluation and cross-border scaling of trustworthy, clinically relevant and multilingual European AI systems.
- 6. Align mental-health data standards and access pathways** with the European Health Data Space and EP BrainHealth data roadmap, with strong safeguards and meaningful patient governance.
- 7. Improve harmonisation of evidence requirements** across regulators, health technology assessment bodies and payers, and test evidence-linked access models while respecting national competences.
- 8. Invest in implementation capacity and the mental health workforce**, including training in precision approaches, data literacy, digital tools, artificial intelligence, implementation science, as well as leadership development and structured European exchange of best practices.
- 9. Embed patients and carers as partners** in priority setting, study design, evidence assessment, implementation and evaluation.
- 10. Support prevention across the life course and strengthen community-based**, integrated mental health care, ensuring sufficient and needs-based funding for services.

Draft Brussels Declaration

We call on the European Parliament, the European Commission and Member States to move from European roadmaps to implementation in mental health. Building on Healthier Together, the Comprehensive Approach to Mental Health, EP BrainHealth, the ECNP Precision Psychiatry Roadmap, the ECNP AI in Mental Health Network, the EPA Action Plan and the European Health Data Space, Europe should connect scientific excellence in precision psychiatry with cross-border validation, regulation, implementation, workforce development and equitable access. The objective is not to create another parallel structure, but to ensure that validated advances translate more rapidly and responsibly into better outcomes for people living with mental disorders and their families across Europe.

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