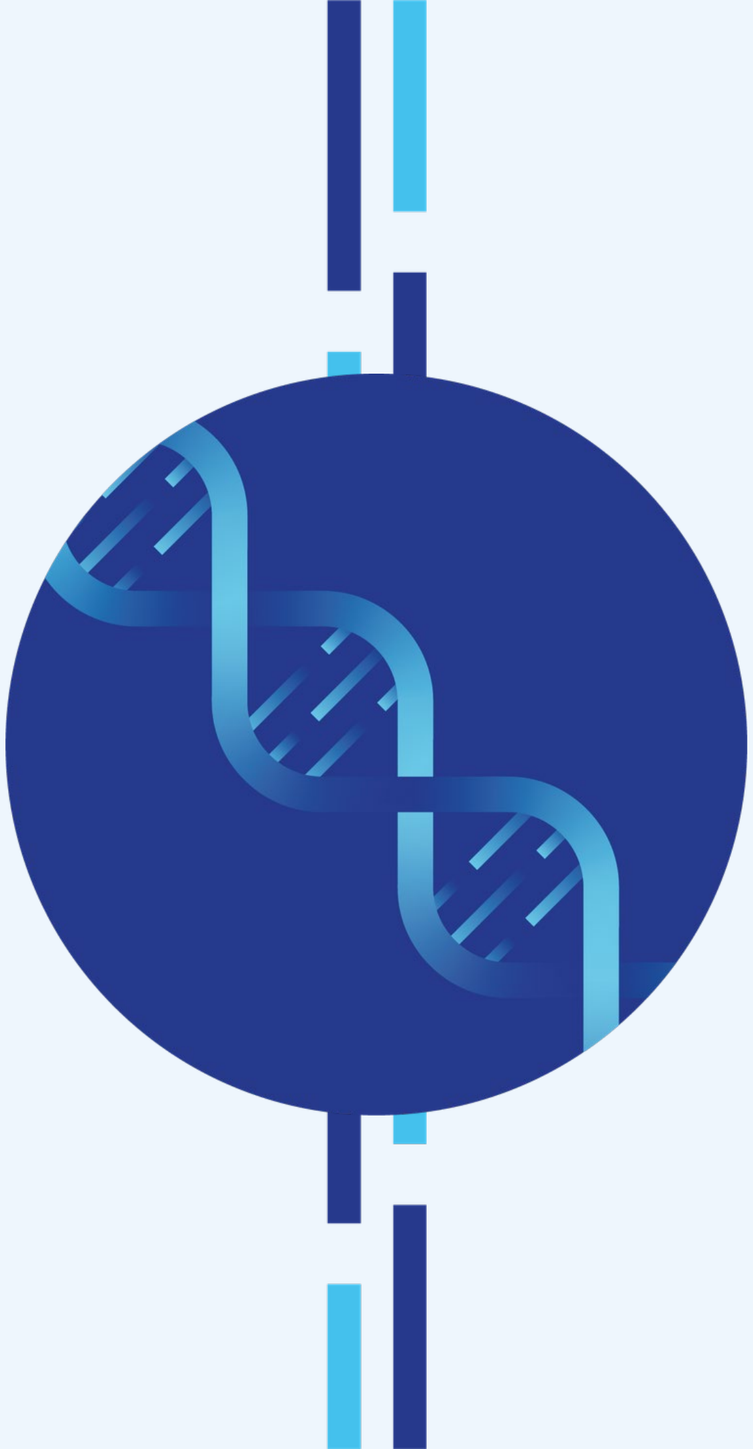
HEREDITARY

# Advocacy Workshop
## Bridging Science and Policy

14:00 -17:00 CEST
30 June 2026,
Online



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# Welcome!

## Frédéric Destrebecq

Executive Director, European Brain Council - EBC

# Workshop Agenda

**14:00 - 14:15 | Welcome & Introduction**

**14:15 - 14:25 | Peer to Peer Dialogue – Why Science-policy Dialogue Matters**

**14:25 - 15:00 | Session 1 – Science and Policy in the EU**

**15:00 - 15:50 | Session 2 – From Research Findings to Policy**

**15:50 - 16:00 | Break**

**16:00 - 16:50 | Session 3 – Policy Mockup Exercise**

# Workshop Objectives

- **Policy Understanding**:
  - Understand how the EU policymaking environment works and where researchers can have an impact;
  - Explore key EU legislation shaping brain health, health data, and AI in research
- **Skills Development**: Learn how to communicate complex research findings to policy audiences
- **Engagement and Advocacy**: Discover career pathways at the science-policy interface
- **Applied Learning**: Experience firsthand how evidence, ethics, and competing interests shape real policy decisions

# Introduction to HEREDITARY

**Gianmaria Silvello**

Full Professor, University of Padua - UNIPD; HEREDITARY Project Coordinator

# HEREDITARY

https://hereditary-project.eu/

Gianmaria Silvello
University of Padua, Italy

**HEREDITARY Advocacy Workshop**
30 June 2026

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# The Gut-Brain Interplay

- HEREDITARY focuses on two cross-domain groups of diseases

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  - **Neurological diseases**: Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis (MS), Parkinson's (PD), Alzheimer's (AD), Frontotemporal Dementia (FD), and stroke
    - Integration of multimodal and genomic data to inform the phenotypic characterization of neurological disorders
    - Examination of the eye, specifically the retina and optic nerve, to establish ocular analysis as a non-invasive and cost-effective means of detecting neurological diseases

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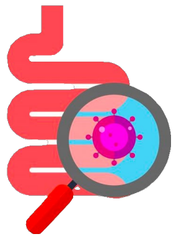
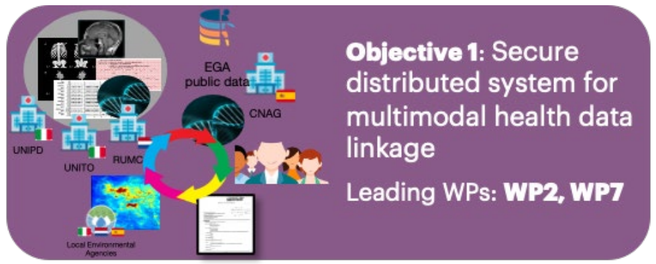
    - Integration of multimodal and genomic data to inform the phenotypic characterization of neurological disorders
    - Examination of the eye, specifically the retina and optic nerve, to establish ocular analysis as a non-invasive and cost-effective means of detecting neurological diseases
  - **Gut microbiome related disorders** that interact with the brain. The gut microbiome, also called the body's "second brain", comprises the collective genome of roughly 100 trillion microorganisms residing in the gastrointestinal tract
    - The precise mechanisms underlying these connections between neurological diseases, ocular diseases, psychiatric disorders and the gut microbiome are not yet fully understood



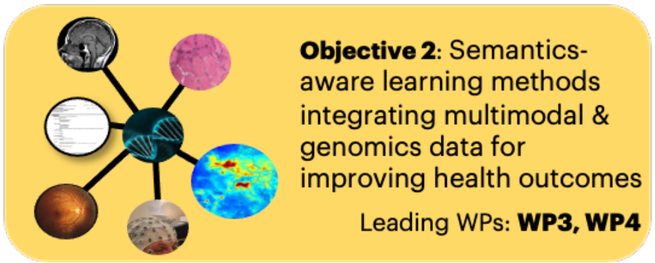
# The Objectives




**Objective 1**: Secure distributed system for multimodal health data linkage

Leading WPs: **WP2, WP7**

To develop a federated, scalable, secure, and privacy-preserving system for linkage of health data enabling querying of multimodal data across sources and disease groups.



**Objective 2**: Semantics-aware learning methods integrating multimodal & genomics data for improving health outcomes

Leading WPs: **WP3, WP4**

To develop advanced analytics and learning methods for a better understanding of the risk factors, causes, development and optimal treatment for disorders related to the gut-brain interplay.


**Objective 3:** Interactive data driven solutions to empower decision-making, prevention and strengthen citizen's trust

Leading WPs: **WP5, WP6**

To develop data-driven and evidence-based solutions for decision-making and information campaigns.



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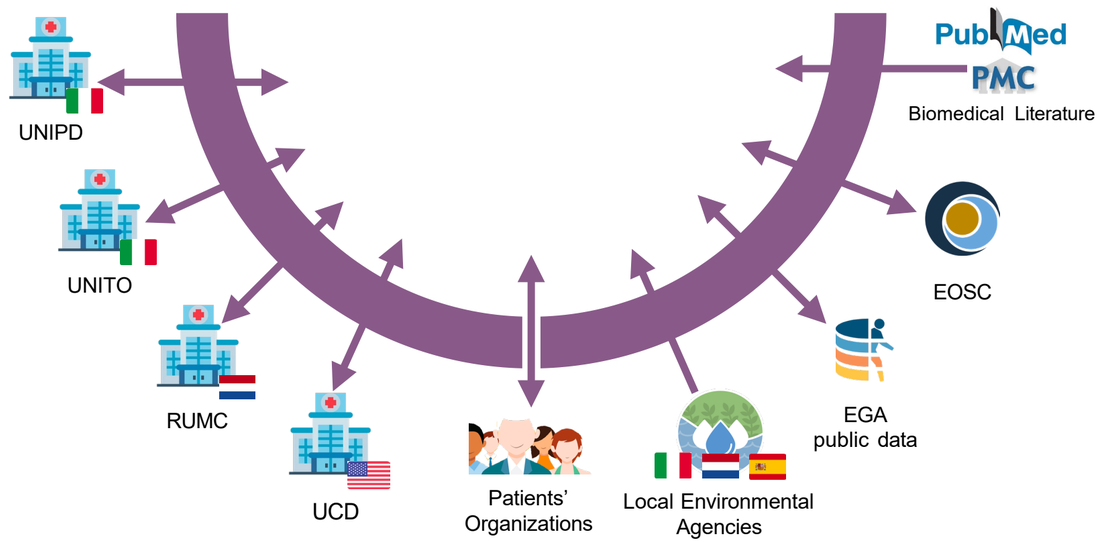
# Secure distributed system for multimodal health data linkage

- HEREDITARY **data sources** are timely and legally available thanks to the consortium's inclusion of the data providers.
- HEREDITARY considers **various data sources**, including electronic health records, genomic data, medical imaging (OCT, (f)MRI, [18F] FDG-PET, and histopathological Whole Slide Images), laboratory and diagnostic tests, pathogen data, public health registries, and **GWAS/WGS data**.





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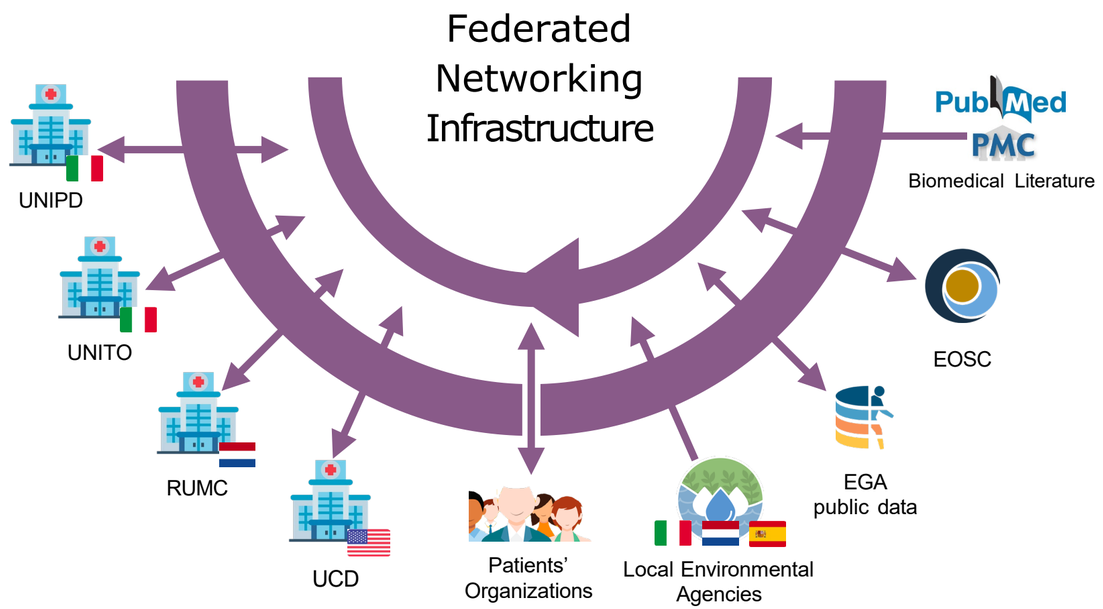
# Secure distributed system for multimodal health data linkage

- The "Federated Networking Infrastructure" is designed for **collaborative training of machine learning models** and **analytics** while ensuring **strict privacy and security**.
- The layer allows for **data- and model-centric federated analytics** and learning by decoupling access to data and sharing query or learning results, ensuring that no sensitive data crosses organization boundaries





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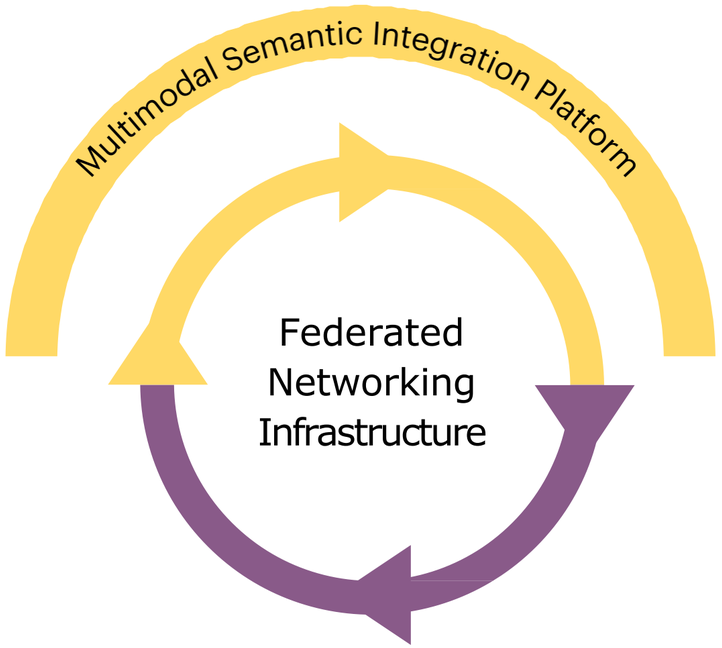
# Semantics-aware learning methods and multimodal integration

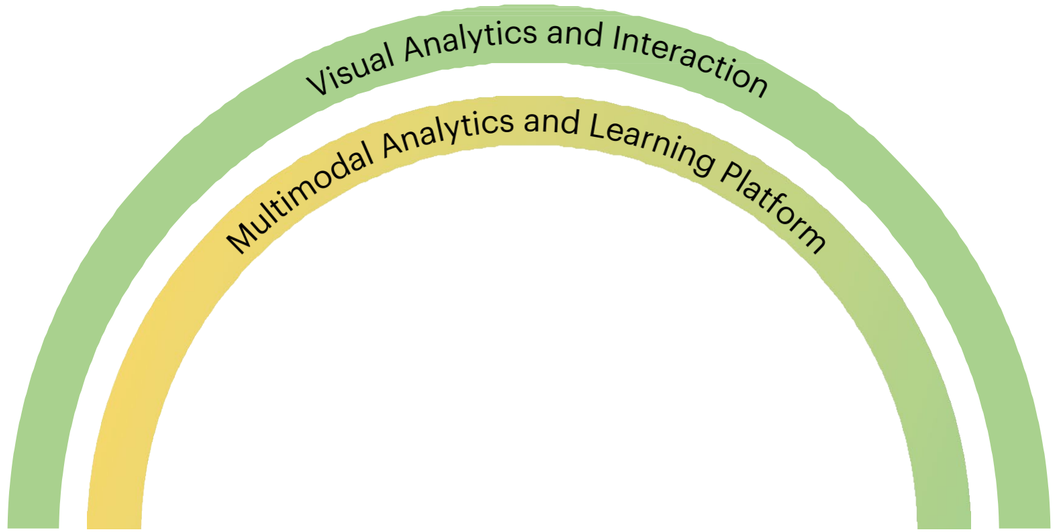
- The **polystore** harmonizes access to public and private data, making medical data islands **interoperable** and **integrated**, and executes training and query plans from higher layers while maintaining security and **privacy**.
- By enabling **secure and efficient access** to medical data for analysis and model development, the layer ensures the seamless functioning of the HEREDITARY framework.



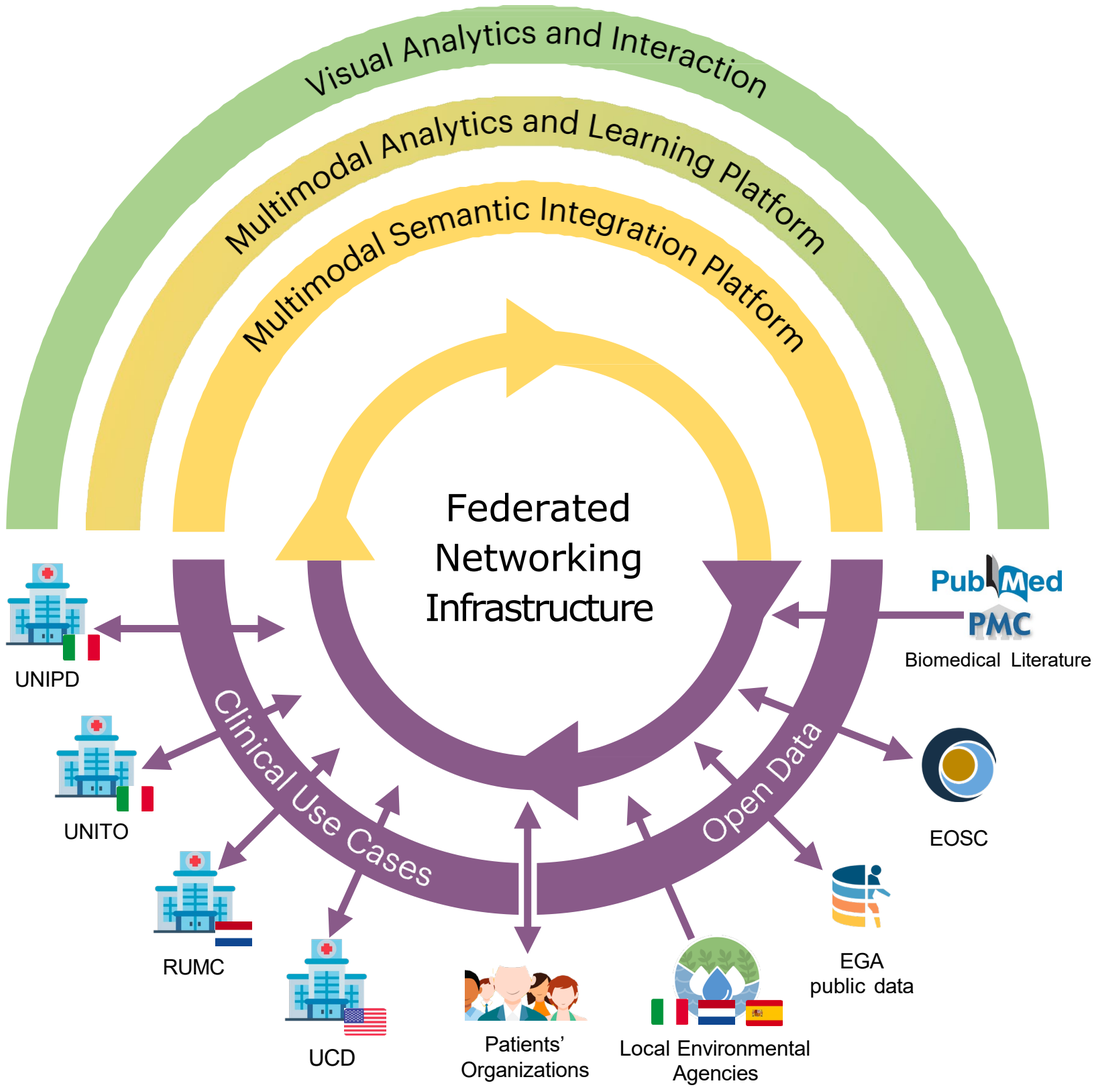

***Polystore***
a DBMS built on top of multiple, heterogeneous, integrated storage engines

# Interactive data-driven solutions to empower decision-making, prevention and strengthen citizen‘s trust

- **Data science pipeline**: including data preparation, exploration, analysis, **visualization**, and interaction.
- HEREDITARY incorporates the analysis of **multiple data types**, including clinical data, genomics, imaging, signals, and texts, going beyond the state-of-the-art in **data analysis**.
- The **Health Social Laboratories** will facilitate the **co-design** of the HEREDITARY architecture with patients, citizens, and domain experts.



# The HEREDITARY Architecture




**Key outputs 1:**

- Shared framework for *secure & lawful federated access to linked multimodal health data* across Europe and beyond.
- Healthcare data *normalization libraries* targeting *data formats, quality* and *interoperability*.

**Key outputs 2:**

- Multimodal ontology for healthcare targeting gut-brain interplay.
- Federated semantic polystore to efficiently query multimodal health&genomics data
- Privacy-aware, federated learning models targeting gut-brain interplay and risks detection

**Key output 3:**

- Visual analytics platform to discovery and aggregate efficiently, effectively and securely data from multiple sources for multiple groups of diseases.
- Evidence-based recommendations for patients and citizens.

# The 5 Use Cases

| Use Case 1 | Use Case 2 | Use Case 3 | Use Case 4 | Use Case 5 |
|---|---|---|---|---|
| Neurodegenerative diseases phenotyping & prognosis evaluation | Next-generation diagnosis and treatment response for neurodegenerative diseases | Signs of Parkinson's disease in multimodal data | Phenotyping of the gut-brain axis in healthy individuals | Gut-Brain linkage and disease relevance |
| **Single neurodegenerative disease, multimodal data, single center** | **Multiple neurodegenerative diseases, multimodal data, multi-center** | **Single neurodegenerative disease, multimodal data, single and multi-center** | **Gut-related diseases Healthy individuals, multimodal data, single center** | **Gut-Brain Linkage, multimodal data, multi-center** |



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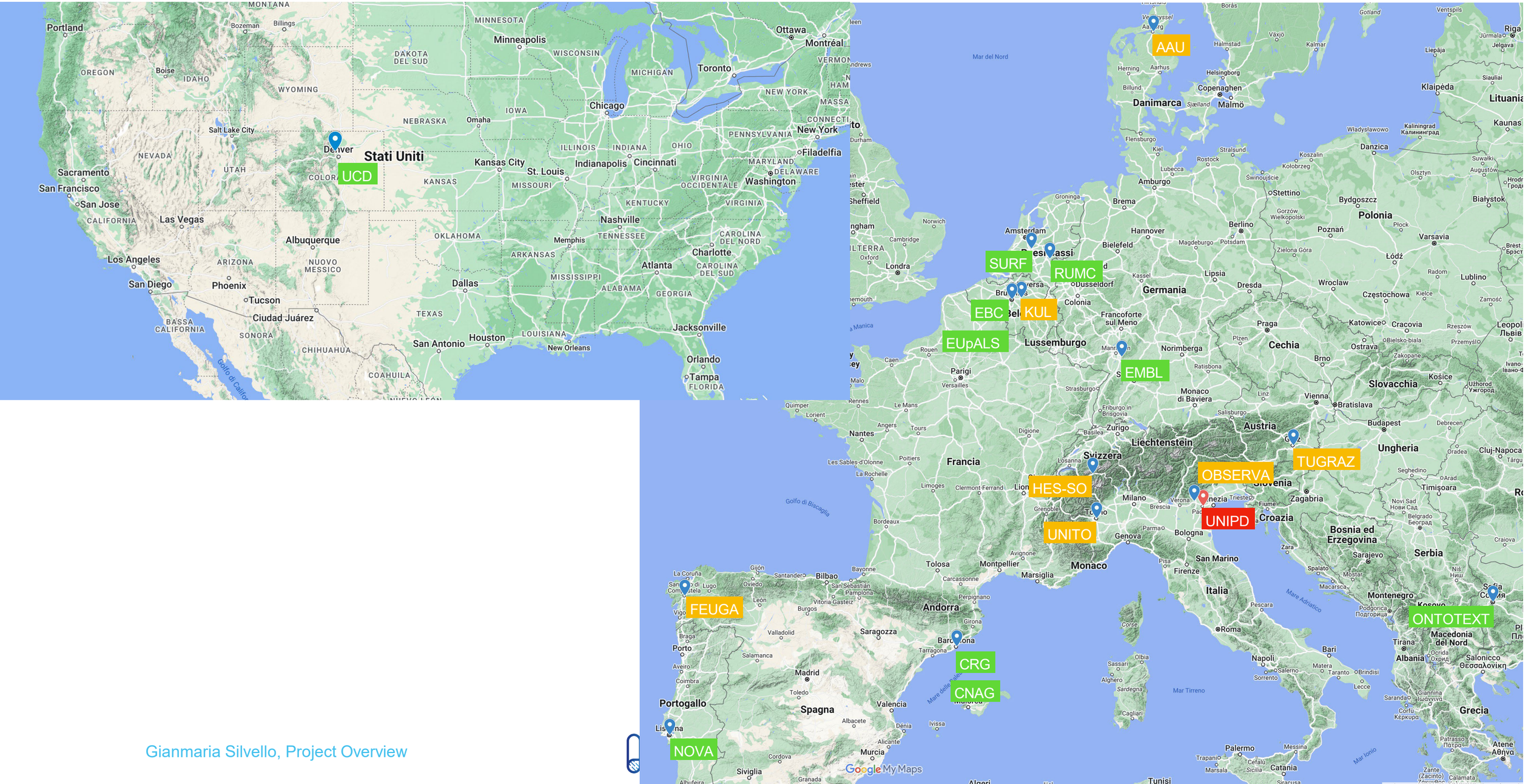
# The Consortium



# THANKS

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# Peer to Peer Dialogue – Why Science-policy Dialogue Matters

**Joëlle Rüegg**

Professor of Environmental Toxicology, Uppsala University; Re -MEND Project Coordinator

**Vebjørn Andersson**

Medical Doctor, Oslo University Hospital; AI -Mind Assistant Project Coordinator

**Narsis Aftab Kiani**

Senior Researcher; Lab Leader, Karolinska Institutet; WISDOM Project Representative

# Session 1 – Science and Policy in the EU

## Hugo Hermantin

Policy Coordinator, European Brain Council - EBC



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# Science and Policy in the European Union

30 June 2026 – HEREDITARY World Café

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# Standing United for the Brain










**National Brain Councils & Industry Partners**

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# EBC Mission

Fostering **cooperation** between member organisations and other stakeholders

Promoting **dialogue** between scientists, industry and society

Interacting with EU Institutions to build stronger health policies

Raising **awareness** and encourage **education** on the brain

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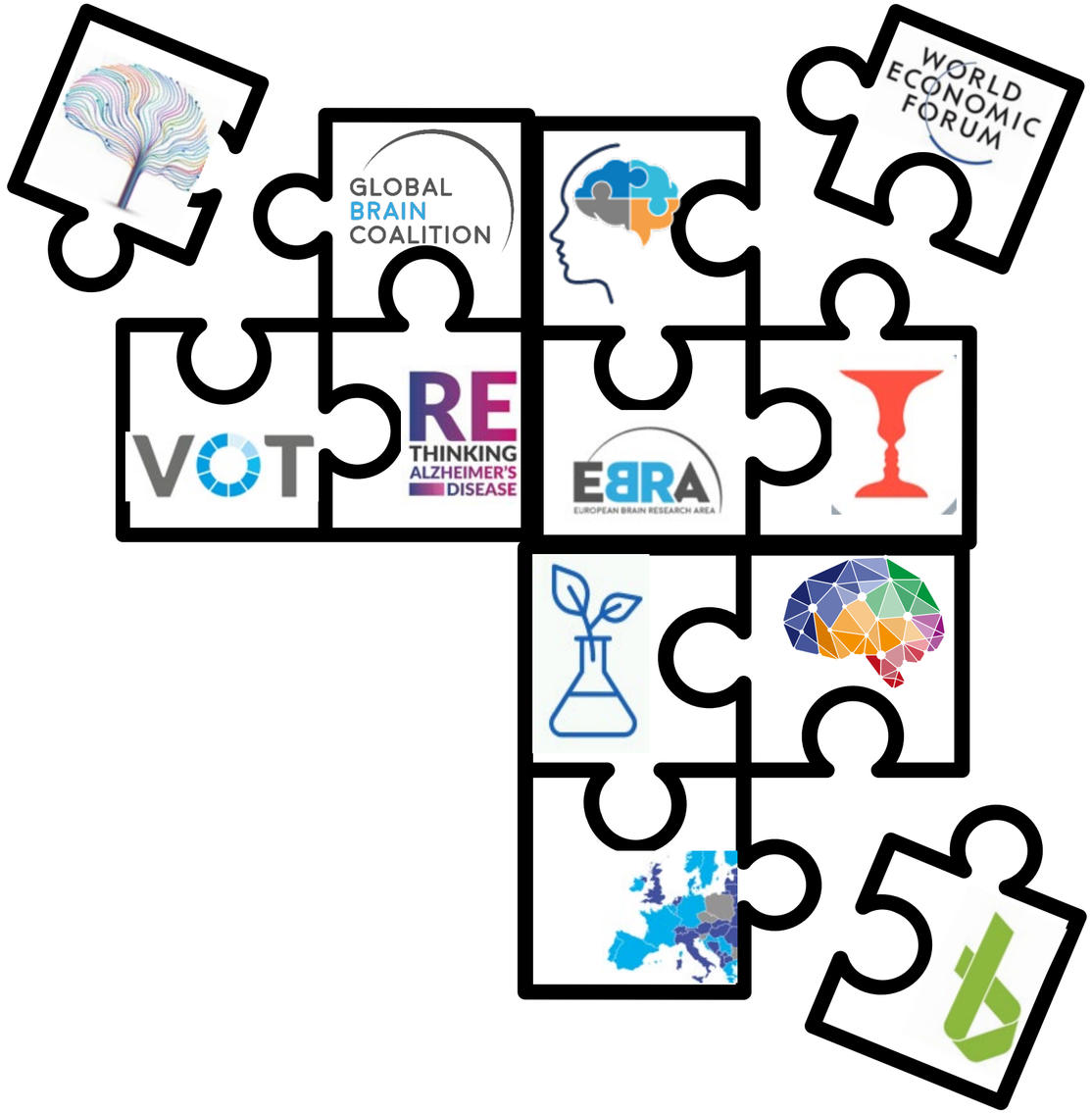
# Combining Building Blocks…

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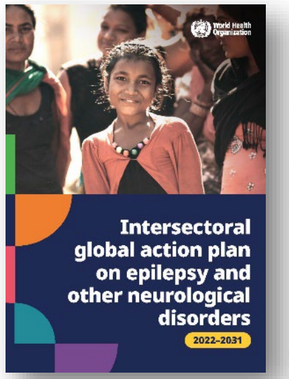
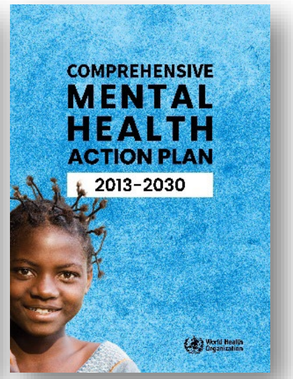
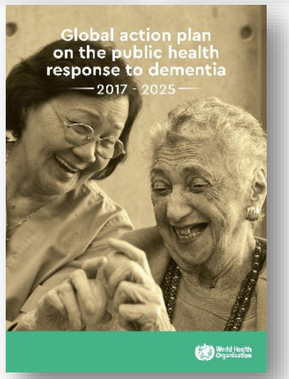
# WHO Action Plans




- Comprehensive Mental Health Action Plan 2013 – 2030
- Global Action Plan on the Public Health Response to Dementia 2017 – 2025
- Intersectoral Global Action Plan on epilepsy and other neurological disorders (IGAP) 2022 – 2031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# Brain Health at the Global Level

- Addressing brain health has a growing momentum in Europe and beyond, with key milestones taking place within the European Parliament, the United Nations General Assembly (UNGA), the G7 Health Ministers' Meeting, the European Health Forum Gastein and more.

- With very concrete achievements:
  - Launch of a Global Brain Coalition
  - Adoption of the Yaoundé Declaration on Brain Economy, Brain Health and Brain Capital



GLOBAL BRAIN COALITION

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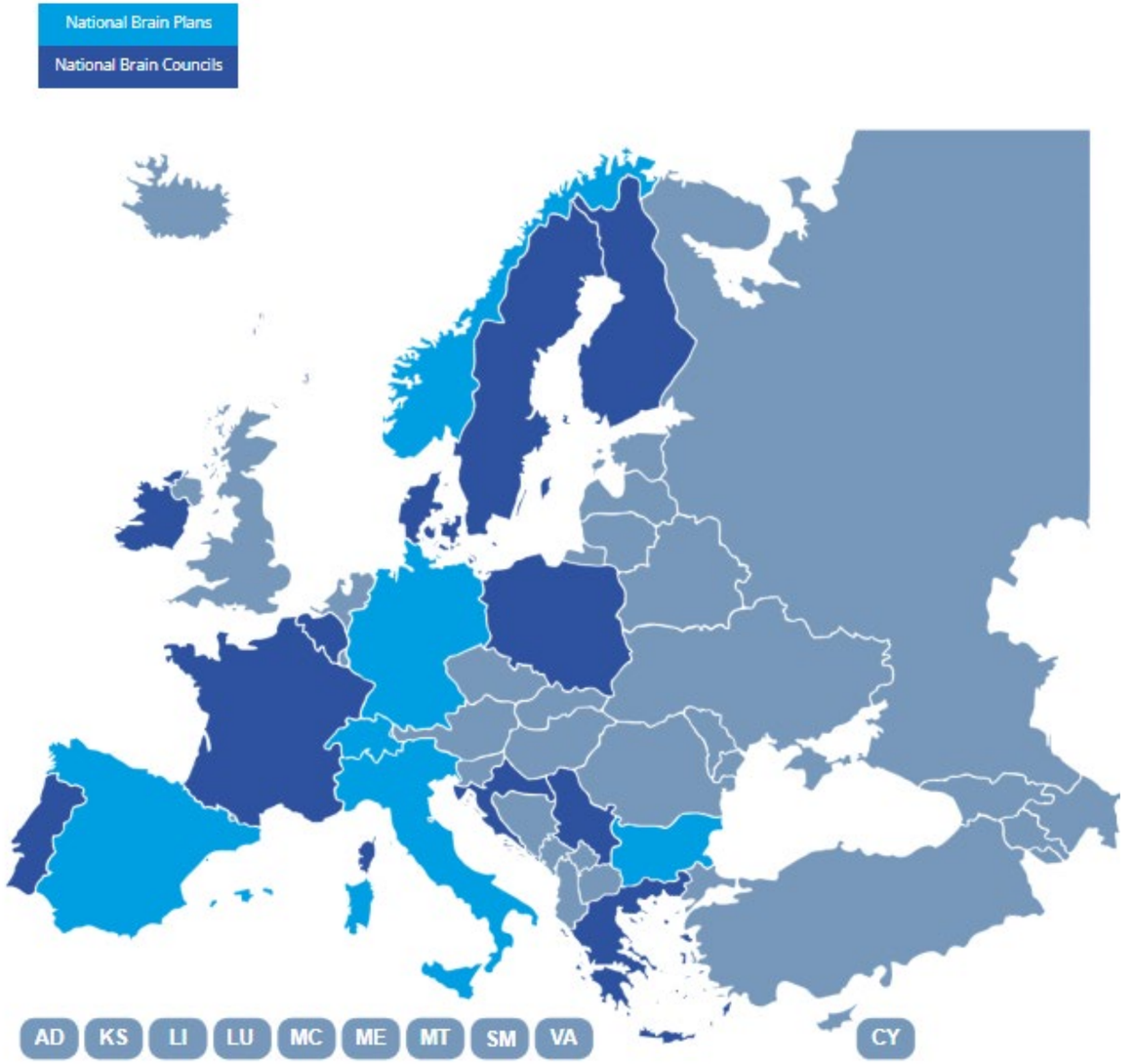
# Brain Health at National Level

**Countries with an existing National Brain Strategy:**

- Norway ✅
- Spain ✅
- Finland ✅
- Italy ✅
- Germany ✅
- Switzerland ✅
- Bulgaria ✅

*+ several more in the making.*



# Key Policy Files

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European Commission


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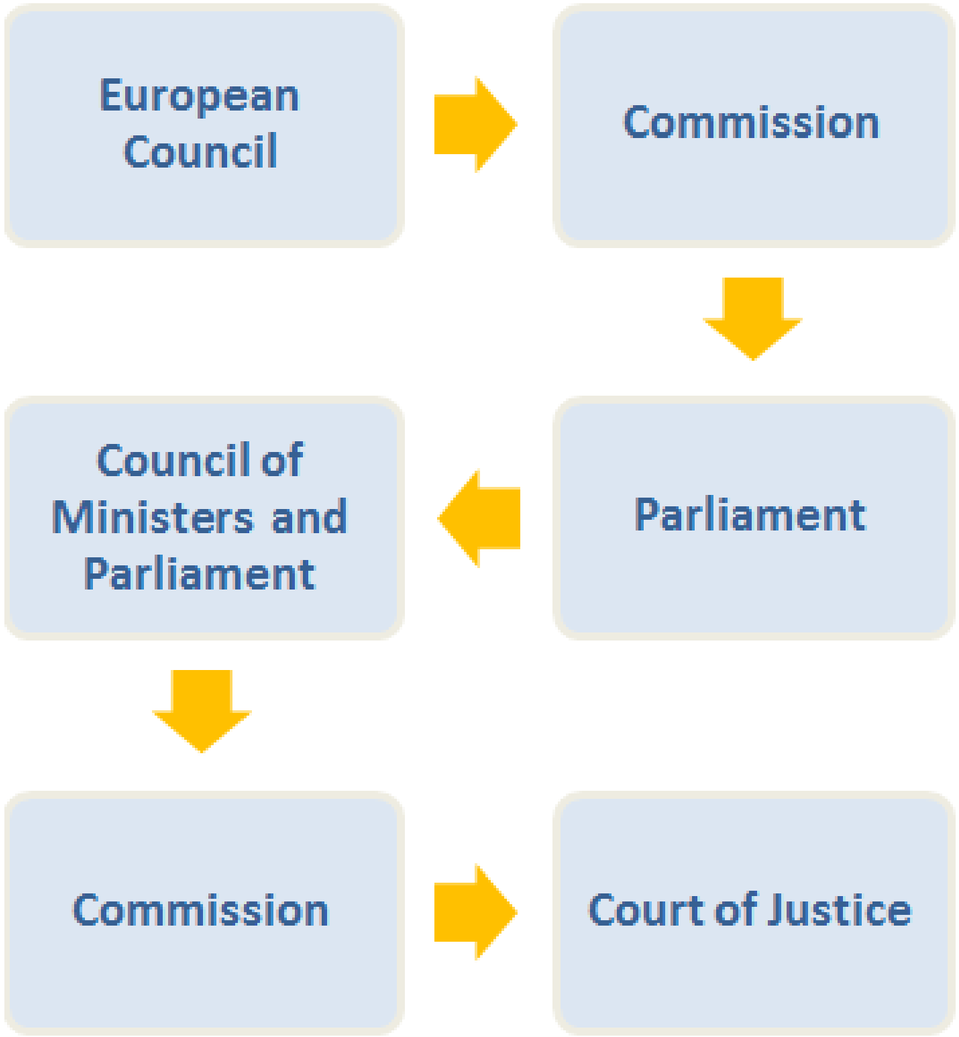
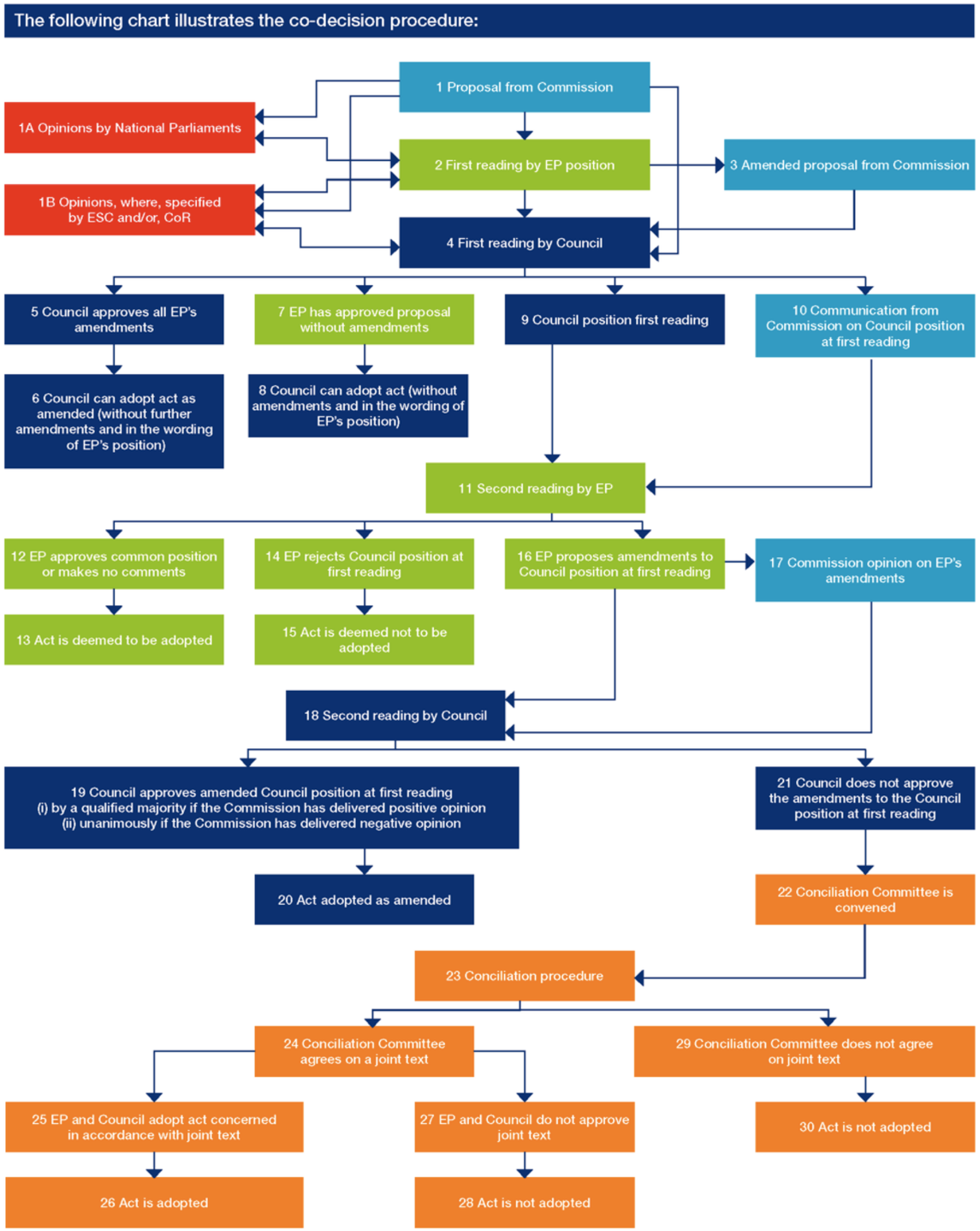
# The EU decision making process



# Recent EU Policy Developments







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# What is the European Research Area?

**A single, borderless EU Research & Innovation Area designed to:**

- Enable free movement of researchers, knowledge & technology
- Align national and EU R&I priorities
- Strengthen Europe's scientific competitiveness
- Boost collaboration, mobility & innovation

**ERA = Europe's "Single Market for Knowledge"**

European Research Area

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# The 2025 ERA Act

- Aims to give the ERA a **stable legal foundation**
- Strengthens governance, planning & accountability
- Links R&I to EU strategic autonomy & competitiveness
- Frames research as an essential infrastructure
- Complements FP10, Life Sciences Strategy, Critical Technologies

➢ **A potential major upgrade to Europe's research architecture.**


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# Recent EU Policy Developments







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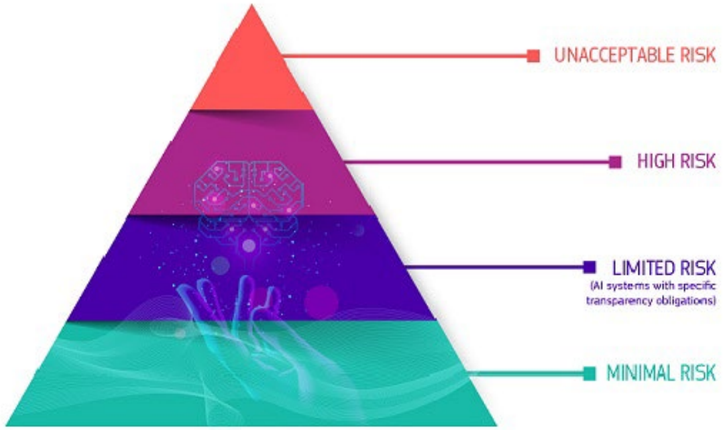
# What is the AI Act?

**A comprehensive framework designed to create a framework of rules for AI, particularly risky ones:**

- Aims at creating a safe and trusted environment on AI in the EU;
- Distinguishes between 4 levels of risk and categories of AI systems;
- Prohibits certain practices and establishes a compliance protocol and conformity assessment.





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# Engaging on the Brain at EU Level

- Event Hosted by **MEP Romana Jerkovic**, Vice-Chair of the SANT Committee of the European Parliament.
- Linked with an engagement activity bringing together **20+ researchers and achieving over 40 meetings** with MEPs and their staff.
- **Key MEPs engaged** in SANT, ITRE and relevant committees.

S&D Group of the Progressive Alliance of Socialists & Democrats in the European Parliament

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**Advancing Brain Research in Europe:**
**A Call for Collective Action**

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# Engaging on the Brain at EU Level

1. Commitments from MEPs to acknowledge the critical role played by animal models in advancing research
2. Several future **engagement opportunities**
    a) Neurological & Mental Health Strategy work in SANT
    b) Brain Innovation Days Opening & Other Events
    c) European Partnership for Brain Health
    d) Consultations & Calls for Evidence
    e) Upcoming Presidencies of the Council of the EU
3. Amendment to the **SANT Opinion on the General budget** of the European Union for the financial year 2026

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# SANT Public Hearing on Brain Health

On 24th February, the Public Health Committee of the European Parliament (SANT) organized a Public Hearing on '**Brain health: Policy challenges and opportunities to manage neurological diseases**.

**Speakers:**

- **Sameer Zuberi, EBC VP & Past EPNS President**
- **Orla Galvin, EBC Board Member & EFNA Exec. Director**
- Miroslaw Zabek, Former President of an EANS National Society
- Ana Verdelho, Member of EAN and ESO
- Elly M. HOL, Vice-Dean of Research of the University Medical Center Utrecht

This followed the **Exchange of Views held in October 2024** with Prof. Claudio Bassetti and will feed into the **SANT INI Report on Brain Health** – which is expected to be delivered before the end of 2026.


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# Brain Health Day During BAW26

**Brain Health Day: Prevention, Policy, Progress**

***In partnership w. Brain Health Mission, EAN & FENS***

***18 March 2026, 09:30 – 18:00, Brussels***

**> 150 in-person participants**

**Key Stakeholders Engaged:**

- President & Vice-President of the EP
- 4 MEPs on the Programme
- ~15 Meetings with MEPs
- Several Articles Relayed  by Media Outlets


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# Fostering Collaboration and Coordination in Brain Research

EJN European Journal of Neuroscience FENS

*European Journal of Neuroscience, Vol. 44, pp. 1919–1926, 2016* doi:10.1111/ejn.13236

EDITORIAL
Consensus Statement on European Brain Research: the need to expand brain research* in Europe – 2015

R. G. M. Morris,[1] W. Oertel,[2] W. Gaebel,[3] G. M. Goodwin,[4] A. Little,[5] P. Montellano,[6,†] M. Westphal,[7] D. J. Nutt[8] and M. Di Luca[1,9]
[1]Federation of European Neuroscience Societies (FENS), Bruxelles, Belgium
[2]European Academy of Neurology (EAN), Vienna, Austria
[3]European Psychiatric Association (EPA), Strasburg, France
[4]European College of Neuropsychopharmacology (ECNP), Utrecht, The Netherlands
[5]European Federation of Neurological Associations (EFNA), Bruxelles, Belgium
[6]Global Alliance of Mental Illness Advocacy Networks-Europe (Gamian-Europe), Bruxelles, Belgium
[7]European Association of Neurosurgical Societies (EANS), Gent, Belgium
[8]European Brain Council, Bruxelles, Belgium
[9]Department of Pharmacological and Biomolecular Sciences, University of Milan, Via Balzaretti 9-20133 Milan, Italy

Recommendation

*The brain – the most complex organ of mankind and the challenge to understand its function and to cure its disorders*

The brain is the most complex organ of the human being. It provides and controls virtually every function of the body including rational thinking, emotions, heart beat, breathing, food and fluid intake, sex, etc. Disorders of the brain are more complicated to analyse, diagnose and treat than other diseases. These brain disorders (to name just the most common ones – depression, Alzheimer's dementia, schizophrenia, stroke, migraine, sleep disorders, Parkinson's disease, pain syndromes in particular back pain, addiction to alcohol and other substances) give rise to a far higher level of disability, including admissions to hospitals and nursing homes, than is widely recognised. Health economists have calculated that brain disorders may cost as much as 45% of the annual health budget of Europe, totaling around Euro 800 billion (Gustavsson *et al.*, 2011; DiLuca & Olesen, 2014). With an aging population in Europe the prevalence of the most common neurological and psychiatric disorders will dramatically increase and we have not found cures or means to delay or reduce their burden and economic impact, as well as the burden of care givers and the loss of productivity and employment associated with this.

*Knowledge of brain function has substantially increased over the last decades*

At the same time, from a position of relatively limited knowledge about the brain some 50 years ago, our basic understanding of the nervous system has expanded markedly since then. Indeed, European basic and clinical neuroscientists have played a major part in this success story. The availability of astonishing new technologies, particularly over the last ten years, has greatly aided this development. It is an area of research in which many young people in both the life and the physical sciences wish to work – the brain represents one of the last truly great frontiers. Thanks to dedicated support and commitment from funders and scientists in recent years, Europe is now at the forefront of the international effort both to understand the brain through basic science and to apply this knowledge in practical and clinically relevant ways.

*Targeted European funding of brain sciences has put Europe at the international forefront – to find the cure of brain disorders must get top priority*

In line with the above, the European Commission provided comprehensive support for brain research in the 7th Framework Programme. Brain Research was finally and rightly considered a priority to be endowed with the necessary, targeted financial resources: more than EUR 3,1 billion has been dedicated to brain related research since 2007, funding 1931 projects. Thanks to these efforts we better understand the diseases and cures are getting closer, but we are not there yet. Thus, at this stage of development in the research towards real solutions, continued support for brain research is still a real and pressing need.

*From basic neuroscience via clinical trials to product approval – the enforcement of the translation workforce in European brain research*

Discoveries and advances in basic neuroscience are the prerequisites for describing the normal function of the nervous system and revealing the etiology and pathophysiology of brain diseases. To move such discoveries forward for the benefit of patients however, we need translational and clinical experts, ideally trained in the laboratory as well as in the clinical setting. These experts will provide the

*Correspondence*: M. Di Luca, Department of Pharmacological and Biomolecular Sciences, as above.
E-mail: monica.diluca@unimi.it
*In this document brain research is used to refer to both fundamental curiosity-driven and translational research on disorders of the brain, spinal cord and peripheral nervous systems and to cover both psychiatric (mental) and neurological disorders.
†The author passed away on the 2nd October 2015.
The board of the European Brain Council (EBC) adopted the present document on November 26th 2015.



**2018-2022** → **2023-2025** → **2026-2035**

*Coordination and Support Action European Brain Research Area*

*Coordination and Support Action BrainHealth*

*European Partnership For Brain Health*

EBRA
EUROPEAN BRAIN RESEARCH AREA

BrainHealth
PARTNERSHIP

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# EP BrainHealth - Key facts

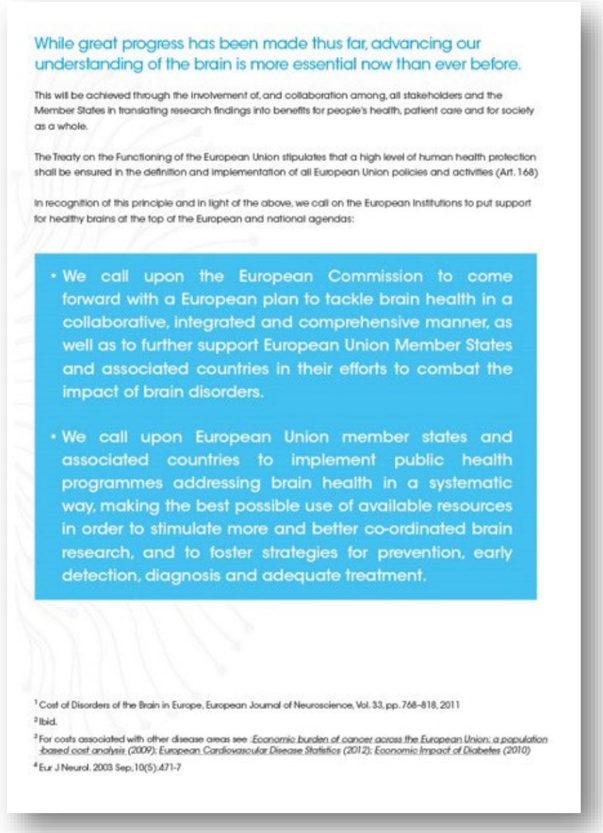
| | |
|---|---|
| **Preparatory phase** | CSA BrainHealth, 11 partners from 21 countries<br>Coordinated by Germany, BMBF/DLR |
| **Expected partners** | Primarily national funding organisations (public or private) |
| **Other participants** | Researchers, healthcare providers/practitioners, patient organisations, the private sector, policymakers, regulators, citizens, etc. |
| **Implementation mode** | Co-funded European Partnership in the 2nd Strategic Plan of „Horizon Europe“ (Cluster 1, Health) |
| **Duration** | 10 years, starting January 2026 |
| **Budget** | European Commission: ~ 150 Mio. €<br>Contributions of Member States / Associated Countries: ~ 350 Mio. € |

# Towards a European Coordination Plan for the Brain

- Echoing WHO's recommendations, EBC issued a Call to Action in 2015, urging:
    - The European Commission to come forward with a European plan to tackle brain health in a **collaborative, integrated and comprehensive** manner
    - EU member states and associated countries to implement public health programmes **addressing brain health in a systematic way**

A European Coordination Plan needs to be **holistic** and **overarching**

***Need to address brain health at global level to make it a priority.***



While great progress has been made thus far, advancing our understanding of the brain is more essential now than ever before.

This will be achieved through the involvement of, and collaboration among, all stakeholders and the Member States in translating research findings into benefits for people's health, patient care and for society as a whole.

The Treaty on the Functioning of the European Union stipulates that a high level of human health protection shall be ensured in the definition and implementation of all European Union policies and activities (Art. 168)

In recognition of this principle and in light of the above, we call on the European Institutions to put support for healthy brains at the top of the European and national agendas:

- We call upon the European Commission to come forward with a European plan to tackle brain health in a collaborative, integrated and comprehensive manner, as well as to further support European Union Member States and associated countries in their efforts to combat the impact of brain disorders.
- We call upon European Union member states and associated countries to implement public health programmes addressing brain health in a systematic way, making the best possible use of available resources in order to stimulate more and better co-ordinated brain research, and to foster strategies for prevention, early detection, diagnosis and adequate treatment.

[1] Cost of Disorders of the Brain in Europe, European Journal of Neuroscience, Vol. 33, pp. 768–818, 2011

[2] Ibid.

[3] For costs associated with other disease areas see: *Economic burden of cancer across the European Union: a population -based cost analysis (2009); European Cardiovascular Disease Statistics (2012); Economic Impact of Diabetes (2010)*

[4] Eur J Neurol. 2003 Sep;10(5):471-7

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# Neuroethics

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# Neuroethics


***Brain health*** is defined as 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.

*Neurotechnologies provide hope for improved brain health but with any new development comes uncertainty and risk*

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# Neuroethics

A multi-stakeholder group building on:

2019 OECD – Recommendation #457 on Responsible Innovation in Neurotechnology
2021 UNESCO report on Ethics of Neurotechnology
2025 UNESCO Recommendation on the Ethics of Neurotechnology
2023 Leon Declaration on European Neurotechnology


**Authors**

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# Neuroethics

## Medical and non-medical applications

Medical devices, defined in the Medical Devices Regulation, cannot be placed on the European market without conforming to strict safety requirements including the affixation of the CE marking of conformity—indicating that *a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.*

Non-medical applications include products for neurostimulation and neurofeedback in work, education, entertainment and marketing. These devices often lack appropriate oversight regarding their scientific foundations, safety, efficacy and ethical supervision: for instance, EEG systems with an intended medical purpose require a pre-market approval, while EEG direct-to-consumer products are only subjected to the CE marking of conformity.

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# Neuroethics

# The Seal of Responsible Neurotechnology

A voluntary, independent ethical label for organisations developing, deploying, or using neurotechnologies — covering medical, non-medical, and research applications.

**Medical neurotechnologies** | **Non-medical neurotechnologies** | **Research & exploratory neurotechnologies**

The Seal operationalises the principles of the European Charter for the Responsible Development of Neurotechnologies, translating its commitments into a concrete, independently verified governance standard.

## WHY IT MATTERS

### Investment readiness

Provides credible, standardised evidence of ethical governance to ESG-mandated investors, public funding bodies, and Horizon Europe ethics appraisals.

### Regulatory foresight

Aligns your organisation with EU AI Act, GDPR, and UNESCO standards — reducing the risk of costly retrofits as regulation evolves.

### Procurement access

Supports access to institutional markets and public tenders that increasingly require responsible innovation credentials.

### Built for startups

Pre-revenue companies can qualify using declarations, draft policies, and roadmaps — the process is calibrated to your stage of development.

Thanks to Pascal Maigne & Hadhemi Kaddour from French Agency of Biomedicine

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## Access the Charter

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# Thank You!

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# Session 2 – From Research Findings to Policy

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# Break

**See you back in 10 minutes!**

HEREDITARY

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# Session 3 – Policy Mockup Exercise

- **Introductions (5 min)** — Share who you are and what you do
- **Icebreaker (10 min)** — Reflect on gaps in EU policy using a guiding prompt
- **Role Assignment** — Each participant is assigned a stakeholder role
- **Scenario Deliberation (25 min)** — Discuss your group's policy scenario and key tensions
- **Deliverable** — Agree on a defensible policy recommendation readable in under 30 seconds
- **16:45** — Back to plenary! Each room's spokesperson presents the group's consensus



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# Concluding Remarks, Key Takeaways and Reflection

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# THANKS

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