Draft proposal for a European Partnership under Horizon Europe:

European Partnership for Brain Health

EP BrainHealth

28.06.2024



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1 General information

1.1 Draft title of the European Partnership

European Partnership for Brain Health (EP BrainHealth)

1.2 Lead entity (main contact)

The German Aerospace Center (DLR) is a non-governmental, non-profit German research organisation. Its Project Management Agency specialises in strategy consulting and the proficient management of programmes and projects. The clients range from ministries, governmental institutions, the European Commission, to institutions from science, business and society and have access to a wide range of services – from analysis and consulting to the development, implementation and communication of strategies and measures. The DLR Project Management Agency is, for example, mandated by the German Federal Ministry of Education and Research (BMBF) and other Federal and State ministries and foundations with regard to the implementation and management of governmental programmes for research funding. Its Health Division supports Federal and State ministries, the European Commission, foundations, and institutions with regard to health research projects and the further development of the healthcare system.

DLR is involved in JPIs, ERA-Net initiatives, and European Partnerships. DLR coordinated and currently coordinates NEURON Cofund 1 and 2 (as well as HDHL-INTIMIC and ERA-CVD) and is beneficiary in JPco-fuND 1 and 2 (as well as ERA PerMed, EJP Rare Diseases, ERA-HDHL, JPI AMR, EDCTP) under the H2020 program. DLR is also the lead entity of Horizon Europe's European Partnership for Personalised Medicine and is participating as a partner in other European Partnerships within the Health Cluster (ERA4Health Partnership, European Rare Diseases Research Alliance) as well as supporting the preparation of future partnerships in the area of One Health/antimicrobial resistance and pandemic preparedness. In addition, DLR leads the German Coordination Offices for the Intergovernmental Panel on Climate Change (IPCC) and the Intergovernmental Platform on Biodiversity and Ecosystem Services (IPBES), where health effects (including brain health) of climate change and through biodiversity loss are key topics of emerging concern.

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1.3 Commission services (main contact)

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1.4 Summary (max 500 characters)

The aim of the future European Partnership for Brain Health is to accelerate the delivery of preventive, diagnostic, therapeutic, and care solutions to foster brain health¹ (including neurological and mental health alike) in citizens, people living with brain disorders at all ages including patients and their caregivers². To reach this aim, a better understanding of the brain's functioning and the effects of environmental, social, socioeconomic and technological stimuli and stressors on brain health is needed. This will be achieved by strengthening the alignment and synergies across European and global brain health research and innovation initiatives.

2 Context, objectives, expected impacts

2.1 Context and problem definition

2.1.1 Scale of the problem and the need for R&I

Understanding **the brain** in its complexity is one of the major challenges of mankind. Our brain determines humanity; its cognitive and emotional capabilities are the motor of technological innovation and societal progress. Consequently, mental disorders and diseases of the brain and nervous system drastically decrease the quality of life of those concerned and their caregivers. In most cases there is no cure, and treatment is suboptimal. This is mostly due to the fact that although important progress has been achieved, crucial aspects of the brain function and dysfunction remain poorly understood as well as efficient ways to use this knowledge to promote brain health and achieve tangible impact. In particular, the enormous adaptative, resilience and conceptual capacities of the human brain represent important assets to preserve and improve quality of life in health and disease and should be better used in the future.

Neurological and mental disorders are a **leading cause of disability and mortality** in Europe and globally, placing a great burden on people living with brain disorders, their professional and informal carers, as well as healthcare systems and national economies as a whole.

In 2021, an estimated 3.4 billion individuals had a condition affecting the nervous system, corresponding to around 43 % of the world's population³. Stroke is a leading cause of death, being fourth on the list of leading causes of global DALYs and accounting for 8% of all deaths across the EU in 2019, while Alzheimer's and other dementias accounted for another 5% of

¹ In the context of the partnership, '**brain health**' should be interpreted along the lines of the World Health Organisation's (WHO) definition* <u>and</u> includes neurological conditions and all elements of mental health. * WHO definition: 'Brain health is the state of brain functioning across cognitive, sensory, social-emotional, behavioural and motor domains, allowing a person to realize their full potential over the life course, irrespective of the presence or absence of disorders'.

² Including professional and informal caregivers

³ Steinmetz et al. Global, regional, and national burden of disorders affecting the nervous system, 1990–2021: A systematic analysis for the Global Burden of Disease Study 2021, The Lancet Neurology 2024



deaths.^{4,5} Importantly, individual lifestyles, living conditions and access to care strongly influence the opportunities for people to maintain a healthy brain throughout their lives. Notably, structural aspects on the population level (economics and social disparities, conflicts, local resources, natural and built environment) and on the individual level (cultural context, education, socioeconomic status, social isolation) shape people's brain health status and mental wellbeing as much as genetics and the quality of medical care, with negative effects on underserved communities and disadvantaged groups. ^{6,7}

During the pandemic, brain health worsened due to the sequelae of the infection and the difficulties of access to treatment, as well as due to multiple challenges to mental health posed by the lack of social interactions and constraints in all spheres of individuals' lives. Consequently, mental disorders have significantly increased. I.e. symptoms of anxiety and depression among young people more than doubled in several European countries and accordingly, the demand for mental healthcare increased, as evidenced by the OECD-EC "Health at a Glance: Europe 2022" report⁵. In addition, the present geopolitical situation including wars and forced migration, and the increasing economic pressure in many countries in Europe and beyond further aggravated brain health problems, in particular for the most vulnerable populations. The same applies for environmental crises, such as global warming, loss of biodiversity and pollution. E.g. research studies provide evidence, that exposure to ambient air pollution belongs to the leading environmental factors contributing to the development of dementia^{8,9}.

National **economies worldwide are strongly affected**. The total cost of brain disorders in Europe was estimated at 798 billion euros in 2010¹⁰ (equivalent to 1093 billion euros in 2024¹¹), including direct costs (37% direct healthcare costs and 23% direct nonmedical costs) and indirect costs associated with production losses e.g. by increased absenteeism rates (40%). Brain disorders encompassing neurological and mental disorders represented the largest cause of disability-adjusted life years (DALYs) in 2015 (10.2% of global DALYs)¹². In 2020, the global cost of dementia was estimated to reach €1 trillion¹³. This situation will only get worse with ageing populations in Europe and globally.

Effective strategies to promote brain health in all population groups, as well as treatments with patients' perceived positive outcomes and without significant side effects to prevent, stop the progression or alleviate symptoms of neurological and mental disorders, are insufficient. **Research and innovation efforts are needed,** including fundamental research to increase

⁴ GBD 2021 Diseases and Injuries Collaborators Global incidence, prevalence, years lived with disability (YLDs), disability-adjusted life-years (DALYs), and healthy life expectancy (HALE) for 371 diseases and injuries in 204 countries and territories and 811 subnational locations, 1990–2021: A systematic analysis for the Global Burden of Disease Study 2021, The Lancet 2024

⁵ OECD/European Union *Health at a Glance: Europe 2022: State of Health in the EU Cycle*, OECD Publishing 2022

⁶ Lock et al. Equity across the life course matters for brain health, Nature Aging 2023

⁷ The Lancet Editorial: *Brain health and its social determinants*, The Lancet 2021

⁸ Air pollution and the risk of dementia

⁹ Parra et al. *Exposure to air pollution and risk of incident dementia in the UK Biobank,* Environmental Research 2022

¹⁰ Gustavsson et al. Cost of disorders of the brain in Europe 2010, European Neuropsychopharmacology 2011

¹¹ Adjusted only to inflation (average inflation rate of 2,27% per year between 2010 and 2024) and not to the scale of the problem, which with the various crises has undoubtedly increased.

¹² Feigin et al. *Global, regional, and national burden of neurological disorders during 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015,* The Lancet Neurology 2017

¹³ Wimo et al. The worldwide costs of dementia 2015 and comparisons with 2010, Alzheimer's & Dementia 2017



the knowledge about brain functioning in all its facets, improving the understanding of different stressors affecting the brain, in order to develop better preventive measures, diagnostics, effective disease-modifying treatments or cures and improved care. **Enhanced collaboration among researchers, citizens, policymakers, regulators, healthcare professionals and patient experts** needs to be strengthened to develop and implement scientific, evidence-based policies. **Improved use of existing European and global resources** is essential to accelerate solutions promoting brain health.

Recent developments in neuroscience and brain-inspired artificial intelligence promise new possibilities in understanding cognition, and digital twin technology opens up ways of testing interventions and innovative treatments. However, questions arise about risk and benefit related to their impact on brain function and the quality of life of individuals. **Equity, socioeconomic and ethical concerns including acceptability for patients, people living with brain disorders and citizens as well as an adequate balance between individual and societal benefits should be considered from conception throughout the deployment stage, requiring stronger involvement of social sciences, humanities and the participation of citizens in research.**

Tackling this global challenge is clearly beyond the scope and resources of any individual country. Enhanced regional and national efforts and their coordination are required to stimulate impact-driven research by bringing together all stakeholders, including funding bodies, researchers, clinicians, people living with a brain disorder, professional and informal carers, healthcare providers and practitioners, citizens, regulators, industry and decision-makers. The aim is to join forces in order to consider the existing research evidence, identify gaps, build a common vision, and facilitate the sharing of data, tools, techniques, and other resources more efficiently. The brain health research landscape is highly interdisciplinary and complex; present efforts should be highly inclusive since only by maximising and synergizing our collective potential, can we expect significant advances in the wellbeing of citizens.

2.1.2 Experience and outcome of aligning R&I initiatives in Europe

Several large initiatives have already been established in Europe since 2008 aiming to achieve a concerted strategic and financial alignment of research in brain health. These include ongoing initiatives like the EU Joint Programme for Neurodegenerative Disease Research (JPND¹⁴) and the Network of European Funding for Neuroscience Research (NEURON¹⁵), each with 30 participating countries from Europe, North America, Asia and Australia, supporting basic, clinical and translational research. JPND is the largest global initiative in neurodegeneration research (Alzheimer's disease, dementia, Parkinson's disease and other neurodegenerative diseases), while NEURON covers the other areas of disease-related neuroscience including neurology, psychiatry, as well as neuroethics. The initiatives also include the recently finished Human Brain Project (HBP¹⁶), a FET Flagship that employed 500 scientists at more than 140 universities, hospitals, and research centres, which has put in place the digital research infrastructure EBRAINS¹⁷ that allows academic, clinical and industrial

¹⁴ JPND

¹⁵ ERA-NET NEURON

¹⁶ Human Brain Project

¹⁷ EBRAINS



researchers to advance knowledge in the fields of neuroscience, computing, and brain-related medicine. The European Brain Council **(EBC)** is a unique organisation network of key players in the "Brain Area", merging all stakeholders in the brain area with a membership encompassing European umbrella organisations such as scientific societies (FENS, ECNP, IBRO), patient organisations (EFNA, GAMIAN-Europe), professional societies (EAN, EPA, EANS, EPNS) and more than 10 industry partners and several national Brain Councils.

Through their working groups and transnational calls supported by Member States, some of which were co-funded by the European Commission, these initiatives have addressed research questions related to determinants of mental health (such as depression, addictions, and compulsive disorders), neurological and neurodegenerative diseases (such as stroke, Alzheimer's disease and Parkinson's disease), and neurodevelopmental as well as sensory disorders. They have identified major drivers, including genetic susceptibility or environmental risk factors, and existing health and care systems limits. The improved understanding, however, needs to translate better into the development of new and effective strategies for prevention, diagnosis, treatments, and care. Prevention strategies have been identified as the most promising way to reduce the high personal, familial, societal, clinical, and economic costs of brain disorders. To create impact in this context, collaboration between the different stakeholders and a continuous dialogue between scientists, industry, and society is fundamental. The EP BrainHealth will intensify activities in this area to ensure the involvement of all relevant stakeholders.

2.1.3 Need for developing a single joint ecosystem for brain research

In 2018, under the Coordination and Support Action (CSA) 'European Brain Research Area' (**EBRA**¹⁸) led by EBC, the partners JPND, NEURON, and HBP/EBRAINS started discussing ways to find strategic and operational synergies, identify gaps, and foster alignment across European and global brain initiatives. In 2022, EBRA delivered a Shared European Brain Research Agenda (SEBRA), which was based on a landscape analysis of European funded research between 2007 and 2019, a consultation process with the wider brain health community, clusters to increase cooperation and collaboration between similar EU-funded projects on brain research, and thorough consultation with the community at large. The SEBRA¹⁹ serves as input for a future strategic research and innovation agenda in the area of brain health.

Additionally, the HBP initiated a discussion in the international community to formulate the scientific vision for the next decade of digital brain research²⁰, with particular focus on digital tools enabling progress in brain medicine.

These initiatives have already generated invaluable experience and trust, are strongly supported by the European Commission, Member States and Associated Countries and encompass many international partners.

¹⁸ CSA EBRA (European Brain Research Area)

¹⁹ SEBRA open consultation

²⁰ https://zenodo.org/records/10035197



In 2022, Member States and Associated Countries restated their strong interest in developing a European Partnership for Brain Health bringing together the different brain research initiatives. They requested a preparatory coordination action (CSA) in the 2023-24 work programme of the Health Cluster. The CSA continues in the line of the EBRA project and integrates JPND, NEURON, EBC, and EBRAINS with the aim of expanding to new partners. It started in November 2023 (**CSA BrainHealth**²¹) and is on its way to develop a strategic research and innovation agenda, an implementation plan and a governance structure including stakeholders from the brain community as well as international players, paving the way to the European Partnership for Brain Health. The CSA ensures a broad geographical representation of European countries in the partnership, notably to strengthen the participation of widening countries.

Seizing the momentum and capitalising on cutting-edge research will unleash a powerful innovation force and create a new ecosystem for brain health research. An ambitious European Partnership for Brain Health will consolidate this ecosystem, thus strengthening the competitive position of its partner countries worldwide.

2.1.4 Timeliness of the Brain Health partnership

The timeline of the current European portfolio of brain health-related initiatives illustrates the concerted effect that is expected by the future European Partnership for Brain Health (see figure 1). With the envisaged start in Q1 2026, the new partnership capitalizes on the momentum created by the existing efforts, aiming to widen them beyond the current boundaries and leading to a new level of cooperation and alignment in the brain health area in Europe and worldwide.

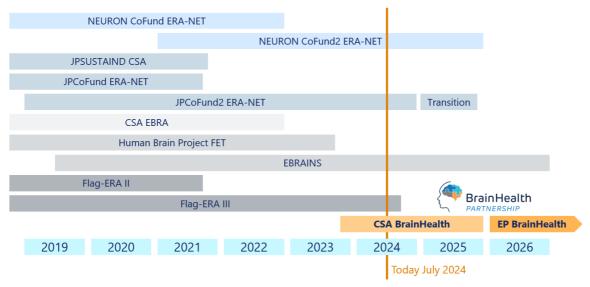


Figure 1: Timeliness of the EP BrainHealth

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²¹ Coordination and Support Action (CSA) BrainHealth



2.2 Common vision, objectives and expected impacts

2.2.1 Common vision and general objectives

The common vision of the European Partnership for Brain Health is improved brain health for all, developing scientific knowledge as a ground to promote brain health throughout lifetime, to prevent and to cure brain diseases as well as to improve wellbeing of people living with neurological and mental disorders in Europe and beyond (vision statement).

The mission is to support brain health research and innovation by strengthening transnational collaboration and alignment to enhance understanding of the brain and to promote the translation of results into tailored solutions for prevention, diagnosis, treatment and care accessible for all (mission statement).

The partnership will develop stand-alone activities as well as close collaborations with other (global) initiatives and a broad network of stakeholders, including researchers, neurologists, psychiatrists, people living with brain disorders and their caregivers, industry, regulators and policymakers, to substantially contribute advances in the field of brain health.

To realise the common vision and attain its overarching goals, the European Partnership for Brain Health will contribute to the following **general objectives** (see figure 2):

- Promote brain health and wellbeing throughout the entire life course and improve the scientific knowledge to strengthen prevention at individual and community levels, through the identification and dissemination of best practices and evidence-based approaches for applicable health policies;
- Promote the generation and uptake of scientific breakthroughs and use enhanced understanding of brain functioning and its determinants to deliver accessible and tailored solutions, for diagnosis, treatment and care and to improve the quality of life for those living with mental and neurological disorders and their caregivers;
- Establish the European Partnership for Brain Health as a trusted and enabling collaboration structure at the forefront of brain-related research and innovation together with international partners.

In attaining these objectives, the partnership will contribute to the **European Health Union** by supporting an important goal in the revision of the pharmaceutical legislation, namely "addressing unmet medical needs", as many unmet needs are in the field of neurological and mental disorders. This includes innovation in medicines e.g. for vulnerable and marginalised groups, and for rare and paediatric diseases. Thereby the partnership also contributes to the goals of the **Pharmaceutical Strategy for Europe**, aiming to ensure access to high-quality, effective and safe medicines for everyone in Europe, while boosting global competitiveness of the sector. It will also feed into the **European Care Strategy for caregivers and care receivers**²², which aims to ensure high quality, affordable and accessible care services for all ages. By fostering data sharing and boosting FAIR and open data, the partnership also

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²² A European Care Strategy for caregivers and care receivers



contributes to the implementation of the **European Health Data Space (EHDS)**²³ and links with the EU regulatory **Framework for Artificial Intelligence** (EU AI act).

The objectives are framed within the wider context of the United Nations **Sustainable Developmental Goal (SDG) 3,** target 3.4 on non-communicable diseases and mental health and are also relating to SDG 10 (targets 10.2 and 10.3) on promoting the inclusion of all and reducing inequality and SDG 11 (targets 11.1, 11.2 and 11.3) on inclusive, safe, resilient and sustainable cities and human settlements. In addition, the aims and objectives of the EP BrainHealth fit into the framework of the World Health Organisation's response to the burden posed by neurological and mental disorders; the **Healthier Together – EU Non-Communicable Diseases Initiative**, which includes a focus area on 'Mental health and neurological disorders'; and the Commission Communication on a **comprehensive approach to mental health**, adopted on 7 June 2023²⁴.

2.2.2 Ambition and specific objectives

To deliver on the overall vision and general objectives of the European Partnership for Brain Health, research and innovation is needed to fill evidence gaps and thereby enable the development of technologies, strategies and policies for the promotion of brain health. The partnership pursues an integrated, collaborative approach towards brain-related research that involves all relevant disciplines, including neurosciences, neurology, psychiatry as well as humanities, social sciences, epidemiology and innovative and emerging technologies including artificial intelligence. The active participation of people living with brain disorders and the interested public at all stages is fundamental for increasing the relevance of research, to raise awareness in the general public on the importance of brain health and brain research and to ensure a smooth societal integration. Moreover, a structure/platform for an effective and timely exchange of information and experience between all key players (such as brain researchers, industry, regulators, policymakers, private sector, healthcare system, etc.) will be instrumental in substantially contributing to the overarching vision of the partnership.

To identify research and innovation priorities, the organisations joining the European Partnership for Brain Health will agree on a common **Strategic Research and Innovation Agenda** (EP BrainHealth **SRIA**, see section 2.6). This will be prepared by the CSA BrainHealth and based on the Shared European Brain Research Agenda (SEBRA) developed during the EBRA project, consolidating the strategic research and innovation agendas of NEURON, JPND and the HBP/EBRAINS scientific vision for digital brain research, with a commonly agreed prioritisation of actions to improve brain health in Europe and beyond.

The following **specific objectives** substantially contribute to the general objectives of the European Partnership for Brain Health and will be further developed in the EP BrainHealth SRIA (see also figure 2):

²³ European Health Data Space

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²⁴ This communication draws on three guiding principles: to (i) have access to adequate and effective prevention, (ii) have access to high quality and affordable mental healthcare and treatment, and (iii) be able to reintegrate society after recovery. One of its flagships is to strengthen research on brain health, including on mental health by working closely with Member States to create an ecosystem, that maximises EU and Member States' research investments. An ambitious partnership for brain health would support the implementation of this communication.



I. Promote brain health and prevent neurological and mental disorders

Our ability to comprehend, prevent and treat disorders affecting the brain and sensory organs fundamentally relies on our understanding of the nervous system's physiology. There is still limited understanding of the numerous fundamental molecular mechanisms of the brain and aetiologies of brain-related diseases. The challenge is to build on an improved understanding of brain development and functioning to identify the determinants (from prenatal stages to later in life) that shape and impact brain health as well as individual susceptibility and resilience for disease development. Key priorities include unveiling the influence of genetic, epigenetic, psychological and behavioural, social, socioeconomic, diet and lifestyle aspects, and digital factors as well as environmental determinants, such as rural and urban settings, residential isolation and pollution, utilizing both, smart data and big data, and integrating information from diverse sources and various levels. The direct and indirect impacts of environmental and worldwide threats on brain health, especially pandemics, forced displacement, wars and climate change also need to be addressed. Particular emphasis will be on the identification and promotion of factors capable of protecting brain health and increasing resilience, thereby informing the development of strategies that foster health-promoting living conditions, including exposure to natural environments, and promote early, affordable, accessible, fair and sustainable prevention of neurological and mental disorders. Brain health will be addressed in a dynamic and lifespan perspective, which includes citizens' empowerment at all ages. A particular focus will be on diversity aspects such as the demographic, cultural and (socio)economic context, sex and gender, as well as on sociocultural and regional inequities and barriers in healthcare. To fulfil this objective, it is essential to adopt a multifaceted, inclusive approach, including diverse and in particular underrepresented population groups like those of low socioeconomic status as well as ethnic minorities in all research approaches.

II. Improve early recognition, diagnosis, monitoring, intervention and care for people living with brain disorders

Understanding the pathophysiology and identifying the mechanisms underlying brain disorders are necessary to enable the development of accurate and precise diagnostics, characterise appropriate time windows for intervention, and to select or combine appropriate and effective therapeutic intervention(s). Fundamental to this is a deeper understanding of the functioning and structure of the healthy brain, including through virtual human twin models and technologies. The aim is to identify key genetic and altered biological mechanisms that underly multifactorial diseases, comorbidities and their symptoms in order to better understand pathophysiology, disease progression and epidemiology. In addition to this, a better understanding of the influence of sex, gender and age-related factors as well as behavioural, cultural, social and (socio)economic aspects to fulfil this objective. The ultimate goal is to translate this knowledge into novel approaches for reliable and early diagnosis and monitoring of disease progression from the prodromal stage as well as effective and early pharmacological, non-pharmacological, and digital health interventions tailored to the individual biological, psychological, environmental and socioeconomic context at all ages. Critical appraisal of risks and benefits of (early) diagnosis and therapeutic and technological interventions and regulatory concerns will complement the basic and clinical research. For this, a multidisciplinary approach will be adopted that includes clinical and experimental expertise, data sciences, implementation research, social sciences, and humanities. To ensure efficacy and relevance of the medical, technological and social innovations, the partnership strives for



a close dialogue with the research community, healthcare professionals, the private sector, regulatory bodies, people living with brain disorders as well as professional and informal carers.

III. Improve care and support for people living with brain disorders and their caregivers

Improving care and support for people living with brain conditions and their caregivers requires a comprehensive approach that encompasses research translation into clinical practice. The aim is to bridge the gap and accelerating the translation process between research and practice, involving patients in the research process, and tailoring interventions and care to their needs. A central challenge is to ensure equitable access to tailored care and treatment options for everyone in a sustainable healthcare system. Individual, economic and social burden and barriers as well as stigma of brain conditions and discrimination of people living with brain disorders need to be reduced, while preserving social inclusion, social diversity and active life, to safeguard personal dignity, wellbeing and quality of life. This will include the need for an increased acceptability of treatment and care in brain disorders by involvement of and targeted communication to citizens, persons living with brain disorders as well as professional and informal caregivers to empower them as active players in their health trajectories. With regard to healthcare systems, the aims are to reduce and delay the need for institutional care and to increase, improve and diversify the offer of care options. Best practices, public health policies, evidence-based approaches and standards for optimised clinical management, care and support systems need to be identified and shared, while research results need efficient translation into novel strategies. All activities will be grounded on robust evidence from implementation science²⁵ including leveraging on real-world data and assessing the cost-benefit ratio of preventive measures, (early) diagnosis as well as therapeutic interventions with the potential to appropriately steer actions that address the needs of patients, caregivers and healthcare systems in Europe and beyond.

IV. Integrate the social, ethical and legal dimension to advance research and innovation for brain health

The aim is to promote research in the social sciences and humanities research to better understand the impact of the societal, socioeconomic, cultural, legal and ethical determinants on brain health across the lifespan as well as the individual, psychological, social, and environmental factors which promote resilience and brain health. This includes improved knowledge on the brain's development, maintenance, and function and in particular a better understanding of the effects of external stimuli and stressors, e.g., identifying key factors of wellbeing and resilience related to lifestyle, the workplace, schools or within urban versus rural areas. In order to successfully translate this research into policy and practice that are accepted and used, it needs to be carried out in collaboration with social parties – governments, cultural and social organisations, companies and (end) users who are concerned. In addition, strategies for enhancing brain health must be attuned to different communities' perceptions and understandings and in particular to the needs of vulnerable communities, which may be less perceptive to neurobiological models and biomedical interventions and may place greater emphasis on other ways of thinking about brain health and disease, for example on the

²⁵ Sarkies et al. *Improving clinical practice guidelines with implementation science*, Nature Reviews Cardiology 2021



preservation of personhood or communal relations. To fulfil these objectives, appropriate metrics that weigh the consequences of brain disorders and related therapies need to be developed to identify individual, gender, social, and cultural determinants of brain health and wellbeing. In addition, ethical aspects such as therapeutic acceptability, for example in the context of emerging technologies, need to be considered and responsible research needs to be fostered.

Complementary to the general and specific objectives, a number of **transversal priorities** have been identified in the SRIA that are related to the specificities and current gaps of the brain health field and are therefore relevant to all objectives outlined before (see also section 2.2.6). The future partnership will address these transversal aspects in its various activities (see also sections 2.2.5 and section 3.1).

- Improve translation of brain health innovation to the market and better integrate socio-economic aspects
- Improve the use of existing resources and infrastructures and foster sharing of and access to brain health data
- Increase reproducibility and potential of joint exploitation of scientific results
- Foster participative research, involving patients, caregivers and citizens in all stages of the design of research programmes
- Develop a strong framework for the systematic integration of ethical, social and legal aspects in brain health research approaches
- Foster a holistic view and transdisciplinary approaches on brain health in the training for new generations of researchers and health care professionals
- Promote the appraisal of the complexity and specificity of brain health research to develop effective approaches to tailored interventions for brain health

2.2.3 Collaboration with other partnerships and Union programmes

Horizon 2020

The European Partnership for Brain Health builds on the groundwork of several large EU-funded initiatives and programmes that have been established in the last decades to structure and align brain research in Europe (see section 2.1.2). Notably, these include the ongoing initiatives JPND and NEURON, as well as the recently finished HBP, which has put the EBRAINS digital research infrastructure in place. Beyond the boundaries of these individual initiatives, the CSA EBRA was launched in 2018 as a catalysing platform to further streamline and coordinate brain research, reduce fragmentation and duplication of research efforts at the EU and global level.

Horizon Europe

In 2023, this process of aligning and structuring brain research in Europe and beyond was driven forward by the launch of the CSA BrainHealth under Pillar II, Cluster 1 (Health). The aim of this action is to prepare the European Partnership for Brain Health which links to the other **public-public (co-funded) partnerships under Cluster 1**: Rare diseases; Personalised



medicine; Transforming health and care systems; ERA for Health; Partnership for the assessment of risks from chemicals, the **institutionalised partnerships** Global Health EDCTP3 Joint Undertaking and Innovative Health Initiative (IHI) as well as the EIT Health. In addition, there will be connections to the partnerships currently being planned in Cluster 1: EP One Health/AMR as well as EP Pandemic Preparedness.

Networking

The coordinator of the European Partnership for Brain Health, DLR, as well as its envisioned partners are well connected to all the Horizon 2020 and Horizon Europe partnerships. The existing initiatives in the brain health area (ERA-Net NEURON and JPND) are coordinated by DLR and INSERM, respectively. Future EP BrainHealth partners are also involved in all other European Partnerships within the Health Cluster that are currently running, with central work packages and responsibilities: EP PerMed (coordinated by DLR), ERDERA (coordinated by INSERM), EP THCS (coordinated by IT MOH), ERA4Health (coordinated by ISCIII), and PARC (coordinated by ANSES). The same is intended for the planned partnerships One Health/AMR and Pandemic Preparedness. This guarantees a close collaboration and an intensive exchange of information without hurdles even on short notice and ensures coherence and complementarity of activities as set out in the working document on 'Coherence and Synergies of candidate European Partnerships under Horizon Europe'26.

In addition, partners of the future EP BrainHealth are also represented in the joint undertakings Innovative Health Initiative (IHI) and EDCTP via their respective country delegates.

The European Partnership for Brain Health will be an active partner in all established and foreseen exchange platforms of all health-related partnerships and beyond under Cluster 1.

Other links

A link with Cluster 2 (Culture, creativity and inclusive society) is expected regarding socio-economic transformations that contribute to inclusion and growth, as well as to how culture and arts can contribute to mental health and wellbeing. Links with Cluster 4 (Digital, Industry and Space), Cluster 5 (Climate, Energy and Mobility) and Cluster 6 (Food, Bioeconomy, Natural Resources, Agriculture and Environment) are expected to improve our understanding of the impact of pollution and climate change on brain health and neurological and mental disorders and how blue and green spaces can contribute to mental health and wellbeing.

A link with Pillar I Research Infrastructure is expected, fostering the use of Research Infrastructures e.g. EBRAINS.

There are also links with the Cancer Mission e.g. regarding cancers of the central nervous system or good mental health and wellbeing for cancer patients and survivors.

Furthermore, in the preparation of the EP BrainHealth the partners of the CSA BrainHealth will cross-fertilize with the Thematic Network Towards an EU Coordination Plan for the Brain²⁷. This Thematic Network is led by the CSA-BrainHealth partner EBC and aims to unite stakeholders from across the brain community to reach a consensus on what defines brain health and brain capital and to develop policy recommendations for a comprehensive European Brain Health

²⁶ Coherence and Synergies of candidate European Partnerships under Horizon Europe

²⁷ EBC led Thematic Network Towards an EU Coordination Plan for the Brain



Research and Innovation Plan, thereby aligning well with the vision and aims of the future EP BrainHealth.

The following Union programmes / legislations have links to the envisaged partnership:

- EU4Health²⁸ programme, which supports the implementation of the Healthier Together
 EU Non-Communicable Diseases Initiative (with a focus area on 'Mental health and neurological disorders') and the communication on a comprehensive approach to mental health,
- the **European Health Data Space**²³(with EBRAINS research infrastructure participating as a partner in a pilot project)
- **Digital Europe Programme**²⁹, which contributes to the deployment of the European Health Data Space, including through health data infrastructures such as Cancer Image Europe, Genomic Data Infrastructure, Intensive Care Units (ICU) data space, as well as the advanced Virtual Human Twins platform.

2.2.4 Investment required

Contributions and commitments expected from partners:

The European Member States as well as the EU invested heavily in brain health-related research over the last years. Using the overall contributions (national and EU funding) of JPND, NEURON, and HBP under Horizon 2020, a sum of €77 million/year has been observed.

The funding schemes of JPND and NEURON are likely to be continued under the umbrella of the European Partnership for Brain Health. Their national contributions could therefore, be extrapolated to an expected 200-300 million € for the next seven to ten years.

Tentative Union contribution for the entire duration of the partnership:

Depending on future discussions with Member States and Associated Countries regarding their commitments, an EU contribution in the range of €100-150 million is expected.

2.2.5 Transformational changes in the R&I ecosystem (qualitative impacts)

To achieve its general and specific objectives including the transversal priorities as outlined in sections 2.2.1 and 2.2.2, the European Partnership for Brain Health will develop pathways alongside the following **operational objectives**. These will be translated into concrete activities as described in section 3 (see figure 2).

i. Joint support of research and innovation (R&I)

To address R&I priorities as outlined in the EP BrainHealth SRIA, the partnership aims to support responsible research and innovation, networking, training, open science, and other appropriate measures to strengthen and expand our knowledge in the aforementioned specific and transversal priority areas, thus addressing major challenges in brain health research. The joint funding will bridge fundamental, clinical, biomedical and social/humanities

²⁸ <u>EU4Health programme 2021-2027 – a vision for a healthier European Union</u>

²⁹ The Digital Europe Programme



research, theoretical and data approaches, engineering resources, industry as well as real-life interventions, participatory and implementation science. The ultimate goal is to maximize the translational value of the results and accelerate impact. In particular, consideration of healthcare delivery and health economic needs as well as the societal perspective of brain health will be encouraged. The Responsible Research and Innovation (RRI) principles will be fundamental, integrating potential short- and long-term environmental and societal effects as well as ethical considerations in the design and the conduct of funding activities, and in funded research projects themselves. This also comprises the active participation of patients and patient advocacy organisations throughout all stages of the design and conduct of research programmes, thus becoming central to generate meaningful impact for society (see also iii.). To avoid duplication and create synergies, common goals will be tackled in collaboration with specialized existing funding initiatives as much as possible (see section 2.2.3).

ii. Collaboration and strategic alignment across disciplines and countries, and global dialogue

The European Partnership for Brain Health recognizes the capital importance of international and multidisciplinary cooperation to tackle its ambitious challenges. Enlarging the adherence and participation of public and private actors in as many regions and countries as possible and beyond those that are already engaged in present EU-driven actions will be a continuous task. A particular focus will be the integration of EU Member States that do not yet have specific brain health-related agendas, including exchange of good practices. The partnership will regularly refresh the EP BrainHealth SRIA to ensure flexibility, and to reflect the priorities of participating countries and international organisations as well as scientific developments in the brain health field. Appropriate processes will be developed during the implementation of the EP BrainHealth SRIA that enable countries to provide input and contribute actively to the different partnership activities. To foster alignment of broad national strategies as well as dissemination and exploitation activities within one country the establishment of dedicated structures (e.g. national mirror groups) is envisaged. Pooling of different national and regional resources will maximise the impact of investments in research programmes and the healthcare system.

The European Partnership for BrainHealth has the ambition to be a true pan-European initiative, establishing solid links, continuous dialogue, and alignment with key global organisations (WHO, OECD, UN), global initiatives and research organisations in the field³⁰ (GACD, NIH Brain initiative³¹, International Brain Initiative, Brain/MINDS, Australian Brain Alliance, InTBIR, IBRO, etc). Further internationalisation, especially towards interested South-American, African and Asian countries will be sought. Continuous dialogue with and integration of a broad range of stakeholders on regional, national, European and international level to fine-tune R&I priorities along the whole value chain is intended e.g. via providing input to the SRIA updates. To this end, a collaboration and a networking platform will be created within the EP BrainHealth to address the importance of stakeholder engagement and to strengthen collaboration on different levels (see section 3.3.3.).

³⁰ Entities include the Global Alliance for Chronic Diseases, several global brain initiatives, the International Initiative for Traumatic Brain Injury Research (InTBIR) and the International Brain Research Organisation (IBRO).

³¹ Brain Research Through Advancing Innovative Neurotechnologies



iii. Facilitating the use of EU infrastructures and platforms and improving brain health data access, sharing and harmonisation

European research infrastructures are currently under-utilised, despite their high quality. The European Partnership for Brain Health will contribute to facilitating the use of European infrastructures and platforms by fostering exchange how to tailor services to the current and emerging needs of brain research, to promote tailor-made services and to foster collaboration between infrastructures. In general, better access to and sharing of pre-clinical and clinical brain research data will be advocated to improve understanding of brain function and research outcomes. The lack of reproducibility of key scientific results in clinical trials has been particularly prejudicial to the brain health field, having led to reduced investment in applied research and industry disengagement from the field. In addition, better access to high-quality health data, including real-world data, is essential to accurately assess citizens' and patients' needs and promote the efficacy of treatments for patients. Therefore, the EP BrainHealth aims to improve the access and sharing of standardised, structures and well-annotated data, including federated approaches.

For this, the partnership strives for a continuous and shared dialogue between existing and emerging platforms and resources (e.g. ESFRIs³², EOSC³³, health portals, data centres including the European Health Data Space, brain banks, cohorts) and the research community. This goes hand in hand with the development of standardised guidelines, methods and tools (e.g., software) to improve convergence between preclinical and clinical research data, facilitate the harmonisation of data from different sources and support transnational cross-centre studies. A particular focus will be the facilitation of data sharing by boosting FAIR³⁴ and open data, and supporting the access to unique infrastructures such as EBRAINS, ELIXIR³⁵, EATRIS³⁶ and the BBMRI-ERIC³⁷. The ultimate goal is to strengthen the open science policy, increase the re-use of data to produce new research knowledge in the field, and improve research quality, reproducibility, efficiency and societal responsiveness. The approach will use information gathered in previous collaborative projects in the field (JPND and FLAGERA) concerning the actual needs and will lead a close dialogue with other initiatives and European Partnerships (e.g. EP Permed) working to improve the integration of European infrastructures on the everyday work of scientists.

iv. Improving translation of brain health innovations by bridging with healthcare providers, the private sector, regulators and policy-makers

To this date, there is a critical lack of connection between scientific production and availability of innovative solutions inspired by scientific knowledge for citizens' and professionals' use. The partnership strongly emphasizes the appropriate and responsible translation of research outcomes into accessible, fair and tailored policies, technologies, and products to foster wellbeing and quality of life in health and disease. Multi-stakeholder collaboration is the most efficient way to approach these relevant needs. The aim is the delivery of efficient strategies for collaborations between industry, academia and policy-makers designed together with

³² European Strategy Forum for Research Infrastructures

³³ European Open Science Cloud

³⁴ Findable, Accessible, Interoperable and Reusable

³⁵ ELIXIR

³⁶ EATRIS

³⁷ BBMRI-ERIC



stakeholders such as the EIT Health, IHI, and its partners, the European umbrella organisations for industry and innovation such as EFPIA, MedTech, EuropaBio, and COCIR in order to promote and accelerate translation from research to innovation while increasing the economic capacity in Europe. In this context, the development of digital and neuro-derived technologies, brain modelling, and computing, that result from 10 years collaborative work in the HBP and are provided via EBRAINS will facilitate medical innovation. In the future this will be further developed via the European Virtual Human Twins Initiative³⁸.

Apart from R&I activities, the partnership will also address the need for suitable framework conditions, including in particular regulatory and ethical/legal aspects, since brain function largely determines an individual's cognitive and emotional processes as much as their social interactions, in health and disease. The EP BrainHealth should contribute to pushing forward a strong frame of actions promoting ethical, societal/social and legal considerations in brain health research, together with leading actors in the field, e.g. OECD, International Bioethics Committee (IBC) IBC-UNESCO, International Neuroethics society (INS) as well as the aforementioned public-private partnerships IHI and EIT Health to become the European reference in the field and to allow for a broader uptake of innovations into the healthcare system. Equally important is a focus on driving equal access to brain health innovations for all in Europe and worldwide, reducing deprivation and inequality both between and within countries and regions, in particular with regard to population groups with low socio-economic status.

The partnership aims to provide input with regard to brain health to policy- and decision-makers, payers, and regulators in the healthcare system via e.g. policy briefs and white papers to create awareness for the potential of promoting and restoring brain health, specificities related to interventions in this area, to initiate discussions and to develop recommendations for regional, national, and European policies dedicated to improving brain health in the EU and beyond.

v. Involving and empowering citizens and people living with brain disorders

The involvement of citizens and people living with brain disorders, including patients and their caregivers, in research, innovation, policy and healthcare development is crucial for conducting relevant and impactful research and initiatives in the future partnership. The EP BrainHealth is dedicated to include the perspectives of citizens, patients, their representatives and caregivers in the whole spectrum of activities: from the definition of research questions and study design, data collection and analysis to the development of recommendations issued from the scientific work, enhancing quality and impact wherever possible. Experiential knowledge of patients and caregivers will be particularly relevant for defining research end-points for truly meaningful results and for all activities in the context of practical aspects of treatment and care. To effectively facilitate this approach, frameworks must be established within the partnership to prioritise inclusivity and ensure representation of diverse perspectives.

In addition to that, the EP BrainHealth is dedicated to empower all citizens and patients to be active in their health trajectories, i.e. risk and protective factors, clinical trials, therapeutic options. The partnership will disseminate good practices and high-quality scientific outputs to engage and inform the interested public using a variety of media. In addition, a dialogue with

³⁸ Virtual Human Twin | digital twin



stakeholder communities including patients, caregivers and decision-makers on national and international levels to disseminate research findings in an accessible manner and foster societal acceptance will be pursued. *Vice versa*, the EP Brain Health will welcome public input through open dialogue formats to guarantee that citizens' wants and needs are appropriately considered in all activities of the partnership.

vi. Capacity building in research and innovation

Capacity building and in particular education and life-long training of scientists, healthcare practitioners, health policy experts, innovators, engineers, and other professionals contributing to preserve and improve brain health represents an important goal in the workplan of the partnership. The aim is to raise awareness amongst early career professionals towards holistic, inclusive, and transdisciplinary approaches to improve brain health for individuals in health and disease and towards development of the necessary skills. Among others, the growing need for standards and common approaches for the sharing and exchange of data (open science) and improved use of infrastructures will be addressed as well as reducing hurdles specific for the transfer of brain health research results into the private sector and healthcare system. As mentioned already (see objective iv), the consideration of ethical, legal and social/societal aspects (ELSA) in the activities of the partnership is of paramount importance for a holistic and inclusive view, to build trust and promote citizen participation. EP BrainHealth will gather all the expertise needed to jointly develop standard practices and policies concerning ELSA related to brain health research, healthcare and technology; while promoting the development of responsible innovations in the field.

As part of its implementation, the EP BrainHealth will conduct an impact assessment based on a clear intervention logic³⁹ to be drafted within the -EP BrainHealth full proposal and further developed in the future EP workplan. The aims and objectives will be derived from the SRIA and the future implementation plan and whenever possible delineated with the SMART parameters (Specific, Measurable, Achievable, Relevant, and Time-bound). Appropriate impact pathways and key performance indicators will be developed that follow this intervention logic and that are based on the general and specific objectives described in the foregoing sections. In addition, indicators and methods for monitoring the partnership's progress towards its objectives and impact will be harmonised and aligned with the new Horizon Europe monitoring framework and its key impact pathways and key performance indicators. The monitoring concept will fulfil the requirements on common indicators and data structure for the European Partnership monitoring and the biennial monitoring reports in Horizon Europe.:

Intervention pathways may include but are not limited to the following aspects:

1. To promote brain health and prevent neurological and mental disorders

- Identified factors capable of protecting brain health and increasing resilience
- Novel strategies for early, affordable, accessible, fair and sustainable prevention of brain disorders
- Improved knowledge on compensation mechanisms in the healthy brain and its exploration for preventive and therapeutic approaches

³⁹ Intervention logic is a tool used to improve the design of interventions. It outlines the connection between the ends and means of an intervention. The Intervention logic shows in a linear way how we think our objectives can be pursued by specific activities and their consequent outputs, outcomes and impacts.



2. To improve early recognition, diagnosis, monitoring, and effective intervention for people living with brain disorders

- Novel approaches for reliable early diagnosis and prediction of disease progression
- Evidence-based (non) pharmacological, and digital health interventions

3. To Improve care and support for people living with brain disorders and their caregivers

- Identified and shared best practices, public health policies, evidence-based approaches and standards for optimised clinical management care and support systems.
- Research results are translated into novel strategies for care and support of people living with brain disorders.

4. To Integrate the social, ethical, and legal dimension to advance research and innovation for brain health

- Improved knowledge and integration of the social dimension in the prevention, treatment and care of people living with brain disorders
- New strategies to address the needs of vulnerable communities

2.2.6 EP BrainHealth Strategic Research & Innovation Agenda (SRIA) development

The CSA BrainHealth already developed a document, 'EP BrainHealth SRIA – framework document'⁴⁰, laying out a framework concept for the strategic research and innovation agenda (SRIA) of the future partnership (see figure 3). It is based on the work of previous initiatives, as well as input by the CSA partners.

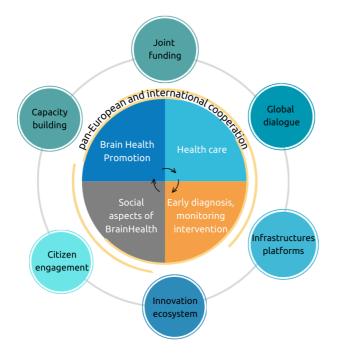


Figure 3: Strategic Research and Innovation Agenda of the European Partnership for Health. The CSA BrainHealth consortium has identified four main target priorities that the EP BrainHealth activities are expected to substantially advance. 1) Promote brain health and mitigate the risk of brain disorders, 2) Tackle brain diseases with scientific breakthroughs, 3) Improve quality of life for people living with brain disorders and their carers, Understand and consider social aspects of health. addition, possible activities/actions are envisaged implement these priorities.

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⁴⁰ Framework EP BrainHealth



The CSA BrainHealth also published an analysis report, focusing on previous and on-going initiatives in the field of brain health. This analysis focuses on European (section I) and National (sections II and III) initiatives. At the European level, the objectives and achievements of previous and on-going European initiatives in the brain health space funded under FP7, H2020 and Horizon Europe for the 2008-2023 period have been analysed. These include JPND, the ERA-Net NEURON, HBP/EBRAINS, IMI/IHI and EBRA. At the national level, on-going initiatives have been analysed through two complementary approaches: (i) a survey was circulated to ministries and funders in the EU Member States and Associated Countries to generate a snapshot of current topics of interest and suggested actions in the brain health field (section II) and (ii) a systematic analysis of national roadmaps in the field of brain health (2008-2024) was performed to gain insight into the national perceptions of research priorities and their evolution over time (section III). Taken together with an analysis of recent consensus publications in neurology and psychiatry published in top-tier journals, these documents represent the foundations of the SRIA of the EP BrainHealth.

The Strategic Research and Innovation Agenda (SRIA) is the central strategy/plan of the future EP BrainHealth, outlining the strategic priorities and the main lines of action and research and innovation initiatives, while encouraging maximum engagement of Member States, Associated Countries and relevant players in the brain field - including not only researchers but also neurologists, psychiatrists, people living with brain disorders, industry, and global organisations - to join forces and align efforts and funding. The SRIA is being developed through an iterative process, benefiting not only from extensive contributions from partners of the CSA BrainHealth but also from consultations of the SAB members, of stakeholders (including the private sector) and of the general public (see Annex I).

The SRIA is structured around four priorities with specific objectives and strategies to accelerate scientific and medical breakthroughs and innovation in the brain space with the expected societal impact to decrease the burden of brain disorders (see figure 3). According to these four priorities the specific objectives of the future EP have been formulated.

- Priority 1: Promoting brain health and preventing brain disorders
- Priority 2: Improving early recognition, diagnosis, monitoring, intervention, and care for people living with brain disorders
- Priority 3: Improving care and support for people living with brain conditions and their caregivers
- Priority 4: Integrating the social, ethical, and legal dimension to advance research and innovation for brain health

2.2.7 Transition strategy – measure for phasing-out

tbd



2.3 Necessity for a European Partnership

2.3.1 Addressing the objectives of Horizon Europe

The extent of environmental and societal challenges, including the rapidly growing impact of the ageing European population and its declining mental health⁴¹, and the inherent complexity of the brain requires a highly coordinated response. A long-term, holistic research and innovation strategy in brain health is necessary, which complements traditional calls from the EU Framework Programmes and national programmes.

The overall aim of Cluster 1 'Health' of the Framework Programme Horizon Europe is to improve and protect the health and wellbeing of citizens of all ages. Answering this aim with a specific focus on brain health requires innovative solutions in order to offer research opportunities and develop pathways to improved health and care systems and digital and technology innovations to support these approaches. This can only be achieved in collaboration with all relevant stakeholders and in a close alignment of national and regional research programmes with the objectives of Horizon Europe, such brain health promotion, mitigate brain health risks, and prevent, diagnose, treat, cure brain disorders and diseases as well as improve quality of life through appropriate care and support for those who live with brain disorders.

A collaborative effort such as a European Partnership for Brain Health contributes to **all** expected impacts of Cluster 1, in its Strategic Plan 2025 - 2027⁴², and will be particularly impactful on all aspects, particularly on 1), 3), and 5)

- 1) 'Staying healthy in a rapidly changing society'
- 2) 'Living and working in a health-promoting environment'
- 3) 'Tackling diseases and reducing disease burden'
- 4) 'Ensuring equal access to innovative, sustainable and high-quality healthcare'
- 5) 'Developing and using new tools, technologies, and digital solutions for a healthy society'
- 6) 'Maintaining an innovative, sustainable, and competitive EU health industry'

2.3.2 Supporting meaningful collaboration among countries

Within Horizon 2020, the ERA-Net programmes co-funded by the EC have significantly boosted the funding commitments of the participating Member States and Associated Countries. By applying a variety of 'widening' measures and additional activities beyond translational calls for funding, these efforts contributed to the integration of research policies and research communities from countries and disciplines that were previously not well involved in the European Research Area. It is paramount to ensure much-needed overall coordination of such activities and the continuation of existing ecosystems while there are still so many unmet brain health needs. Cross-fertilisation and synergies between previous and existing initiatives supported by the EU Framework Programmes and Member States (e.g.

⁴¹ As also recognised in the <u>Report</u> on the final outcome of the Conference on the Future of Europe, calling to dedicate more attention to mental health.

⁴² Horizon Europe Strategic Plan



JPND, NEURON, EBRA, and HBP/EBRAINS) can be accommodated by **integrating them or their tangible results under one single umbrella**. Intense collaboration of these initiatives in the frame of the CSA BrainHealth already resulted in synergetic effects and proof of concept as demonstrated in a published consensus paper⁴⁰, the EP BrainHealth SRIA Framework, delineating the envisaged strategy for future joint activities.

Brain diseases contribute significantly to the global burden of disease (see section 2.1.1). Therefore, the World Health Organisation (WHO) and the Organisation for Economic Cooperation and Development (OECD) are actively working at a global level on improving the knowledge base for interventions on brain health and support countries in increasing their capacity to address related challenges. E.g. in July 2023, a new WHO global action on epilepsy and other neurological disorders have been published, setting out the actions that are needed to improve access to care and treatment for people living with neurological disorders through a comprehensive, coordinated response across sectors⁴³. This intersectoral action plan complements the already existing WHO "Comprehensive mental health action plan 2021-2030"44 and the "Global action plan on the public health response to dementia 2017–2025"45. Focussing on neuroscience-inspired investment and public-policy innovation the OECD together with various actors has developed the concept of the neuroscience-inspired policy initiative "Brain Capital Alliance" as a multi-national and multi-organisational programme that brings together a wide range of stakeholders from science to policy, economics and finance⁴⁶. To address the ethical, legal and social challenges by novel neurotechnologies and while promoting innovation in the field, the OECD has also published "Recommendations on Responsible Innovation in Neurotechnology" as the first international standard in this domain⁴⁷.

Many of the current activities are focused on the links between climate change and human health, providing strong implications for brain health including mental wellbeing. For example, the first-ever Health Day at the COP28 UN Climate Conference in December 2023 in Dubai featured amongst others a dedicated event on mental health and climate change. In addition, the response to climate change is one of the six key strategic objectives of the WHO's 14th General Programme of work for 2025-2028. At the 77th World Health Assembly of the WHO in 2024 a Strategic Roundtable also focused on the links between climate change and health, including the adoption of a resolution that recognizes climate change as an imminent threat to global health and people's wellbeing, including mental health⁴⁸. Furthermore, in line with the G7 declaration of 2023, commitments have been made to promoting policies and resources to care for people living with dementia and welcome the development of potential disease-modifying therapies for the various types of dementia, including Alzheimer's disease⁴⁹.

The enhancement of global collaboration in the field of brain research and innovation is also featured by the United Nations (UN). For example, in the framework of the UN General Assembly Science Summits there has been a dedicated meeting on "Global Partnership in Brain

⁴³ Global action plan on epilepsy and other neurological disorders

⁴⁴ Comprehensive Mental Health Action Plan 2013-2030

⁴⁵ Global action plan on the public health response to dementia 2017–2025

⁴⁶ Brain Capital Alliance

⁴⁷ OECD Recommendation on Responsible Innovation in Neurotechnology - OECD

⁴⁸ Climate change and health

⁴⁹ G7 Hiroshima Leaders' Communiqué



Research" at the 77th Science Summit with leading organisations in the field. In addition, the United Nations Educational, Scientific and Cultural Organisation (UNESCO) initiated a global dialogue process to develop an ethical framework to harness the potential of neurotechnology and address the societal risks with an international conference at the UNESCO Headquarters in July 2023.

Furthermore, international research organisations such as the International Brain Initiative (IBI), the International Initiative for Traumatic Brain Injury Research (InTBiR), or the NIH Brain initiative as well as cross-indicational platforms like Global Alliance for Chronic Disease (GACD), also intend to catalyse and advance neuroscience through international collaboration, alignment and knowledge sharing.

Bridges need to be established among these multinational efforts in order to acquire the best expertise and know-how available worldwide, to leverage a critical scale of resources and to achieve the greatest impact. There is a strong need to continue and further capitalise on the experience and trust that were built over the last decade among numerous European and international countries, initiatives and organisations. The participation of the European Commission has proven to be a very powerful incentive to boost commitment of funders and leverage the impact of joint actions. As pointed out in Horizon Europe, the EU is a major leader in research and innovation to promote health and wellbeing and prevent, treat, and cure diseases in Europe and worldwide. In order to achieve the greatest impact and live up to its leadership role, international cooperation and partnerships with third countries and international partners are key. Thus, the new European Partnership for Brain Health will align with major global initiatives in brain health, striving to build on and intensify international cooperation, collaboration and alignment and reaching out to interested third countries e.g. from the Australian, African, South-American, and Asian continent.

The new partnership will seize the momentum and accelerate the creation of the largest European and global collaboration, essential to improve brain health by motivating and mobilising all the stakeholders under a common and strong transnational banner. It will become a single reference point for brain health at European level and beyond while at the same time connecting with relevant initiatives, national and regional activities, programmes, and stakeholders that allow addressing the challenge.

2.4 Partner composition and target group

2.4.1 Building on existing and previous EU initiatives

The constant improvement and growth of brain health research have been catalysed by several EU-funded projects and initiatives, some of which are currently active:

• **ERA-Net JPcofuND2** (ending 31/12/24) aims to establish synergies between the Joint Programming on Neurodegenerative Diseases Research (JPND) and Horizon 2020. JPND is the largest global research initiative tackling the challenge of neurodegenerative diseases (Alzheimer's disease, dementia, Parkinson's disease and other neurodegenerative diseases). The action aims to achieve the highest possible impact for patients, their carers and society as a whole. This activity is the latest in a series of predecessor EU-funded



activities all related to the support of JPND: JPco-fuND (01/2015 - 09/2021) & JPsustaiND CSA (11/2015 - 10/2021).

- **ERA-Net NEURON Cofund 2** (ending 31/12/25) is a funding platform focused on neurological and mental disorders, holding a strategic position in bringing pre-clinical and clinical research communities closer together and fostering translational research, while covering the entire value chain. The ERA-Net NEURON network started more than 15 years ago with ERANET NEURON I (01/2007 12/2011), NEURON II (01/2012 12/2015) and NEURON Cofund (01/2016 12/2020).
- The FET Flagship Human Brain Project (HBP; 2013-2023) pioneered a new paradigm in brain research at the interface of computing and technology, aiming to lay the technical foundation for a new model of ICT-based brain research and driving integration between data and knowledge from different disciplines. The HBP resulted in the implementation of the digital research infrastructure EBRAINS supported by the EBRAINS 2.0 project (ending 31/12/2026), which gathers an extensive range of data and tools for brain-related research, providing the scientific community with an open state-of-the-art infrastructure and fostering access and use of data for collaborative brain science to help to translate the latest scientific discoveries into innovation in medicine and industry, for the benefit of patients and society.
- FLAG-ERA III (linked to HBP, ending 30/11/24) with its predecessors FLAG-ERA II (12/2016 11/2022) & FLAG-ERA (10/2013 11/2016) gathers most regional and national funding organisations in Europe with the goal of supporting the Future and Emerging Technologies (FET) Flagship concept and more specifically, the FET Flagship initiatives Graphene and Human Brain Project (HBP).
- **CSA BrainHealth** (ending 31/10/25) is an EU-funded Coordinating and Support Action to prepare for the future European Partnership for Brain Health. It aims to create a wide ranging and diverse brain health ecosystem to enable broad discussions and input into the preparation of the European Partnership and the development of a joint research and innovation agenda (EP BrainHealth SRIA) and implementation plan for the upcoming years.
- The **European Brain Research Area Project (CSA EBRA,** 11/2018 10/2022) was created as a catalysing initiative for brain research stakeholders (researcher, clinicians, people living with brain disorders, patients, governments, funders etc.) to streamline and better coordinate brain research across Europe while fostering global initiatives.

The European Partnership for Brain Health builds on these foregoing and existing initiatives, offering an umbrella for calls of current funding streams as well as adding new activities to bridge current funding segments and address new challenges and emerging needs. In addition to transnational funding calls, the future partnership will integrate best practice examples of cross-cutting activities of each initiative into a compelling portfolio (e.g. for foresight symposia, networking, capacity building, patient and citizen empowerment, health literacy, engagement of the private sector and healthcare system etc.), as described in section 3.

2.4.2 Type and composition of partners

The European Partnership for Brain Health will benefit from the partners already participating in the existing brain research initiatives and will be primarily composed of institutions and agencies that fund brain research in Europe.



At **country and regional level**, the existing partnerships have already enrolled funding bodies from many Member States, Associated Countries and Third countries. JPND and NEURON each have 30 participating countries, with many countries represented in both initiatives. These existing initiatives on brain health have gained recognition in Europe and beyond and their strategic and innovation agendas, transnational calls and international influence have created a visible and recognised European research area in the field of brain diseases.

Maintaining the availability of national and regional budgets for brain-related research is increasingly relevant, particularly in view of potential budget restraints under the challenge of several simultaneous crises. Therefore, the European Partnership for Brain Health strives to further enlarge to additional national and regional ministries and funding agencies in coherence with its enlarged scope. To start this process, the CSA BrainHealth has established the "Funders Forum" as a centrepiece. Representing the view of regional, national and private funding organisations, this forum is the pivotal hub for an inclusive and an interactive approach, when collecting commitments, aligning strategies and building the partnership for brain health. The Funders Forum is currently composed of more than 50 representatives of ministries and funding bodies from European Member States, Associated and Third Countries, including Canada, Israel, Norway, Taiwan, Türkiye, Switzerland, Ukraine, United Kingdom and USA The CSA pursues an inclusive approach, actively encouraging participation from not yet involved European and third countries, including those that do not yet have a specific brain health agenda. The national and regional focus and prioritisation for this extension process will be discussed further within the CSA BrainHealth; e.g. strengthening the collaborations with the USA as well as further extension to interested countries from the Australian, South American and Asian countries are identified targets.

Additionally, efforts will be made to boost the exploitation of research and innovation results by reaching out to other regional and national ministries, in charge of e.g. health, industry or employment policies.

This widening of thematic and geographical coverage within the partnership contributes to the ultimate goal of promoting and preserving brain health for everyone in Europe and worldwide.

In addition, collaboration with major **international funding organisations and global initiatives**, will be actively sought to foster strategic engagement and investments in brain research (see also section 2.3.2).

Next to national and international funding organisations and agencies, the partnership provides a major opportunity to seek advice from and collaborate with a broad range of **stakeholders** that integrate all the essential expertise that is needed to implement meaningful research and innovation activities, overcome existing hurdles and barriers for collaboration and support translation and implementation of research results into practice. These stakeholders include researchers (academic and research institutions, scientific associations, research organisations, research infrastructures, EP Partnerships, educational institutions), healthcare professionals (healthcare providers, professional associations), people living with brain disorders (patients, professional and informal carers, patient advocacy groups), industry (pharmaceutical and biotechnology companies, technology and instrumentation companies), regulatory agencies (e.g. HTA, EMA), funders (ministries, research funding agencies, foundations, public-private funding organisations, investors and venture capitalists) and policymakers (ministries). Within the CSA BrainHealth a "**Stakeholder Forum**" has been



established to integrate this broad range of stakeholder groups, keep them in the information loop and seek advice in the preparation process for the EP BrainHealth (e.g., in the consultation process for the SRIA development).

In the structure and governance of the future partnership, various levels of participation for the stakeholder groups are foreseen, e.g. as non-funding partners, third parties or stakeholders in the collaboration or networking platform (see sections 3.2. and 3.3). According to these different participation modes, stakeholders could fulfil a variety of roles and tasks, ranging from giving advice for the identification of research priorities, collaboration and alignment, implementation, cooperation in joint activities and active participation in the work programme and funding initiatives of the partnership including dissemination of results and communication activities.

More concretely, the following tasks bridging science, healthcare, policy and society could be envisaged:

- to enhance collaborative research and sharing of data and results (e.g., researchers, people living with brain disorders, healthcare professionals, industry, regulators, etc.);
- to contribute to the optimal exploitation of resources for the advancement of brain health research and innovation (European and global research infrastructures, European Health Data Space, industry);
- to form synergies, shared knowledge, and mutual recognition of planned work and results, fostering exchange of learnings and building competencies across the EU R&I landscape (closely related European partnerships and European missions);
- to strengthen links with overarching strategies (large European and global initiatives/organisations/associations representing researchers, people living with brain disorders, healthcare professionals);
- to develop evidence-based policies and strategies to promote brain health and improve the prevention of brain disorders including neurological and mental disorders (health and care authorities and policymakers, associations representing researchers, people living with brain disorders and healthcare professionals);
- to increase brain health literacy in citizens and health and care professionals (citizens, people living with brain disorders, healthcare professionals);
- to foster the translation of research results into successful innovations (innovators and private sector stakeholders, regulators, associations representing researchers, people living with brain disorders and healthcare professionals);
- to implement innovative solutions in the health system to increase wellbeing and quality
 of life for people living with brain disorders and their caregivers (healthcare professionals,
 people living with brain disorders including patients and their advocates, citizens and
 society as a whole).
- To contribute to the strong visibility of the future EP BrainHealth through the consortium's websites, social media, articles published in relevant magazines (e.g. Parliament Magazine) and organization of targeted dissemination events to liaise with:
 - EU and MS policymakers: e.g. European Brain Summit
 - Private sector: e.g. Brain Innovation Days, connecting researchers, clinicians and patients with the business world including brain-related industries (pharma, medtech, biotech), start-ups, SMEs and investors.
 - Patients: Patient organisations will be involved in all activities



3 Planned Implementation

3.1 Activities

To realise its overarching vision, the European Partnership for Brain Health identified seven operational objectives (see section 2.2.5), which are translated into concrete activities as follows:

• Development and implementation of annual work plans, including joint calls for proposals, priority setting for research and innovation

(Relates to operational objectives: **i:** Joint support of research and innovation (R&I); **ii:** Collaboration and strategic alignment across disciplines and countries, and global dialogue; **iv:** Improving translation of brain health innovations by bridging with healthcare providers, the private sector, regulators and policy-makers; **vi:** Capacity building in research and innovation).

Building on the joint strategic research and innovation agenda (EP BrainHealth SRIA) an implementation plan/roadmap to accomplish the objectives and expected impacts of the partnership will be established in a dialogue with the involved funders, researchers, patients and all relevant stakeholders (see above, section 2.2.6). To guarantee an inclusive approach, the complementarity of activities and to avoid unnecessary duplications with other initiatives of Horizon Europe, relevant stakeholders are involved in the priority setting, such as scientists, as well as patient representatives, the private and the healthcare sector. Sufficient and balanced resource allocation will be ensured. These joint funding actions will focus on transnational collaboration, improved translation, benefits for patients and society and capacity building for research and innovation. Furthermore, they will foster strategic alignment and synergies on European and international level. Measure to facilitate the search for international collaborators will be provided.

The partnership will establish several different joint transnational call formats:

- Transnational, Multidisciplinary Research Funding

Based on successful ERA-Net NEURON and JPND experiences, joint calls for funding transnational research projects in the field of brain health will be implemented. A wellestablished two-stage process, with a pre-proposal and full-proposal phase, will allow efficient call management and ongoing funding commitment. A peer review will ensure the promotion of scientific excellence and funding of high-quality research projects. According to the Responsible Research and Innovation (RRI) principles great attention will be payed to ethical considerations, i.e. in the conduct of research itself, e.g. in diversity and sex and gender equality at all levels (from animal experiments to cohort inclusion to equal access to care); and in community engagement and easier and open access to scientific results. Emphasis will be put on the participation of early career researchers in the projects to include fresh views and ideas and to strengthen research capacity for the future. Finally, the active participation of patients and patient advocacy organisations in all phases of the research projects will be central to generate meaningful impact for society. The funding organisations participating in the calls will be engaged in developing the call topics based on the priorities set in the SRIA and the partnership's implementation plan/annual work plans. To refine the call topics, input by scientific experts in the respective research fields, patient representatives as



well as by the Scientific Advisory Board and relevant stakeholders of the partnership will be sought via joint symposia.

- Working Group Calls

Working Group calls are designed to foster interdisciplinary networking interactions among experts on strategic topics and current and future challenges in the field of Brain Health. They shall identify research gaps, identify and increase the potential for translation and implementation, identify meaningful outcomes, form synergies, promote exchange between actors, help to avoid duplication and increase harmonisation of data and protocols in the field of brain health. They aim to connect different key players in brain health (healthcare professionals, clinicians, researchers, data experts, social science and ethics experts, industry/private sector, patients and their families and carers), to exchange, share knowledge, align resources and maximise existing and future efforts. This type of call will foster the development of position papers, guidelines and recommendations, and best practice frameworks to identify key questions and potential solutions to overcome barriers related to brain health research and innovation. Working group calls will create synergies through new collaborations e.g. for knowledge exchange across sectors. Furthermore, these calls can potentially bridge the gap between research and market-access by fostering exchange and collaboration between all relevant actors. Companies of all sizes (start-ups, SMEs, large pharmaceutical companies) may use this vehicle to offer additional and complementary input on diverse aspects including but not limited to availability and development of digital applications and novel technologies, drug repurposing as well as feedback on needs and difficulties of the market. Furthermore, dialogue and cooperation with key transnational and national regulatory agencies could be established to contribute to the harmonisation of the health care systems. In addition, through working group calls, the partnership will foster the participation of underrepresented countries in new and existing research networks and consequently in future consortia funded via JTCs.

- <u>Transnational, Multidisciplinary Research Funding for Ethical, Legal, and Social/Societal</u> Aspects (ELSA) related to Brain Health (ELSA calls)

Another set of collaborative research projects will be funded through joint transnational calls for projects in the area of Ethical, Legal and Social/Societal Aspects (ELSA) related to brain health. Brain health research is a highly sensitive field that requires an interdisciplinary discourse among e.g. humanities experts, social scientists, legal experts, and neuroscientists. Current technology developments such as brain-computer-interfaces, brain stimulation, virtual reality, and brain organoids, or new methods for early disease prediction give rise to questions of trustworthiness of neuro-technologies and their limitations, (risk)communication and informed decisions. Interdisciplinary, international, and intercultural exchange is crucial to find acceptable solutions for individuals and societies. The ELSA calls will foster the required interdisciplinary approach through research projects with high societal impact. This area is yet to be established in all national and regional strategies. By investments of a potential subgroup of funders, awareness for this highly relevant field will be raised in the entire partnership and likely increase future engagement of additional partners.



- <u>High risk – high reward calls</u>

With this new funding instrument, highly innovative translational research with transformative potential but associated with a certain level of risk shall be funded, with the aim to foster disruptive research results and to support emerging new researchers with innovative ideas. With this tool, highly innovative research approaches shall be supported e.g. to generate the necessary preliminary data to establish a new concept and ask for larger grants (e.g. JTCs). The targets could comprise completely new concepts based on limited preliminary findings, newly appointed PI (new lab and topic separation from mentor), or a PI attempting to change fields. The high risk will be mitigated by including a small number of funding countries, limited funding (e.g. half of regular budget for calls for translational research projects JTCs), for a limited time (e.g. 2 years).

- Joint actions with industry

The EP BrainHealth aims to strengthen the ties between academic researchers, clinicians and industry. For this, the establishment of collaborations with industry driven initiatives (such as the public-private institutionalised partnership Innovative Health Initiative (IHI) and EIT Health) and a dialogue with industry representatives (e.g. EFPIA) is envisaged, with the aim to develop innovative approaches that are broadly applicable. The EP BrainHealth will align strategies with regional and national industry by funding transnational research and innovation projects in dedicated innovation calls. These will enable translation of research results into innovative applications to ultimately facilitate the translation and uptake of brain health approaches into new solutions and technologies.

More funding formats may be developed in the course of the preparation of the partnership. The different calls will be open for joint funding from EP BrainHealth partners as well as additional regional and national funders in the field of brain health, including third countries to Horizon Europe ("ad hoc funders" see section 3.3.1). The EP BrainHealth will strive to increase funding partners' participation beyond the predecessor initiatives, NEURON and JPND. Furthermore, the partnership will enable and increase the participation of underrepresented countries by the employment of a set of widening instruments, particularly within the joint funding actions. To this end, national ambassadors may be installed and networking tools established to ensure active participation in the partnership of as many countries as possible.

• Networking Events (conferences, workshops, networking and outreach events, round tables) to foster knowledge exchange

(Relates to operational objectives: **ii:** Collaboration and strategic alignment across disciplines and countries, and global dialogue; **iii:** Facilitating the use of EU infrastructures and platforms and improving brain health data access, sharing and harmonisation; **iv:** Improving translation of brain health innovations by bridging with healthcare providers, the private sector, regulators and policy-makers; **v:** Involving and empowering citizens and people living with brain disorders; **vi:** Capacity building in research and innovation).

The partnership envisions strong support for and exchange between multidisciplinary research and innovation projects and all relevant stakeholders (e.g. scientists, industry, regulators, health care providers, and patient representatives). Furthermore, alignment will



be sought with other regional and international initiatives including other European Partnerships (e.g. Rare diseases; Personalised medicine; Transforming health and care systems; ERA for Health, Partnership for the assessment of risks from chemicals), European research infrastructures (e.g. ECRIN, ELIXIR, EATRIS, BBMRI, EU-OPENSCREEN, EBRAINS, EURO-Bioimaging, etc...), European clusters (e.g. Prevention of severe mental disorders, TRISOMY21, PREMOS, BRAINFOOD, etc...), EIT Health and the European Medicines Agency (EMA). These activities will take the form of networking events such as world cafés, round tables, conferences, dedicated education or training activities among others. The expected outcome is to build trust, increase exchange, and reflect on relevant aspects among professionals leading to new collaborations and identification of potential alignment actions in the field of brain health. Special emphasis will be given to identify ways to increase investment and venture creations in the future, and how to accelerate a successful implementation in different healthcare systems across regions and countries.

Dissemination, communication, education

(Relates to operational objective: **v:** Involving and empowering citizens and people living with brain disorders).

The research results funded by the partnership will be disseminated within the scientific community as well as with relevant users and stakeholders, including policy makers, people living with brain disorders, including patients and their organisations and the interested public. An approachable, barrier free, and laymen comprehensible website will keep the interested lay and expert audience informed about events, news, research results and main achievements of the EP BrainHealth. The partnerships social media channels will allow for direct interactions between scientists and the interested public. By this, a high visibility of the European Partnership for Brain Health will be ensured and new partners and stakeholders can be engaged to increase impact of the partnership.

Patients and patient advocacy groups are engaged at various levels of the EP BrainHealth, e.g. they contribute to priority-setting, reviewing funding applications and on project level, they support the design of research studies, dissemination and research uptake. To strengthen this link, the EP BrainHealth will establish a set of patient enabling activities, e.g. patient reviewer trainings, increasing patient literacy and fostering their active participation in the partnership.

Furthermore, the EP BrainHealth will pay special attention to encouraging the widespread dissemination of research results among civil society. Dialogue among scientists and the interested public will be fostered to empower citizens with knowledge concerning their own health, to make science approachable, to (re)build trust and to promote brain health literacy. For this EP BrainHealth will share information with the interested public to disseminate research findings in an accessible manner; educate them about the benefits of joining registers, cohorts and trials; spread societal acceptance and reduce stigma associated with certain syndromes and conditions. On the other hand, EP BrainHealth will welcome public input through open dialogue to stay abreast the citizens' needs throughout the lifetime of EP BrainHealth. This could take the form of educational activities, patient enabling activities, innovative formats (such as short video interviews and debates about controversial topics) and open for a or consultations (surveys, webinars,



Q&A sessions). For this the integration of social sciences and humanities in the partnership will be crucial.

Brain health data, knowledge and resource hub

(Relates to operational objectives: **iii:** Facilitating the use of EU infrastructures and platforms and improving brain health data access, sharing and harmonisation; **vi:** Capacity building in research and innovation).

Brain health research is increasingly data driven, making easy access to clinical and preclinical data with the required level of standardisation, curation and metadata for longterm storage and re-use critical, particularly in the context of the development of AI for data processing.

The Partnership plans to employ mapping exercises and gap analysis with additional key initiatives at the European level, including EBRAINS, ECRIN, ELIXIR, EATRIS, BBMRI, EU-OPENSCREEN, EURO-Bioimaging, and other RI worldwide. The objective is to improve efficiency and trust in data science by increasing collaboration and coordination between RI, within the framework of the European Open Science Cloud (EOSC) and other ESFRI computing and digital infrastructures. Within the EP BrainHealth, EBRAINS is a cornerstone by providing a unified platform for sharing, integrating, and analysing brain data, thereby enabling researchers across Europe to collaborate more effectively. Furthermore, the EP BrainHealth will identify aspects how to facilitate the use of existing infrastructures while working out, which tools would make the existing infrastructures more usable.

The Partnership plans to create a knowledge and resource hub to facilitate and improve data sharing, the establishment of data standards and protocols, data interoperability, and harmonisation. To this end, the research community will be encouraged to use existing data infrastructures. Workshops, surveys and webinars could serve to receive feedback from and to educate the community.

The EP BrainHealth will strongly require data management plans (DMPs) and open access data, as well as the adherence to the FAIR data principles. For this, a knowledge hub on the website and workshops/trainings are envisaged. The joint calls will encourage the exploitation of responsible data reuse, including the use of data repositories and European infrastructures, and harmonisation to produce new research results. The EP BrainHealth recognizes the crucial need for the acquisition of standardised, structured and wellannotated health data and will contribute to the implementation of the European Health Data Space (EHDS). This is essential for the immediate use of data, as well as for further secondary mining in cross-centre or longitudinal studies. An additional challenge is the integration of clinical healthcare data with real-world data to provide a comprehensive view of a person's experience, encompassing both physiology and quality of life aspects. Thus, intense communication efforts between researchers, medical practitioners, policymakers, and the public are envisaged to build trust among citizens and guarantee data privacy and accessibility in the process of digitalisation. Special attention will be payed to the inclusion of gender, social and ethnic backgrounds in cohorts and databases, data gaps in this regard will be identified. Moreover, any prejudice or stigma that may come from the release of health-related information (e.g., genetic risk of developing a brain disorder) should be assessed beforehand to limit negative societal outcomes.



Quality and responsibility in research knowledge and resource hub

(Relates to operational objectives: **i:** Joint support of research and innovation (R&I); **ii:** Collaboration and strategic alignment across disciplines and countries, and global dialogue; **iii:** Facilitating the use of EU infrastructures and platforms and improving brain health data access, sharing and harmonisation; **iv:** Improving translation of brain health innovations by bridging with healthcare providers, the private sector, regulators and policy-makers).

Fostering responsible research and innovations (RRI) actions in an inclusive, impactful, and sustainable manner is central for the EP BrainHealth. To reduce fragmentation and bundle information in this area a quality in research knowledge hub will be formed. Existing and new measures are collated here, which may comprise templates, workshops, webinars, best practices and guidelines on various aspects of quality in brain health research, such as standards in the design of (animal/biomedical) research, meaningful patient involvement, quality assurance, openness, regulatory issues, integrity and reproducibility, translation, sex, gender, and generally equity aspects in brain health research, intellectual property rights issues as well as social and ethical aspects in the field of brain health research.

• Support actions for early career researchers (schools, trainings, webinars, prizes, networking ...)

(Relates to operational objectives: **iii:** Facilitating the use of EU infrastructures and platforms and improving brain health data access, sharing and harmonisation; **vi:** Capacity building in research and innovation).

Promoting capacity building through promoting early career researchers, training and exchanges will eventually improve the competitiveness of the overall European scientific community in the field of brain health The EP BrainHealth will build on the existing measures of the predecessor initiatives, e.g. summer/winter schools, webinars, workshops, awards and mobility grants, as well as develop additional support formats. It will benefit from the pan-European GEANT Research and Education network and its services⁵⁰. In addition, excellent young investigators will be integrated in the strategic work of the partnership, e.g. as members of the SAB or collaboration platform, bringing in emerging views and advocating for the needs of early career researchers. Training scientists, and particularly the next generation of scientists, is integral to shaping the future of brain health research. Trainings on cross-sectional issues, such as reproducibility in research, open science including data and instrument sharing, use of new technologies and software, available research infrastructures, patient engagement, bench-to-bedside research as well as inclusion and diversity in science will be particularly encouraged. Increased recognition of early career researchers' achievements (e.g., through excellent paper in brain health award, explain your project video competitions) will contribute to their motivation.

• Commissioned studies and surveys

(Relates to operational objective: **iv:** Improving translation of brain health innovations by bridging with healthcare providers, the private sector, regulators and policy-makers).

A major issue in enabling progress and innovations in a certain field is that often the best solutions are not obvious. Often there is no clear information or even consensus on the

⁵⁰ GÉANT (geant.org)



needs, gaps and bottlenecks for implementation and the best way forward, i.e., alignment in these questions is crucial. Surveys and commissioned studies among people living with brain disorders and patients, caregivers, healthcare professionals, providers and payers, ministries as well as researchers from biomedical and social sciences and/or humanities will be an effective tool employed by the partnership to map and clarify such aspects in order to improve annual work plans and impact. To design, conduct and analyse the results of surveys and studies, dedicated calls could be installed.

• Ensuring management and coordination, including monitoring activities.

The EP BrainHealth requires, and will have, a comprehensive coordination and management structure to guarantee appropriate, inclusive, transparent and flexible governance, programme management and a smooth information flow as well as cooperation within the partnership, with other related initiatives and the diverse stakeholders. The activities described above will be coordinated and managed by the partnership through dedicated work packages and governance bodies including wide representation of EP BrainHealth partners (see section 3.3).

A transparent, relevant, and reproducible monitoring process within the various activities and organisational units of the partnership, incorporating learning cycles into the decision-making process will be created, ensuring flexibility of the implementation. Indicators and methods for monitoring the partnership's progress towards its objectives and impact will be harmonised and aligned with the Horizon Europe monitoring framework and its Key Impact Pathways and Key Performance Indicators.

This list of activities may be further elaborated in the course of the evolution of the EP BrainHealth proposal and will be addressed in dedicated work packages.

3.2 Resources

The European Partnership for Brain Health capitalises on the networks and the trust built in the predecessor initiatives. Thus, an engaged pool of funding partners and stakeholders, engaging with public and private brain health community in fundamental, translational, and clinical research as well as in the ELSA field is in place. Within the CSA BrainHealth, a Funders Forum was established, comprising > 50 ministries and public and private brain health funders from Europe, North-America and Asia. This ensures a solid basis for a more inclusive and broader partnership that is well-positioned to implement a wide range of activities with considerable national commitments to create impact.

ERA-Net NEURON, JPND, EBRA, EBRAINS and the CSA BrainHealth, have established a multitude of contacts and collaborative networks, especially for the internationalisation and expansion of the partnership's activities. These networks merged synergistically in the partnership to increase collaboration and fulfil its objectives.

The predecessor initiatives have established partnering tools, public project directories, social media appearances with high numbers of followers and websites, on which the partnership can build upon to engage a broad research community in the joint calls and other activities. Furthermore, multiple strategic publications such as the NEURON Strategic Research



Agenda⁵¹, the JPND Research and Innovation Strategy⁵², the EBRA Shared European Brain Research Agenda¹⁹ and the EBRA landscape analysis are fruitful sources for the development of the EP BrainHealth SRIA and the implementation of activities, in particular joint transnational calls.

To achieve the defined objectives and impact, all partners of the EP BrainHealth are and remain committed from the preparatory phase (i.e. CSA BrainHealth, EP BrainHealth SRIA, proposal preparation and submission), via the official start until the end of the envisaged duration of the EC funding and beyond. Financial commitments for the transnational research projects and other activities will be necessary. In addition to the national and EU budget, participating partners may additionally contribute in-kind, e.g. by hosting events or support to carry out activities (summer/winter schools, webinars, workshops, surveys). The partnership will aim at long-term funding commitments of members but remain open to annual funding commitments in joint transnational call activities. Partners of the EP BrainHealth will participate along their expertise and available resources.

A non-binding survey was conducted amongst potential funders (a total of 53 members of the Funders Forum were asked, 32 responded). It revealed that for the majority of them it will be important to receive financial support for their participation in the partnership, e.g. reimbursement for management in form of personnel costs and for travel expenses for internal meetings. The role and commitment (budget and time invested) of each partner/beneficiary in the EP BrainHealth has to be clearly defined at the beginning of the partnership.

Partners of EU Member States and Associated Countries are eligible to receive EC contribution for research funding in the form of top-up, when participating in calls co-funded by the EC. The partnership will seek participation of all European countries, several of its regions and international funders. International partners and non-beneficiaries will also be encouraged to join as funders of calls to be launched within EP BrainHealth. Integrating new partners over the course of the EP BrainHealth will also be possible, while the overall structure will not be impacted.

Before the start of the partnership, partners will agree on a common brain health strategic and innovation agenda (EP BrainHealth SRIA) and initial implementation of activities helping to align European, regional, and national strategic agendas and research priorities in the field of brain health. The expected impact of joint actions for the regional/national research communities is high and includes the establishment and maintenance of transnational collaboration also with non-European countries, the promotion of research dedicated to brain health and support of innovative research. The EP BrainHealth aims to be a global leader through its joint transnational coordination and funding efforts.

The currently active networks, ERA-Net NEURON and JPND, fund transnational research consortia with an overall volume of approximately 25M€ per year (including four co-funded calls). EBRAINS supports the development of digital brain research and data management at the European level with an amount of 15M€ per year (EBRAINS2.0 and other sources). With more participating funding organisations, an even larger total budget for EP BrainHealth is expected. A non-binding survey amongst potential funders revealed that the majority of them generally plans for a participation in Joint Translational Calls within the future partnership and

⁵¹ ERA-NET NEURON Strategic Research Agenda

⁵² JPND Research and Innovation Strategy



is interested to actively contribute to work-packages. More than two thirds of the funders predicted an equal or even increasing trend for funding commitments compared to the predecessor initiatives in the future. Building on past experience up to two joint transnational calls for multinational and translational research projects per year and additional calls, e.g. ELSA (on a non-annual basis) can be envisioned. The EP BrainHealth will be designed for a tenyears runtime. The first seven years will be devoted to a mix of transnational funding and crosscutting activities, and the last three years are reserved for cross-cutting activities and completion of the funded transnational projects.

3.3 Governance

With its dedicated partners, the EP BrainHealth will provide a framework to initiate and support brain health research, communicate and exchange on funding and implementation, align strategies, educational activities, and policy development and dissemination. The partnership aims at involving organisations from all European countries as well as global partners (see chapter 2.4.2). This will allow for the alignment of research and funding activities at the European level and beyond.

3.3.1 Modes of participation

Different modes of participation within the EP BrainHealth will be possible to provide tailored solutions to best engage all relevant partners to their desired level of commitment (see figure 4). In this way an inclusive partnership is formed, in which all relevant stakeholders (e.g. funders, patient organisations, industry representatives, infrastructures, ...) can be included and represented appropriately. On the other hand, leverage for restriction to enter the partnership is provided. In this way the number of partners and the size of the partnership remains meaningful and manageable.

The core of the EP BrainHealth are the Partners, who have voting rights in the Governing Board as the main decision-making body. This group comprises the Funders (funders from MS, AC), Third Country Funders (funders from non-EU, so-called Third Countries), and Non-Funding Partners, which are essential stakeholders to be included under certain conditions (substantial contribution e.g. as work package leads, complementary expertise and/or in-kind contributions).

In addition to the Partners there are Third Parties. These are also stakeholders (like the Non-Funding Partners), however they only sign the Consortium Agreement (not the GA), have no seat or voting rights in the GB and have less reporting duties. An active participation in the workplan, however to a lesser amount as for Non-Funding Partners, is also obligatory for them. They may have an observer role in the GB, if beneficial.

Lastly, there will be the option for other institutions, which do only strive for a loose connection to the EP BrainHealth (no legal binding, no possibility to shape the EP BrainHealth strategy, no active contribution to the workplan) but which want to stay informed and connected on ad hoc basis via the EP BrainHealth ecosystem, such as Ad Hoc Funders or Stakeholders. The majority of potential funders agrees with the different modes of participation described above and depicted below.



Ad-hoc Funders EP BrainHealth Consortium (sign Consortium Agreement) · From MS/AS/third EP BrainHealth Partners (seat in the Governing Board) countries not participating in EP Third Parties Third Country consortium **Funders** • Participate in **Partners** Sign the CA only May receive funds for work in WPs (tbd in CA) selected calls (sign MoU) Have voting right in projects • Receive funds for work in CSC Substantial work in WPs (e.g. WP lead obligatory) Percentage of Stakeholders projects) • May work in WPs • Sign the GA partners May be allowed as observers in GB E.g. stakeholders with which a close collaboration is • Exchange and advice · Do not receive funds · Do not sign the GA Do not work in WPs

Figure 4: Modes of participation in the EP BrainHealth

3.3.2 Decision-making bodies

The governance of EP BrainHealth includes a strategic, an advisory, and an operational level (see figure 5). The different bodies are outlined below. The governance structure described is based on joint discussions within the CSA BrainHealth consortium, the General Assembly (including the Funders Forum) and on feedback from a survey amongst potential funders. Potential funders, generally agree with the governance model described.

The concrete functioning, main tasks, and working processes will be elaborated in the further preparation and is subject to discussions with future partners of EP BrainHealth.

Governing Board

The Governing Board (GB) will be the highest decision-making body for general strategic decisions central to achieve the defined vision and objectives of the EP BrainHealth.

Each partner will have two seats (main/proxy) in the GB. It shall be strived to take all decisions by consent. If a consent is not possible, a voting system will be established (e.g. 2/3, Quorum 50%). To guarantee a balance between countries, each country will have one vote, also in case if several funders come from the same country. In this way, several organisations from one country will have to form a common position. The formation of national mirror groups is recommended to facilitate the formation of consented views per country. Additional rules may be set when voting is needed. Depending on the number of non-funding partners, the possibility of a blocking vote of funding partners may be considered in the terms-of-references.

The coordinator of the partnership takes up the position of the chair of the GB for the first 2 years of the partnership to guarantee continuity and consistency. After this, the chair will be elected in regular time intervals (with the possibility of re-election of the coordinator).



Furthermore, a vice chair will be installed. The vice chair will be an alternating position and elected by the partners.

Observers are allowed in the GB and are standing members without voting rights, e.g. chairpersons of Scientific Advisory Board or representatives of the collaboration platform (e.g. in case patient organisations are not included as Partners, they should have a permanent observer seat in the GB). They can bring their ideas/viewpoints to the discussion, but are not entitled to vote. Additional observers are allowed to the GB meetings on demand and by explicit invitation.

The GB shall meet in three annual meetings (ideally two physical and one online). Learning cycles will be incorporated into the decision-making process to re-adjust activities towards the objectives of the partnership.

Call Steering Committee

The Call Steering Committee (CSC) is a subgroup of the GB. It will be formed for each joint call/funding activity and composed of those members taking part in the joint call (cf. 'variable geometry' principle), as well as additional partners outside the GB, who may join a joint transnational call on ad hoc basis. The call steering committee shall decide on the topic of the joint call, oversee the evaluation process, and monitor the activities of the Joint Call Secretariat. Decisions in the CSC are taken by consent. If a consent is not possible, a voting system shall be established. For decisions taken in the Call Steering Committees, each funding organisation will have one vote (in contrast to one vote per country for highest strategic decision taken in the GB), since these decisions concern the budget and funding strategies from individual organisations.

To guarantee compliance, the CSC meetings are closed. Only research funding and no research performing organisations are allowed in the CSC. Any potential conflict of interest will be decided within the CSC. Other funders not participating to the specific call may be allowed to attend as observers upon consent of the CSC. In co-funded calls, an observer of the EC will be invited to the CSC meetings.

3.3.3 Executive bodies

Coordination Office

The Coordination Office (CO) establishes the communication channels and formats between consortium partners, for reporting to the EC and serves as contact point and information hub for internal and external relations. It supports partners in budgetary and administrative matters, cross-cutting discussions, and synergies. The CO will prepare agendas, meetings, and minutes. It ensures compliance with rules and good practice principles of European Partnerships, a smooth implementation of the partnership, and efficient internal and external communication. For this, day-to-day business decisions will be taken by the CO. The CO ensures that all activities regarding research funding are compliant by building a firewall around those activities to avoid any potential conflict of interest.

Executive Board

An Executive Board (EB) will be installed to oversee and coordinate the activities in the work packages (WPs): it will be composed of the work package leaders and the CO. This board will



meet regularly e.g. in online meetings every 2 months to discuss the progress in the WPs. While central strategic decisions will be made by the GB, operational decisions with overarching scope in between the work-packages can be made by the EB in accordance with the SRIA and to achieve the EP BrainHealth's vision and objectives. In this way the alignment of the work in between the work-packages is guaranteed. Day-to-day business decisions will be taken by the WP leads.

The EB will implement and organize follow-up activities for the GB decisions and provide support and advice to the CO regarding solutions to any emerging questions, preparation of the GB meetings, i.e., contribution to the elaboration of agendas, and review of the meeting documents.

The EB will manage and create transparent, relevant, and reproducible monitoring processes within the various work packages. This will help to track progress towards the objectives envisioned in the partnership and provide evidence showing their contribution to the partnership's goals and the EU's policy objectives. The monitoring function will fulfil the requirements on common indicators and data structure for the EP BrainHealth monitoring and the biennial monitoring reports in Horizon Europe.

Joint Call Secretariats

The Joint Call Secretariats (JCS) will manage the entire traffic of documents (proposals, evaluation reports, etc.) and act as the central communication point between applicants, reviewers, and funders in joint calls for research funding. If problems are identified in funded consortia at any stage, the JCS will contact the respective funder to find appropriate measures to support the researchers. Funders, in turn, will inform the JCS if they encounter major administrative or funding problems.

Responsibility for the JCSs will alternate between partners of EP BrainHealth. Standard operation procedures (SOPs) for the harmonization across Joint Call Secretariats will be elaborated, verified, streamlined, and updated.

The JCS will ensure suitable call operations, follow-up, and monitoring. Furthermore, the JCS encompasses formulating call texts that follow the partnership's overall strategic focus and consider synergies and alignment with other (European) initiatives and overarching strategies.

3.3.4 Advisory bodies

Scientific Advisory Board

In the set-up phase (first two years) of the EP BrainHealth the scientific advisory board (SAB) will be partially comprised of the SAB of the CSA BrainHealth to ensure a smooth transition and timely set-up of transnational calls. SAB members will be proposed by the EB based on their scientific knowledge and reputation. They will be approved and mandated by the GB. The SAB will be half renewed every two years, unless specific needs for additional expertise are identified. In this way, SAB terms are rolling and overlapping. A chair and a vice-chair will be installed by the GB. Collectively, the SAB shall cover the entire thematic spectrum of the EP BrainHealth, use a trans-disciplinary approach, cover the diversity of methodological and paradigmatic approaches, be balanced with regard to gender and geographical spread and have experience with applied research and research policy. 12-18 members are envisaged.



The Collaboration Platform

This platform includes closely related initiatives (e.g. Public Privat Partnerships, European Partnerships, European Missions, the private sector and patient associations, healthcare system representatives, global initiatives etc.). A close collaboration and exchange, e.g. in joint workshops, is sought here, to build relationships and partnership networks and foster synergies with existing structures. Knowledge will be shared, aiming at mutual awareness and recognition of planned work and results, fostering the exchange of learnings and building competencies and synergies across partnerships. This will contribute to coherence and synergies with the EU R&I landscape. Dedicated sub-boards may be established, e.g. a patient advisory board. In this way, the different stakeholder groups can speak with one voice to the GB and the GB is able to address them as a group.

The Networking Platform

This platform is a flexible format for a heterogeneous group of stakeholders. It mainly serves to inform the stakeholders or seek their advice on an ad hoc basis. The Networking Platform will address a wide range of goals and activities of the partnership, ranging from community and citizen engagement, communication, and dissemination measures and more. The Networking Platform will increase the overall impact of funding and other activities, e.g. by considering the necessary range of needs and collecting a diverse range of perspectives (such as researchers, practitioners, consumers, prosumers, industry, etc.), by fostering the exploitation of projects results, and by accelerating transformation of the research and innovation system and the adoption of outcomes in the healthcare framework.

3.3.5 European Commission

To enable a coherent strategic focus of the EP BrainHealth with EC policies, the EC representatives is involved in the governance as a partner, thus having two seats (main, proxy) and one vote in the highest strategic decision-making body, the Governing Board. This allows to efficiently address high-level policy objectives. The strategic coordination and management processes will be handled in close cooperation with the EC. A regular meeting with the EC, the CO and if required individual work package leaders (reflection group meetings) will be installed to discuss the direction of the partnership strategy and to ensure that the EC representatives are informed and involved in aspects of strategic importance to the EU.



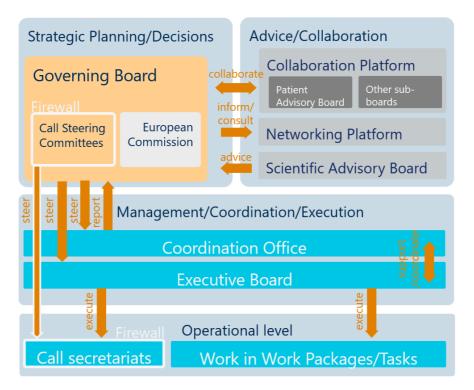


Figure 5: Governance of the EP BrainHealth

3.4 Openness and transparency

The EP BrainHealth will maximise its impact by involving all relevant organisations in its structure as partner or stakeholders, aiming to broaden participation beyond current core partners. The details on the involvement of partners and stakeholders will be elaborated in the course of the EP BrainHealth proposal.

The partnership will be open for new collaborations and the integration of new partners during its lifetime and across different activities. EP BrainHealth will foster openness and transparency on three different levels by:

- Creating synergies and dedicated communication and dissemination channels
 - EP BrainHealth will develop communication and dissemination strategies tailored to different audiences among the key stakeholders and players. Furthermore, it will implement and maintain an information channel through a dedicated partnership website and social media, enabling information to be shared about work plans, outputs such as protocols, data, and results, as well as strategic developments and other outcomes. Promotion of dissemination of research outcomes from projects.
- Promoting open science in funded research projects (joint funding activities)

 EP BrainHealth plans to integrate recommendations for open-access publication and openness and transparency for results obtained during the joint funding activities that will have to follow the FAIR principles. Explore activities to actively engage researchers in harmonisation and data reuse to produce new knowledge



Developing recommendations around openness and transparency

Sharing of strategic documents and outcomes of the partnership are key success factors in achieving the implementation and acceptance of EP BrainHealth approaches. Transparency and communication are thus needed for successfully translating research into clinical practice but also for improved literacy and participation of citizens, people living with brain disorders, patients and healthcare providers, e.g. for a better understanding of diagnostic and treatment options and towards future prevention. Furthermore, dedicated communication with higher authorities is needed to allow and enable a future uptake of brain health strategies in regional and national healthcare systems.

• Promoting equality, diversity and inclusion in the brain health research culture (EDI principles, anchored amongst others in the charter of fundamental rights of the EU, 2021/2009)⁵³. Foremost on the level of joint calls for research projects, all applicants should have the same chances and rights, independent of their socio-economic background, gender, ethnicity, disabilities, care duties etc. Discriminatory effects, e.g. through structural or social barriers, will be avoided. Furthermore, when designing joint funding actions, attention will be payed to not exclude certain dimensions in research questions, e.g. race, ethnicity, sex, gender, socio-economic background, etc. Research questions should consider aspects to promote equity, e.g. accessibility, affordability, sustainability, and diversity. Within the EP BrainHealth, an inclusive environment on every level will be created, while acknowledging diversity and equal opportunities.

With the inclusion of a broad variety of European countries, international partners as well as the high-level participation of ministries, the EP BrainHealth will foster cross-border collaborations with the goal that citizens, people living with brain disorders and patients will benefit from the most suitable preventive, treatment and care options available regardless of their home region/country, social status or gender. A high level of openness and transparency regarding a common vision will be achieved by EP BrainHealth thanks to the involvement of international organisations and stakeholders from different sectors.

Creating synergies is one essential objective of the partnership including consultations with the brain health community around the entire value chain and engaging with new organisations to participate in activities, while adding value to the partnership. As there are different levels of participation, involvement of external stakeholders is possible anytime, will be actively pursued and is highly welcome.

EP BrainHealth seeks the involvement of all EU Members States and regions and international partners, as well as related initiatives and others via the Networking Platform to integrate their perspective and include all relevant key players that could benefit from the partnership's outcome.

Considering the long run time and a steadily advancing brain health environment, the EP BrainHealth will act dynamically, adjust its focus areas over the time of the partnership and take advantage of emerging opportunities during the lifetime of the partnership. By following well-defined annual work plans while simultaneously being responsive and allowing a level of flexibility, EP BrainHealth will adapt approaches to the key bottlenecks for brain health improvement as they evolve.

⁵³ EDI strategy, European Union Agency for Fundamental Rights (2021/2009)



4 Annexes

4.1 SRIA process

The structures and content of the SRIA have been generated based on existing strategic documents, and other available information such as published position papers. Additionally, the document benefited from the input of the scientific advisory board (SAB), the project steering committee (PSC) and the CSA BrainHealth stakeholders. Several successive steps were followed to finalize the SRIA.

1. Analysis of previous actions and key publications/statements

The SRIA structure was based on multiple sources.

- Several EU-funded projects and initiatives in the brain health field have developed their own strategic agendas. This includes JPND, the ERA-NET NEURON, HBP and IMI/IHI. Recently, the CSA EBRA also produced the Shared European Brain Research Agenda (SEBRA). These documents, analysed in a comprehensive report published by the CSA⁵⁴, represent the foundations of the SRIA of the EP BrainHealth.
- These documents were supplemented by an analysis of recent consensus publications in neurology and psychiatry published in top-tier journals (reported in the SRIA bibliography).
- In addition, a survey was launched by EBC to identify national and regional priorities among EU countries to identify possible topics not yet identified but of possible interest to the funders. Results of this survey (EBC/ZonMw) were added to the CSA report⁵⁴.
- Finally, a systematic search of national plans in the field of BrainHealth was carried out by ANR to map current national research priorities and understand similarities/disparities at the European level⁵⁴.

Based on all these documents, a table of content of the SRIA was generated by the drafting group (DG), composed of partners of the CSA, with the additional expert contribution of the European Alliance for Social Sciences and Humanities (EASSH).

2. Writing of the first draft of the SRIA by the DG

Writing of the different chapters of the SRIA were assigned to DG participants based on their own expertise. INSERM and ANR consolidated the first draft of the SRIA. Written comments from all participants of the DG were requested and they were discussed collectively during a videoconference to generate a first version of the SRIA.

3. Input from SAB, industry and project steering committee (PSC)

- The first version of the SRIA was shared with the SAB on May 6th, 2024, and a videoconference organized on June 3rd, 2024. All comments were considered by the writing group, and bilateral exchanges were organized between INSERM/ANR and SAB members upon request.
- The first version of the SRIA was shared with the industry-related think tank on May 6th, 2024, and a videoconference organized on June 6th, 2024. All comments were considered

⁵⁴ <u>Analysis Report</u>: Achievements, synergies and challenges of previous and ongoing initiatives in the Brain Health area, surveys and national roadmaps



by the writing group, and bilateral exchanges were organized between ANR and think tank members upon request.

• All versions of the SRIA were sent to PSC for consultation, and their comments incorporated at each step of the process.

4. Stakeholders consultations

The first version of the SRIA was sent to Stakeholders by EBC on May 8th, 2024, with a survey to gather their overall feedback as well as their detailed comments. Results of this survey were analysed by ANR and added to the SRIA.

5. Public consultations

An online public consultation takes place between July 8, 2024, to August 21, 2024. Written answers to the comments are prepared by the DG. They will be attached as an annex to the SRIA.

6. Validated SRIA and public answers

The SRIA and the answers to the open consultation will be adopted by the PSC in September, 2024 and published online in October, 2024 on the CSA BrainHealth web site.

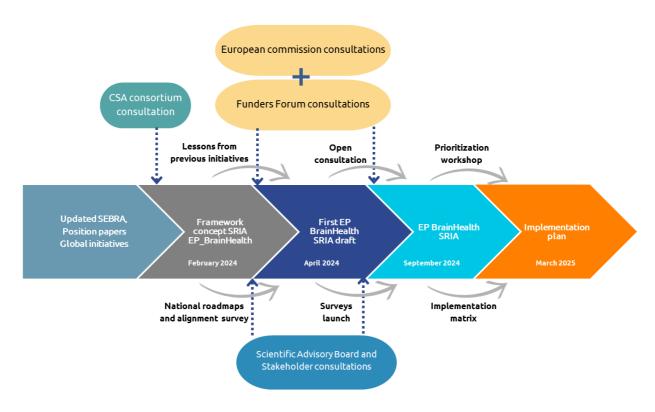


Figure 5: SRIA Process at a glance



4.2 List of Abbreviations

AC	Associated Countries
AMR	Antimicrobial resistance
ANR	Agence nationale de la recherche
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail
BBMRI-ERIC	European research infrastructure for biobanking - European Research Infrastructure Consortium
BMBF	Bundesministerium für Bildung und Forschung (German Federal Ministry for Education and Research)
СО	Coordination Office
COCIR	European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries
CSA	Coordination and support action
CSA EBRA	Coordination and support action for a European Brain Research Area
CSC	Call Steering Committee
COP28	28 th Conference of the Parties
DALYs	Disability-adjusted life years
DG	Directorate-general
DG CNECT	Directorate-General for Communications Networks, Content and Technology
DG EAC	Directorate-General for Education, Youth, Spot and Culture Directorate-General for Employment, Social Affairs and Inclusion
DG EMPL DG ENV	Directorate-General for Employment, Social Affairs and inclusion Directorate-General for Environment
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG JRC	Directorate-General for Internal Warket, Industry, Entrepreneurship and SWES
DG RTD	Directorate-General for Research and Innovation
DG SANTE	Directorate-General for Health and Food Safety
DLR	Deutsches Zentrum für Luft- und Raumfahrt (German Aerospace Center)
DMP	Data Management Plan
EAN	European Academy of Neurology
EANS	European Association of Neurosurgical Societies
EASSH	European Alliance for Social Sciences and Humanities
EATRIS	European infrastructure for translational medicine
EB	Executive Board
EBC	European Brain Council
EBRA	European Brain Research Area
EBRAINS	European Brain Research Infrastructures
EC	European Commission
ECNP	European College of Neuropsychopharmacology
ECRIN	Early Career Researcher Furguean Clinical Research Infrastructure Network
ECRIN EDCTP	European Clinical Research Infrastructure Network European & Developing Countries Clinical Trials Partnership
EDI	Equality, Diversity, Inclusion
EFNA	European Federation of Neurological Associations
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHDS	European Health Data Space
EIT Health	European Institute for Technology - Health
EJP	European Joint Programme





EJP Rare Diseases	European Joint Programme on Rare Diseases
ELIXIR	European life-sciences Infrastructure for biological Information
ELSA	Ethical, Legal, and Social Aspects
EMA	European Medicines Agency
EOSC	European Open Science Cloud
EP	European Partnership
EPA	European Psychiatric Association
EPNS	European Paediatric Neurology Society
EP PerMed	European Partnership for Personalised Medicine
EP THCS	EP on Transforming Healthcare Systems
ERA PerMed	ERA-Net Cofund Action on personalised medicine
ERA-CVD	ERA-Net Cofund Action on cardiovascular diseases
ERA-HDHL	ERA-Net Cofund Action, implementing JPI HDHL objectives
ERA-Net	European Research Area Network
ERDERA	European Rare Diseases Research Alliance
ERA4Health	European Partnership ERA for Health Research
ESFRIs	European Strategy Forum for Research Infrastructures
EU	European Union
EuropaBio	The European Association for Bioindustries
EU4Health	European Union for Health Research
EU Al act	EU regulatory Framework for Artificial Intelligence
FAIR	Findable, accessible, interoperable and reusable
FET	European Future and Emerging Technologies
Flag-ERA/	Flagship ERA-NET
FLAGERA	Hugship Live NET
GA	Grant Agreement
GACD	Global Alliance for Chronic Disease
GAMIAN-Europe	Global Alliance of Mental Illness Advocacy Networks-Europe
GB	Governing Board
GEANT	Collaboration of European National Research and Education Networks
НВР	Human Brain Project
HDHL	Healthy Diet for a Healthy Life (Joint Programming Initiative)
HDHL-INTIMIC	ERA-Net Cofund Action on intestinal microbiomics, diet and health, implementing
	JPI HDHL objectives
H2020	Horizon 2020
IBC	International Bioethics Committee
IBI	International Brain Initiative
IBRO	International Brain Research Organisation
ICT	Information and communication technology
ICU	Intensive Care Units
IHI	Innovative Health Initiative
IMI	Innovative Medicines Initiative
INSERM	L'Institut national de la santé et de la recherche médicale
INS	International Neuroethics society
InTBIR	Initiative for Traumatic Brain Injury Research
IPBES	Intergovernmental Platform on Biodiversity and Ecosystem Services
IPCC	Intergovernmental Panel on Climate Change
ISCIII	Instituto de Salud Carlos III
IT	Information technology
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JCS	Joint Call Secretariat
JPco-fuND	ERA-Net Cofund Action for establishing synergies between the Joint Programming
	on Neurodegenerative Diseases Research and Horizon 2020
JPI	Joint Programme Initiative
JPI AMR	Joint Programme Initiative on Antimicrobial Resistance
JPND	Joint Programming on Neurodegenerative Diseases Research
JPsustaiND	Coordination Action in support of the sustainability and globalisation of the Joint
	Programming Initiative on Neurodegenerative Diseases
JTC	Joint Transnational Call
MedTech	European trade association for the medical technology industry including
	diagnostics, medical devices and digital health
MS	Member States
NEURON	Network of European Funding for Neuroscience Research
NGO	Non-governmental organisation
NIH	National Institute of Health
OECD	Organisation for Economic Co-operation and Development
PARC	European Partnership for Chemicals Risk Assessment
PREMOS	PREDICTIVE MODEL SYSTEMS EBRA cluster
PSC	Project Steering Committee
RI	Research Infrastructure
R&I	Research and Innovation
RRI	Responsible Research and Innovation
SAB	Scientific Advisory Board
SDG	Sustainable Developmental Goal
SEBRA	Shared European Brain Research Agenda
SMART	Specific, Measurable, Achievable, Relevant, and Time-bound
SMEs	Small and Medium Entrepreneurs
SOPs	Standard operation procedures
SRIA	Strategic Research and Innovation Agenda
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organisation
WPs	Work Packages
ZonMw	Netherlands Organisation for Health Research and Development