

Innovation Across the Lifecycle of Brain Health

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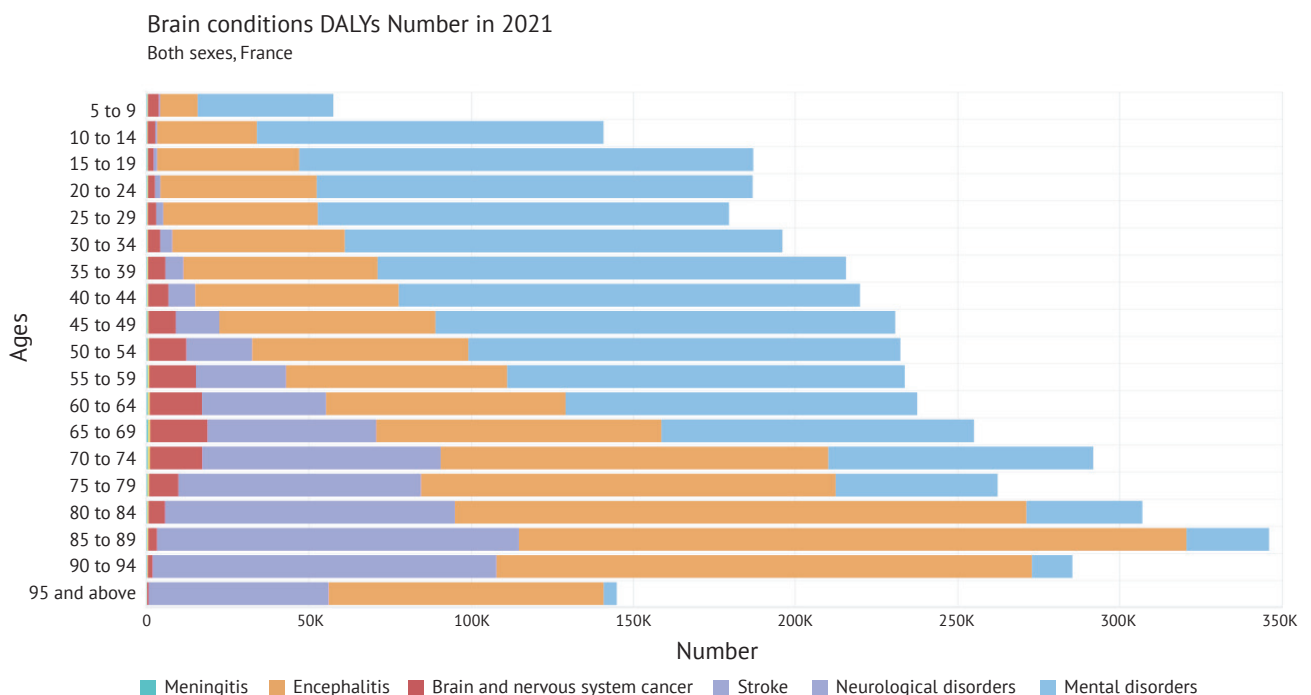
1. BACKGROUND: THE ROLE OF INNOVATION IN TACKLING THE BRAIN HEALTH CHALLENGE

Brain disorders are one of our health systems – and this century's – most pressing challenges. As in other areas of health, demographics greatly influence **brain health and its impact is evident across the entire lifecycle**, first through the appearance of mental disorders, which peak in middle age, and later in life through increased risk of neurological conditions and stroke (see Graph 1).

An estimated one-third of all healthy life years lost in the EU is attributable to brain disorders. The burden of mental, neurological and addiction diseases is not only direct, but indirect, as brain conditions exacerbate physical and chronic diseases. Looking only at dementia, 46 million people were living with the condition globally in 2015, and that number is expected to climb to 131.5 million by 2050.¹

Graph 1

BURDEN OF BRAIN CONDITIONS PER AGE GROUP (FRANCE)



Apart from the often devastating consequences for the individuals concerned and their families and caregivers, **there is also a double-squeeze on public policy and health budgets.** In 2050, 11% of all healthcare spending is expected to be earmarked – and needed – for dementia alone. Depending on the scenario, attributable dementia spending in France is expected to rise three-fold (baseline scenario), or 4.2 times (in the scenario with accelerated diagnosis and treatment rates), 4.6 times (scenario with accelerated nursing home-based care), or 5 times (scenario with accelerated unit costs).²

The enormous and growing burden of brain disorders calls for innovation to give patients hope and better outcomes. Although the field has seen many disappointments in the past, with no new medicines in some disease categories entering the market for decades, there is now renewed hope and expectation for a renaissance of neuroscience.³

Both breakthrough and incremental innovation are needed, whether to identify new molecular pathways and mechanisms that may be modulated to prevent or treat disorders, or to reformulate existing therapies to modify disease trajectories and improve patients' quality of life.

2. STATE OF PLAY: CURRENT AND EMERGING APPROACHES IN DIAGNOSIS AND THERAPY

2.1. Lifecycle approach: key role of early diagnosis

For both neurological and mental health disorders, it is crucial to act early. **Early diagnosis is essential for moving towards best possible outcomes,** as the earlier there is an accurate diagnosis, the earlier interventions can be used to modify the disease, minimise the damage to the central nervous system and delay the aggregation of disability. Yet that is easier said than done. The often-prolonged latency between the onset of underlying pathology and the emergence of clinical symptoms, combined with the significant overlap between psychiatric and neurological manifestations, poses a major challenge to early diagnosis and the implementation of targeted interventions.

Recent advances in biomarkers are in fact making it easier to offer earlier interventions for several brain conditions.

In Multiple Sclerosis (MS), for example, lesions on nerve fibres can be present up to ten years before the patient is diagnosed: there is no strict correspondence between

the severity of brain and spinal cord lesions and the patients' symptoms. Being able to better understand and predict the prodromal phase – the time between onset of an illness and the appearance of symptoms – and to gauge the onset of the inflammatory and other processes, would make it much easier to offer targeted and timely interventions.

Recent advances in biomarkers are in fact making it easier to offer earlier interventions for several brain conditions, with the potential to replicate the trajectory seen in MS. Only five years ago, treatment typically began after symptoms emerged; today, biomarkers allow clinicians to intervene much earlier and with greater precision. Focusing on intercepting the biological onset of the disease and on unmasking prodromal symptoms⁴ via Patient Experience Data⁵ would pave the way for preventive interventions to slow disease progression and protect brain health.

2.2. Streamlining the pathway from discovery to impact

While scientific advances bring the perspective of significant improvements in health outcomes closer, it can be challenging to translate discoveries into application in brain health. This is largely due to several **specific complexities of neurology and psychiatry,** from limited understanding of the mechanisms of disease and lack of objective biomarkers to the absence of validated and agreed clinical endpoints. Disease heterogeneity, wherein patients with the same diagnosis may have different symptoms, etiologies, or responses to treatment, hinders accurate diagnosis and prognosis, and makes drug development more complex. Diagnostic complexity can delay treatment, reduce therapeutic efficacy, and ultimately impact patient outcomes.

Other reasons why **scientific solutions are not being readily put into practice are the lack of funding for early innovation access** and the constraints of reimbursement mechanisms in the healthcare systems. And this is the case despite the enormous burden posed by brain disorders. In mental health, few evidence-based interventions have been scaled up. Overcoming this situation requires better connecting the various components of the research and innovation ecosystem, bringing together stakeholders, tools, and processes to form a more efficient framework. The much-needed increase in funding needs to be integrated into a broader system upgrade that accelerates the translation of high-quality science into startups and scalable industry solutions.

Progress also depends on how we conceptualise the value of investment in brain health. A **transformational, intentional approach is needed** – one that treats brain capital as a core economic asset. It would imply recognising the significance of safeguarding brain health across the life course, supporting recovery, and fostering skills for the future labour force.

2.3. Innovation principle in action

Innovation can only thrive within a supportive and adaptive ecosystem that actively facilitates its uptake. Encouragingly, **the EU is expanding its scope for innovation** through pilot programmes and new regulatory pathways for both medicines and medical devices. These include early engagement with health technology assessment (HTA) bodies, accelerated assessment procedures, and tailored regulatory advice. Beyond driving innovation, these initiatives also enable more meaningful integration of patient perspectives and real-world evidence (RWE) into the regulatory decision-making process.

There is a growing sense that **regulatory engagement should not be an afterthought**. Often, the regulator is perceived as the ‘final door’ to be approached once everything is in place. However, this is not an optimal approach for researchers and innovators, as it may hide important remaining hurdles to the market. Early engagement with regulatory authorities is essential to ensure alignment and efficiency. It requires overcoming the persisting perception that ‘going in too early would be counterproductive.

A key missing element is awareness. The European Medicines Agency should actively promote **regulatory dialogue as a fundamental and potentially mandatory step before public research funding is allocated**. Frequently, the challenge is not differing criteria between payers and assessors, but rather a lack of planning and insufficient understanding of each body’s requirements. In many cases, adding a few targeted, non-burdensome trial amendments could allow a single study to meet the information needs of multiple stakeholders, including regulators and payers.

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2.4. Mobilising investment for brain health innovation

Despite their growing impact, **research on neurological and mental health conditions has long been under-resourced**. It is estimated that less than 10% of the total biomedical research budget of EUR 8 billion is spent on neurological research in the EU, although neurological and mental health conditions

account for 40% of the burden. This funding gap urgently needs to be bridged.⁶ The new Brain Health Partnership is now getting under way with the first calls expected in early 2026. However, a significant increase in allocations is needed, also as part of the new research budget in the forthcoming EU Multiannual Financial Framework for the years 2028-2035.

One central question has to do with the way the funding streams can be mobilised strategically to ensure innovation reaches the patients. There is a need for better alignment between promising scientific ideas and the right mix of equity and non-dilutive funding. One avenue to explore are de-risking frameworks that assess the maturity of different investments and broaden the financial toolbox. Potential instruments include social impact bonds, debt exchanges, or profit-and-loss relief mechanisms, yet to date, these types of models have been applied only in a limited way in the brain health field.

The European Investment Bank is currently the largest provider of venture debt financing in the life sciences sector, playing a critical role in translating EU policy into practical financial support. It provides an extensive financing toolbox, enabling the implementation of EU strategic priorities across the research and innovation landscape. This includes not only venture debt and EU anchor financing, but also crowdfunding in private investment, which is essential to scale promising technologies.

Crucially, EIB financing spans the entire innovation spectrum – from fundamental research to translational science, and increasingly towards critical manufacturing capacity within the EU. While it is not feasible to provide every type of financing for every intervention, the EIB targets a broad range of needs across the innovation pipeline. Ultimately, the goal is not only to improve population-level health, but to foster truly patient-inclusive care, which requires robust data from entire populations.

There remains a significant subgroup of neurological conditions for which development stalls due to a lack of targeted support within the European funding systems – particularly for studies addressing critical, unanswered research questions. As Europe considers mechanisms to fund more clinical trial-driven innovations, it is important to explore whether and **how such EU-funded developments could become shared European assets**.

In the field of brain health, there is a critical need for **a de-risking collaboration platform that facilitates the blending of public and private funding**. Such a platform is essential to supporting the full innovation pathway – from early research and development through to market access and patients benefit. EIT Health serves as a key connecting platform, helping to link fundamental research – particularly in areas of unmet medical needs – with innovative funding models that can drive research forward and support translation into real-world impact.

The EIT Health's innovation model is based on three strategic pillars:

- ▶ Venture creation and startup support – fostering the development of early-stage innovations and startups.
- ▶ Technology evaluation and clinical validation – supporting the assessment and validation of new technologies, with critical input from industry partners and patient associations.
- ▶ Growth and scale-up – providing financial support to scale innovations, combining dilutive (e.g. equity investment) and non-dilutive (e.g. grants) funding sources.

EIT Health aims to bridge these pillars by means of the Deep Tech Venture Builder Programme, offering tailored funding and support infrastructure for deep tech startups, connecting them with experienced partners and advisors; Open Innovation Programmes, facilitating early clinical validation with active corporate engagement; and the Venture Centre of Excellence, accelerating the journey of health innovation to market by connecting startups with venture capital and strategic partners.

2.5. Multiple Sclerosis as a case study for innovation

One of the most compelling case studies of how strategic investment in research and innovation can transform patient outcomes is **changing the disease trajectory** in Multiple Sclerosis (MS). The first disease-modifying therapies emerged in the 1990s, while today there are around 30 approved medications. Some of the key factors behind this success have had to do with a much better understanding of the malfunction of the immune system of people with MS and learning from past clinical trials. The race is now to stop the disease as early as possible, even before it happens.

Progress has been driven not only by the introduction of multiple drug classes but also advances in formulations, delivery mechanisms, and care models. Together, these steps have allowed for the slowing of the progression of MS, including its early and often invisible forms, bringing us closer to the possibility of a cure.

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A key driver of this success has been the shift towards early treatment – **flipping the paradigm** – where patients are treated at the onset of disease with high-efficacy treatments, rather than waiting for advanced symptoms. This approach, combined with appropriate biodrivers, stratified care mechanisms, and clinical guidelines that embedded scientific discoveries into everyday practice, has been central to translating scientific breakthroughs into real-world health gains.

Equally important has been the role of patients: advocacy, participation in clinical research, and co-shaping of care have all accelerated progress. Competition among treatments has also fostered continuous improvement and incremental innovation, complementing breakthrough discoveries.

2.6. 360° multistakeholder engagement in research to build trust in science

Data-driven innovations are foundational for the future of patient-inclusive care. A more complete data ecosystem could greatly improve early diagnosis, while large scale data analysis could help address the heterogeneity of many brain disorders regarding symptoms, sites of damage, and disease trajectory.

One tends to talk about datasets but often forgets that there is a patient behind every piece of data. **The importance of patient-experienced data cannot be underestimated.** Patient-experienced data needs to be better integrated in research and clinical practice. In this context, a science of patient input is needed, which is different from patient advocacy. Enabling a representative engagement of patients in research projects can bridge the right to health with the right to privacy, hence overcoming a substantial barrier to research up to date. Findings of the MULTI-ACT project,⁷ which developed an innovative participatory governance model for patient engagement, should be integrated in future brain health funding schemes. Its added value is that the involvement is representative, moving from the concept of expert patient to the concept of patients' community. A template for a MULTI-ACT brain health pilot should be developed and put forward for broader adoption within the forthcoming European Brain Health Partnership.

3. BRAIN HEALTH INNOVATION AS A POTENTIAL PILOT OF THE EU LIFE SCIENCES STRATEGY

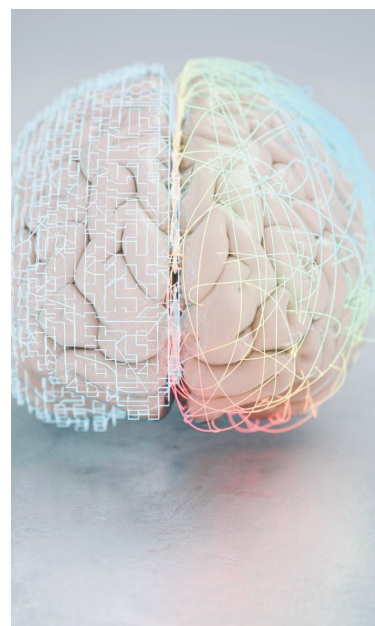
Much of what the European Commission aims to achieve in its recent "[Choose Europe for life sciences](#)" strategy will feed directly into brain health innovation, starting with improving the ecosystem for innovation, all the way to creating better pathways for multi-country clinical trials. The strategy is structured around three main pillars:

- ▶ Optimising the research and innovation (R&I) ecosystem for the life sciences sector.

BRAIN HEALTH AS A PILOT DOMAIN FOR THE EUROPEAN LIFE SCIENCES STRATEGY

Brain health as a pilot domain for the European Life Sciences Strategy

- **FACILITATING MULTI-COUNTRY CLINICAL TRIALS WITH STREAMLINED REGULATORY PATHWAYS**
 - Harmonised ethics committee rules
 - More responsive Clinical Trial Information System
 - Activation of the AI-supported Clinical Trial Data Framework
 - Integration of Patient Experience Data
- **MATCHMAKING INTERFACE TO CONNECT STARTUPS, INDUSTRY AND INVESTORS**



Source: Authors/MSFT Teams.

- Boosting the uptake of, and trust in, science.
- Increasing research activity, particularly through clinical trials.

The strategy outlines two flagship actions for clinical trials that are highly relevant to brain research:

- **Investment plan for clinical research:** designed to facilitate multi-country trials. The latter would be disease agnostic but highly applicable to brain health. The Commission's role as an anchor investor will be critical, moving beyond the current Horizon Europe 'call for funding' model towards a joint-financing mechanism, including a possible 'seal of excellence' to attract co-investment.
- **Streamlined regulatory pathways:** measures will be introduced to shorten the approval process for clinical trials, accompanied by continuous support, monitoring, and evaluation. These reforms aim to strengthen Europe's global competitiveness and will be complemented by the forthcoming Biotech Act.

The Commission plans to create a network of European Centres of Excellence in advanced therapy medicinal products (ATMPs) to coordinate their further development together with Member States, which is another move in the right direction. It also aims to **launch a matchmaking interface to connect startups, industry and investors, leveraging the European Innovation Council portfolio**, and its Trusted Investors Network.

Already the forthcoming Horizon Europe Work Programme 2026 is expected to place a stronger emphasis on innovative solutions, with additional calls focusing specifically on clinical trials.

This level of ambition is particularly important for neurological research. Even though success rates in neurology are improving and approaching those of other domains, the share of neurological trials within all clinical trials has halved since the early 2010s. Reversing this trend will be essential for progress in brain health.

The European Commission already works closely with the European Medicines Agency through the Accelerating Clinical Trials in the EU (ACT-EU) initiative to promote greater multi-country involvement in clinical trials. One example of a valuable partner in this space is the European Infrastructure for Translational Medicine (EATRIS).⁸ Strengthening collaboration with such infrastructures could further enhance translational research and regulatory alignment across Europe.

Brain health is an optimal field for an early pilot of the EU Life Sciences Strategy. The proposed investment plan, with special focus on brain health, could act as a catalyst for future innovations, ensuring that trials are aligned with patient priorities and experiences and backed by state-of-the-art methodologies.

A pilot of multi-country clinical trials should establish **harmonised ethics committee rules** and requirements, to avoid delays and inefficiencies for researchers.

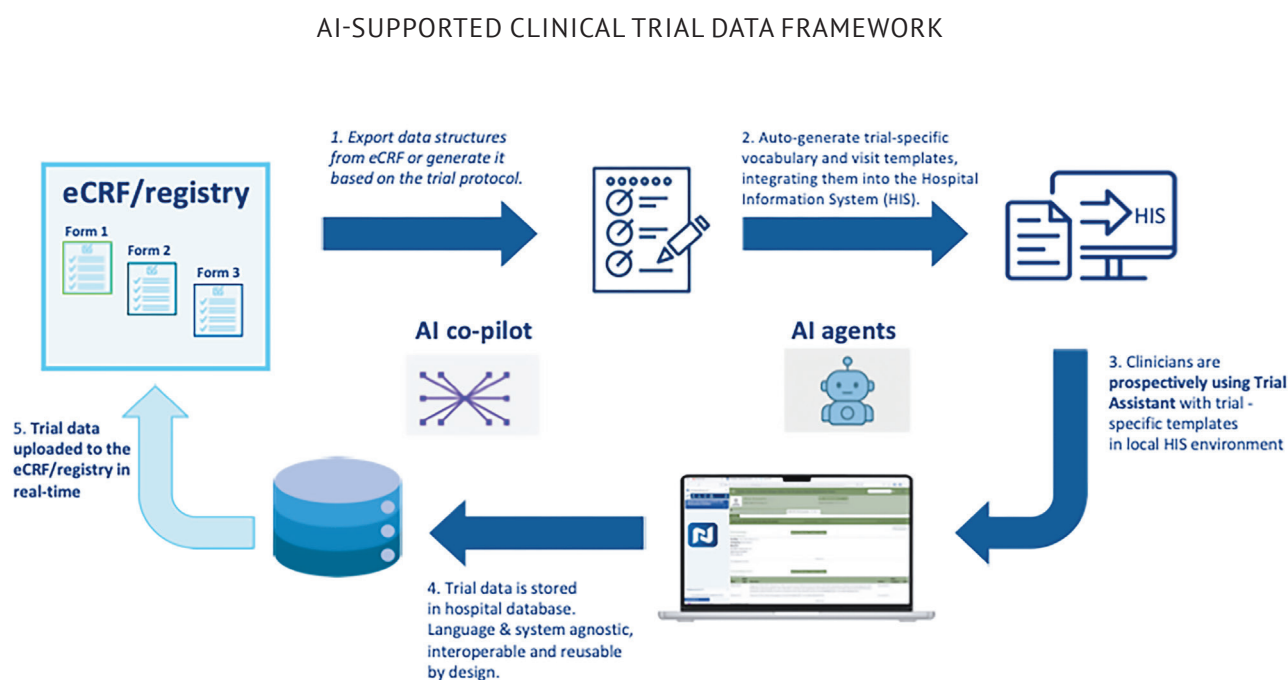
A more flexible and responsive Clinical Trials Information System, introduced as part of the EU Clinical Trials Regulation to streamline and centralise trial applications, would make it easier for researchers to submit and manage data and documentation. In addition, a pilot trial should effectively operationalise the European Reference Networks, with their shared registries and data infrastructures, specialised clinical expertise, and patient engagement structures. This would not only strengthen the feasibility of such multi-country trials, but also ensure that scarce patient populations are reached efficiently, reducing duplication.

Emerging tools – particularly AI and digital technologies – offer new opportunities, with AI-driven recruitment models that can improve patient selection and trial efficiency, and surrogate endpoints and digital biomarkers to accelerate evaluations. If biomarkers could be systematically embedded not only in trial design but also in regulatory dossiers, patient experience data could be integrated into both research and policy decision-making, with greater investment in measurement and collection frameworks. The Life Sciences strategy pilot should apply the AI-supported Clinical Trial Data Framework.⁹

Innovation in brain health requires making the most of the unique contributions of all actors involved, especially those of the patients. The Life Science Coordination Group, proposed by the European Commission, could represent a unique forum to encourage stakeholders' engagement, including the participation of patients and citizens through innovative governance.

Supporting **multi-country clinical trials** should involve the development of databases integrating Patient Experience Data (PED) with clinical, genetic and imaging data capable of phenotyping diseases to identify an algorithm of factors to intercept disease onset and measuring progression, with other quantitative markers measuring the different pathophysiological mechanisms early in the disease.¹⁰ The global PROMS¹¹ and the Barcoding MS Initiatives¹² are shaping and developing the field and could be replicated in other brain disorders. PED represent a unique opportunity to capture experiential knowledge from people living with diseases and to demonstrate that patient engagement is scientifically and economically relevant for all the other stakeholders.

Figure 2



Source: CliniNote (a European start-up redefining clinical data capture).

The multi-country clinical trial pilot should aim to use high-quality Patient Experience Data, and capture hidden symptoms, in the development of medical products and devices. For this purpose, achieving a common understanding of what constitutes PED, and how it evaluates functional domains and interdependencies relevant to people living with the disease,¹³ would be important. More transparency and guidance on the use of PED should be sought, together with its personalised use. It would also be beneficial to increase the sensitivity of PROMs in clinical trials and their monitoring over time by strengthening passive and remote measuring through e-Health.¹⁴

CONCLUSIONS

Brain health represents one of the most complex and pressing healthcare challenges of our time – and an ideal domain to pilot solutions proposed in the European Life Sciences Strategy. From investments to facilitate multi-country clinical trials, to fast-tracking life sciences startups on their journey to market, the strategic alignment around brain health can become a critical tailwind for innovation and a model for integrated health policy implementation.

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This Policy Brief draws on the discussions at the European Policy Centre – NeuroCentury – Brain Capital Alliance Round Table held in Brussels on 3 July 2025. The authors are grateful to the participants of the Round Table for their invaluable insights. This project is financially supported by Merck.

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- ¹ The World Alzheimer Report 2015, “[The global impact of dementia: An analysis of prevalence, incidence, cost and trends](#)”.
- ² See Institute for Health Metrics and Evaluation, Brain Health Atlas, <https://www.healthdata.org/data-tools-practices/interactive-data-visuals/brain-health-atlas>.
- ³ See: <https://www.economist.com/technology-quarterly/2022/09/21/after-fallow-decades-neuroscience-is-undergoing-a-renaissance>.
- ⁴ See: Bebo BF, Banwell BL, Whitacre CC, et al. The refined Pathways to Cures Research Roadmap for multiple sclerosis cures. *Multiple Sclerosis Journal*. 2024;30(10):1242-1251. doi:10.1177/13524585241266483.
- ⁵ Zaratin P, et al. The global patient-reported outcomes for multiple sclerosis initiative: bridging the gap between clinical research and care - updates at the 2023 plenary event. *Front Neurol*. 2024 Jun 20;15:1407257. doi: 10.3389/fneur.2024.1407257. PMID: 38974689; PMCID: PMC11225898.
- ⁶ See: https://pmc.ncbi.nlm.nih.gov/articles/PMC11735729/?utm_source=chatgpt.com.
- ⁷ Zaratin, P, Bertorello, D., Guglielmino, R. et al. The MULTI-ACT model: the path forward for participatory and anticipatory governance in health research and care. *Health Res Policy Sys* 20, 22 (2022). <https://doi.org/10.1186/s12961-022-00825-2>.
- ⁸ See: <https://eatris.eu>.
- ⁹ For more information, see: The Kraków Agenda for Europe's Life Sciences, report from the Polish EU Presidency conference, 15-16 May 2025; https://lifescience4eu.eu/wp-content/uploads/2025/07/LifeScience4EU-Conference-Report_2025.pdf.
- ¹⁰ See Kuhlmann T, Moccia M, Coetzee T, et al. Multiple sclerosis progression: time for a new mechanism-driven framework. *Lancet Neurol*. 2023;22(1):78-88. doi:10.1016/S1474-4422(22)00289-7.
- ¹¹ See: <https://proms-initiative.org/>.
- ¹² Helme A, Kalra D, Brichetto G, Peryer G, Vermersch P, Weiland H, White A, Zaratin P. Artificial intelligence and science of patient input: a perspective from people with multiple sclerosis. *Front Immunol*. 2025 Feb 17;16:1487709. doi: 10.3389/fimmu.2025.1487709. PMID: 40034708; PMCID: PMC11872699.
- ¹³ See: Zaratin P, et al (2024) The global patient-reported outcomes for multiple sclerosis initiative: bridging the gap between clinical research and care – updates at the 2023 plenary event. *Front. Neurol*. 15:1407257. doi: 10.3389/fneur.2024.1407257
- ¹⁴ Helme A, Kalra D, Brichetto G, Peryer G, Vermersch P, Weiland H, White A, Zaratin P. Artificial intelligence and science of patient input: a perspective from people with multiple sclerosis. *Front Immunol*. 2025 Feb 17;16:1487709. doi: 10.3389/fimmu.2025.1487709. PMID: 40034708; PMCID: PMC11872699.

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