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DISCUSSION PAPER

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PUTTING THE BRAIN ON THE EUROPEAN POLICY AGENDA 2024-2029

This Paper is a contribution to the discussion about the forthcoming EU policy agenda 2024-2029. It argues that the EU has a unique opportunity to turn the field around and build on significant new breakthroughs for the benefit of patients. All comments are welcome.

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Brain health and mental health are emerging policy priorities in Europe and globally. However, **the next five years are the time when the approach to neurological and psychiatric care can enter a new era**. There are several factors contributing to this outcome. Demographic trends are already translating into increased centrality of brain health, given the increased prevalence of neurological disorders in older age[1]. Mental health issues remain of utmost relevance, especially among younger population, and have been aggravated by the COVID-19 pandemic. A staggering 50 percent of young Europeans reported unmet needs for mental health care in spring 2021 and again in spring 2022 [2].

At the same time, there are growing scientific advances which translate into phenomenal breakthroughs in diagnosis and treatment of brain disorders. This has led The Economist to recently speak of **a renaissance in neuroscience** [3].There is also a growing awareness and appreciation of the role of the brain among the population at large. This is being reflected in the greater attention and care being attached to brain issues at individual level and in the public debate. A recent study found over 91 percent of respondents being "definitely or probably" interested in taking a brain health test [4].

Policy is increasingly responding to these considerations, stepping up actions aimed at the prevention, early diagnosis, comprehensive care, and rehabilitation of brain disorders. It is now widely accepted that there must be **a holistic, life-course approach to brain health**, as reflected in the European Academy of Neurology's Brain Health Strategy of 2022 [5]. The last few years have seen a dynamic bottom-up activity of the brain research, neurology, and psychiatry communities around Europe, with the development of the first set of Brain Plans in Norway, Poland, Germany and Switzerland. The European Union has also attached growing attention to the issues of the brain health, with the inclusion of neurological disorders and mental health in the Healthier Together initiative of the European Commission [6], and the launch of conceptual work for the Brain Health Partnership in late 2023.

As the preparations for the new 2024-2029 policy cycle advance, **it is important to put forward a vision concerning ways of addressing the importance of brain health in a strategic fashion**. The European Brain Council, acting on behalf of its numerous member organisations, has already put forward a Manifesto for the EP elections [7], in which it called to promote brain health in the EU "to leave no one behind". This Discussion Paper aims to draw on this proposal, suggesting ways in which the call for a strategic emphasis on brain health should be translated into concrete policy actions and instruments.

[1] See "Epidemiology of neurological diseases in older adults", J. Dumurgier and C. Tzourio, Revue Neurologique, November 2020, https://www.sciencedirect.com/science/article/abs/pii/S0035378720303908?via%3Dihub

[2] See "Health at a Glance: Europe 2022" Report by the OECD and European Commission, https://read.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-europe-2022_507433b0-en#page12

[3] See: https://www.economist.com/technology-quarterly/2022/09/21/after-fallow-decades-neuroscience-is-undergoing-a-renaissance

[4] See: https://www.frontiersin.org/articles/10.3389/fpubh.2022.998302/full

[5] See: https://onlinelibrary.wiley.com/doi/full/10.1111/ene.15391

[6] See: https://health.ec.europa.eu/non-communicable-diseases/healthier-together-eu-non-communicable-diseases-initiative_en

[7] See: https://www.braincouncil.eu/ebc-2024-manifesto/#single/0

TOWARDS THE EUROPEAN BRAIN HEALTH STRATEGY

Health policy has been a growing priority in the European Union, fueled particularly by the need to formulate a cohesive and effective policy approach in response to the COVID-19 pandemic. The creation of the European Health Union was proposed by President of the European Commission Ursula von der Leyen when she said in October 2020 that "we cannot wait for the end of the pandemic to repair and prepare for the future. We will build the foundations of a stronger European Health Union in which 27 countries work together to detect, prepare and respond collectively". Given the circumstances of the time, its focus was initially on pandemic response and preparedness. **Issues of brain health have been classified as part of the larger group of non-communicable diseases**, and as such became the focus of the Health Together initiative in May 2022, launched to support Member States in identifying and implementing effective policies and actions to reduce the burden of major non-communicable diseases and improve citizens' health and wellbeing. Mental health and neurological disorders, including dementia, are one of the five strands of the Initiative, which covers the period of 2022-2027.

While efforts to address the challenge of cancer prevention, diagnosis and treatment had been elevated to a central pillar of EU health policy, there has been less support for extending the disease-specific policy focus to other disorders. Instead, **the EU has favoured a comprehensive, transversal approach**, aiming to prioritise interventions which can have a systemic effect, instead of being bogged down in the specificities of each disease area.

While this logic has unquestionable merits in streamlining EU action and ensuring its greater efficiency, it is also the case that **brain health and mental health have characteristics of their own, which necessitate a tailored approach**. In recognition of this fact, the European Commission proposed in June 2023 its Mental Health Strategy[8], following a policy commitment of President von der Leyen in her State of the Union address in September 2022.

As we approach the new policy cycle, **the EU should recognize that it is a moment of particular opportunity in brain health**, which can only result in genuine therapeutic progress if adequately embraced at the level of policy. Thirty years of progress in understanding the malfunction of the immune system in people with Multiple Sclerosis, have led the community to speak of Pathways to Cure[9], as an achievable medium-term target. Similarly, "defeating dementia"[10] has been a point of reference in the scientific discussion following the emergence of the latest disease-modifying medications.

It is therefore **pertinent for the EU to formulate its Brain Health Strateg**y, providing for a comprehensive agenda of action in the area of research support and policy, aiming to capitalize on existing breakthroughs for the benefit of patients across the Union. The next European Commission should commit to present the **European Brain Health Strategy, following close consultations with stakeholders, in the first half of 2025.**

[8] "A Comprehensive Approach to Mental Health", European Commission, June 2023, https://health.ec.europa.eu/publications/comprehensive-approach-mental-health_en
[9] Approach advanced particularly by the National MS Society in the US, see: https://www.nationalmssociety.org/pathways-to-cures
[10] Title of a recent high-level conference hosted by the government of the Netherlands and the World Dementia Council, see: https://www.government.nl/documents/speeches/2023/10/02/speech-mark-rutte-at-the-international-defeating-dementia-conference-kunstmuseum-den-haag

CONSOLIDATED EUROPEAN BRAIN PLANS

Largely as an outcome of an intensive community-wide reflection, a number of European countries have come up with their national Brain Plans to design structured plans of action in the area of brain research and brain policy. The first Brain Plan was formulated in Norway, following the Norwegian Year of the Brain in 2015, and then in Poland and Germany. The latest example of a similar effort is the Swiss Brain Health Plan adopted in 2022. The Brain Plans cover a range of important issues, from the priorities of care to the training requirements for neurologists and specialized personnel. The prevalent bottom-up nature of the current Brain Plans has an enormous merit in being anchored in the community deliberations.

The next generation Brain Plans should become even more systemic in nature and reflect more closely scientific and technological developments, engaging closely with industry. In order to stimulate a pan-European brain health debate, ensure mutual learning through best practices, and address issues requiring the benefit of scale in a cross-border fashion, **the European Commission should propose that all Member States embark on the exercise of drafting their Brain Plans**, according to **a uniform template**, covering issues of prevention, stepping up early detection of brain disorders, and providing for comprehensive programmes of care.

The **consolidation of the European Brain Plans** could be proposed as part of the European Brain Health Strategy with **a structured exercised being launched to ensure mutual learning in the Health Council of the EU.** This process could already begin during the Polish Presidency in the EU Council in the first half of 2025 and aim to be finalized by the end of 2026. The outcome of this process would be both a uniquely extensive overview of the brain health interventions around the EU, as well identification of initiatives which would merit from a collective approach and EU-level support.

Helse- og
omsorgsdepartementet

National Brain Health Strategy (2018-2024)

BRAIN PLAN
dla Polski

The German Brain Plan
Agenda 2030

SFCNS Swiss
Brain Health Plan

NEUROLOGY AND MENTAL HEALTH AS PRIORITIES OF THE EU4HEALTH PROGRAMME

The fourth and largest of EU health programmes, EU4Health is the main financial instrument to support health initiatives in the European Union. The focus of the Programme is on the implementation of established EU priorities such as activities of the Commission's Health Emergency Preparedness and Response Authority (HERA), Europe's Beating Cancer Plan and the Pharmaceutical Strategy for Europe. It is implemented through annual work programmes

In the 2023 Work Programme, **significant attention is devoted to the issues of mental health**[11], given the substantial number of EU citizens affected by mental illness, a situation exacerbated by the pandemic and other stressors like the war in Ukraine, climate crisis, digitalization, unemployment, and the cost of living. The Work Programme outlines the Commission's commitment to improving mental health, including the launch of a comprehensive, prevention-oriented approach.

Key elements of the approach include promoting good mental health and preventing mental health problems through awareness-raising, knowledge sharing, capacity building, and the development of integrated policy approaches. Early detection and intervention in mental health issues, improved access to innovative treatments, and enhancing quality of life through patient-centered care are also emphasized. The EU4Health Programme envisages direct grants to Member States' authorities with the aim of "promoting a comprehensive, prevention-oriented approach to mental health to support vulnerable groups" as well comprehensive approach to mental health, with better detection and intervention strategies for mental health issues, enhanced access to innovative mental health management approaches and development of communication tools to reach vulnerable and disadvantaged groups.

11] See pages 34-38, https://health.ec.europa.eu/system/files/2023-12/funding_c_2023_8524_annex1_en.pdf

In the forthcoming editions of the EU4Health Programme, **substantial emphasis should be placed on the paradigm shift needed in neurology care with the advent of early biomarkers and new disease-modifying treatments**. This is particularly evident in the area of Alzheimer's Disease and other forms of dementia.

Innovative efforts are needed to design healthcare services for **a comprehensive dementia care system.** For the introduction of these novel treatments that slow cognitive decline, it's crucial to have proper protocols and monitoring systems established. Greater preparedness is a matter of urgency, especially considering the involvement of multidisciplinary healthcare teams. Other medical fields like oncology have successfully completed this process, which requires a complex infrastructure including infusion centers, imaging facilities, and various laboratory tests.

Support for the creation of a comprehensive dementia care system **should be an important element of the new EU4Health Work Programme.**

LAUNCH OF AN EU BRAIN HEALTH INVESTMENT PLAN

Given the emerging breakthroughs in science and care across the continuum of brain health, from prevention to early diagnosis and comprehensive treatment and rehabilitation, **there is a need to invest in ensuring that the emerging solutions translate into improved patient care**. Taking into account that neurology is chronically underfunded with a suboptimal number of specialists, while modern approach to care is needed to ensure accessibility, the field of brain health needs to be supported by public investment.

Examples include a) effective organization of stroke management with personalization of care delivery, especially early and rapid diagnosis of stroke, shortening the onset-to-treatment time, or b) extension of the current system of memory clinics to the population at large.

An EU Brain Health Investment Plan should consist of two parts:

- Pillar One to address the needs of the healthcare systems, with upgrades of the infrastructure and extensive training programmes in neurology care.
- Pillar Two focused on investing in innovation, especially in digital care, to nourish the market for neuroscience and neurotechnology solutions.

Digital therapeutics can help to both target heterogeneity of brain and mental disorders and provide for the needs of holistic care, enabling to access patients in their home environment. In addition, they can be impactful throughout the cycle of drug development, offering digital biomarkers and enabling identification of early signals for exploratory studies but also helping with stratification of patients. The market for digital mental health solutions alone is expected to experience strong growth, with projections indicating a tripling in size by 2030 to an estimated global value of 70 bln USD.

CREATION OF AN EFFICIENT EU BRAIN DATA SYSTEM

Benefiting from access to integrated data is essential for improving care delivery. Better availability of data can help progress in the development of innovative modelling-based tools with high predictive value. In addition, data portability can enable patients to exercise their rights to access data held across several data controllers. All these developments will benefit considerably from the development of the European Health Data Space (EHDS).

In this context, **a dedicated solution focused on brain data** is needed to enable researchers to mine the rich pool of neuroscience data, ensuring interoperability and reusability of resources. The EHDS should enable standardized data exchange interfaces, enabling integration of diverse health data types and promotion of data exchange. In order for these solutions to be effectively applied to brain data, the emerging infrastructure needs to be adapted and workflows tested against a number of use cases.

While the EHDS should avoid compartmentalization into disease categories, it needs to reflect the specific requirements of brain data, enabling a federated data analysis and learning.

TOWARDS A "PATIENT AT THE TABLE AND IN A TEAM" APPROACH IN NEUROLOGY CARE AND RESEARCH

Patient-centricity has been an integral part of the clinical research landscape, with incorporation in funding guidelines. Horizon Europe guidelines state that it is of "outmost importance to involve" users – "like patients and healthy citizens, health care professionals providers and payers, public health authorities and regulators, researchers or innovators from academia and industry - early in the knowledge generation or technology development process, including through patient/citizen engagement, community involvement or other forms of social innovation approaches, such that research and innovation activities are adjusted to the users' particular expectations, needs, constraints and potential".

A number of challenges remain, including with respect to **access to information and patients' ability to take informed decisions.** It is also pertinent to ensure that all voices are heard to make sure comprehensive representation of the community. Data systems need to be adapted to the patient-centric approach. In going the crucial extra mile, the **underlying principle must be to focus on symptoms, rather than disease classification**. Patients suffering from a given neurological and mental health disorder may have different symptoms while there can be a lot of similarity of symptoms among patients in different disease categories. Some symptoms, especially pain or fatigue, can be downplayed while they are major factors preventing the integration of patients in the society.

Research should aim to identify mechanisms of disease and neuronal circuits responsible for the particular symptoms[12]. In line with the model of the MULTI-ACT project which aims to capture the experiential knowledge of patients and make it scientifically relevant for all stakeholders, it would be recommended to **move from a "patient-centric" approach towards a "patient at the table and in a team with all the other stakeholders"**.

Finally, in Horizon Europe research projects, **embedding patient researchers should become an underlying principle**, with sufficient budgets being earmarked for patient inclusion. Patients should also play an active role on the trial oversight committees.

[12] This would be in line with the Research Domain Criteria Framework of the National Institute of Mental Health.

CREATION OF THE EUROPEAN NEUROTECHNOLOGY MEDICINE PLATFORM

Given the advances in neurotechnology medicine and its potential to complement pharmacological advances in the treatment of mental health and neurological disorders, **the EU should adopt a holistic support scheme through a platform approach.** This is needed given the interdisciplinary nature of neurotechnology which relies on advances in electronics, computation, brain science, and medicine to repair, restore, and replace lost or impaired functions. Examples of the current application of neurotechnology include cochlear implants and deep-brain stimulation (DBS), with potential applications expanding to mood, sensation, learning, memory, and cognition disorders. Neuroelectronic technologies offer direct, localized, and immediate effects on target areas of the brain, reducing side effects compared to pharmaceuticals and having greater reversibility than surgical methods.

In early 2023, a group of leading European research labs has proposed a blueprint for the ENMP, through **a new organizational structure** combining the innovation and scientific creativity of academic environments with the engineering scale, talent, focus and structure of industry and the deep understanding of clinicians of human disease and disabilities[13].

[13] The approach described here has been conceptualized by a group of leading research labs in a White Paper, available on demand.

The ENMP would nucleate developments in this precompetitive space, enabling and accelerating new scientific fields and commercial medical applications. It envisions a modular solution, in which the to-be-developed components for high channel-count reading and writing, device powering, wireless communication (and more) can be configured in various combinations, tailored to different diseases.

The ENMP would organize **an R&D pipeline structure** with the participating European organizations and create the modular European devices in **a manufacturing platform** that can also provide components in lower volumes, let them pass through regulatory tests and disseminate them to leading European neuro-translational groups. Success would be shared widely and serve as a catalyst for innovation to reach human clinical solutions on a broad scale, and at a much faster pace.

FOCUS ON BRAIN HEALTH IN RESEARCH POLICY AND ENDOWING BRAIN HEALTH PARTNERSHIP

The European Commission's Horizon Europe Health Cluster Work Programme for 2023-2024, under Cluster 1: Health, does not entail a specific focus on brain health. The Programme aims to improve and protect the health and well-being of citizens by generating new knowledge and developing innovative solutions. This includes efforts to prevent, diagnose, monitor, treat, and cure diseases and to develop health technologies. While brain health is not singled out, the scope of the program is broad and covers various health aspects, which could encompass neurological and mental health areas.

The Horizon Europe program prioritizes areas such as health throughout the life course, environmental and social health determinants, non-communicable and rare diseases, infectious diseases, tools, technologies, and digital solutions for health and care, and healthcare systems. This comprehensive approach suggests that **while brain health might not be a standalone focus, it could be included within the broader objectives** of improving health technologies and addressing various diseases

The agenda of **a new Brain Health Partnership** is currently being developed by a preparatory action (so-called CSA) involving 21 entities - ministries, funding bodies, representatives of the brain research community, research associations and professional societies, a research infrastructure and patient organisations and advocacy organisations. A Strategic Research and Innovation Agenda for the Partnership will be developed in the course of 2024. The Partnership will be one of several developed withing the Horizon Europe programme, with the expected lead role of Germany and significant Member State involvement. It is of vital importance for the Partnership to **receive strong support nationally** and build **a sizeable budget** for its research agenda.

Should the mission approach be maintained in the future successor to Horizon Europe (after 2027), the challenge of the brain, with its brain health and mental health components, and extending to brain skills and brain-derived technology would be an excellent candidate for a new 2028-2034 **Mission Brain.**

SUPPORT FOR EMERGING FIELDS SUCH AS PRECISION PSYCHIATRY

One of the emerging areas requiring attention in the 2024-2029 policy period is **development of precision psychiatry as a novel approach** to enhance the treatment of psychiatric disorders and to create innovative, mechanism-based treatment strategies. Precision psychiatry aims to improve prevention, diagnosis, and treatment of major mental disorders. Mental disorders, including mood disorders, anxiety, psychosis, and autism spectrum disorders, are leading causes of disability and have a significant socio-economic impact. Despite advances in neuroscience, psychiatric treatments have not significantly evolved in the past 50 years, often lacking specificity and efficacy. There is a need for personalized treatments based on understanding the pathophysiology of subgroups or trans-diagnostic dimensions.

A strategy to develop precision psychiatry in Europe aims to emphasise the importance of developing large-scale training data and collaborative platforms among European cohorts, focusing on trans-diagnostic and translational bio-clinical dimensions based on quantitative biological parameters, encouraging deeply-phenotyped cohorts studies using various tools like genomics, brain imaging, and exposome maps, back-translating human findings to animal models to expand knowledge and accelerate drug discovery, promoting research collaboration across various fields including academia, industry, and regulatory agencies, creating new guidelines for clinical trials focusing on mechanism-based bio-clinical signatures, evaluating the societal and economic impacts of psychiatric conditions in Europe.

This approach aims to find the right treatment for the right patient, based on a better understanding of the pathophysiology of mental disorders.

CONCLUSIONS

The 2024-2029 EU policy cycle coincides with major developments in brain medicine and brain research, as well as with heightened societal attention devoted to issues of the brain and the mind. This creates unique opportunity for an impactful agenda to support the emergence of breakthroughs in science and to guide them towards application in the clinic. A comprehensive strategy is needed, drawing on the immense community effort in the past few years. **Every prerequisite exists for the 2020s to be Europe's Decade of the Brain.**

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