

HMA/EMA multistakeholder workshop on patient registries for Alzheimer's disease

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EU4Health

EU Health programme (2021-2027)

Joint Action on dementia and other neurological disorders

'Healthier Together' EU NCDs initiative

Strand: neurological disorders

- Prevention and early detection of neurological diseases, in particular Alzheimer's disease and dementia, among the priority areas.
- **JADE Health** – EUR 4.5 million (EU4Health programme)
 - To study, transfer, implement, monitor, and assess evidence-based interventions for dementia and other diseases.
 - WP5 - Health literacy and data accessibility



EU Best Practice Portal of Public Health

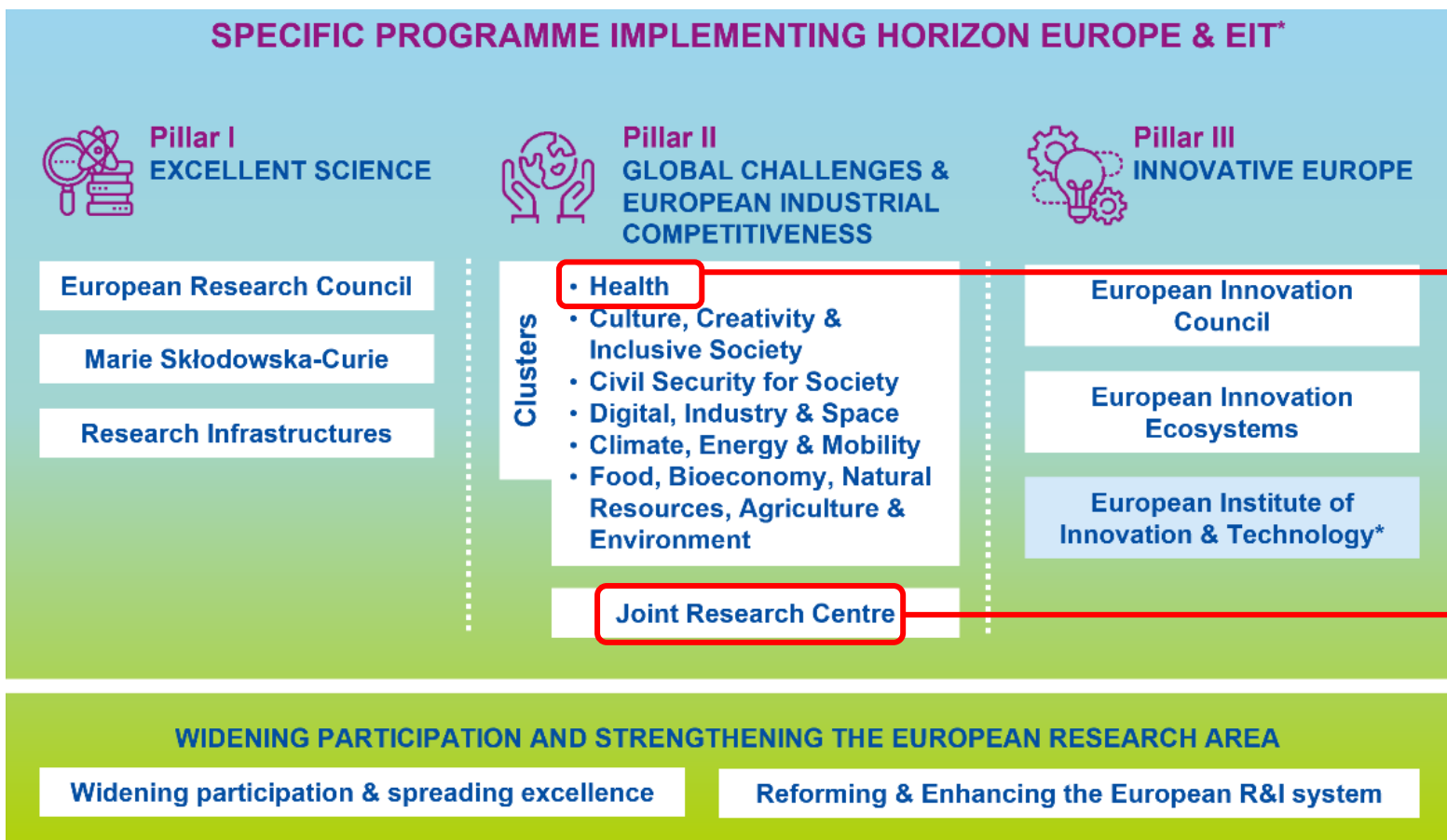
[BP Portal \(europa.eu\)](https://europa.eu/bp-portal/)

[Expert Group on Public Health - European Commission \(europa.eu\)](https://europa.eu/expert-group-on-public-health/)

Horizon Europe

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Pillar II: Global challenges & European Industrial Competitiveness



Health Cluster

- Improving collaboration
- Partnerships

- Public-Private Innovative Health Initiative



- Public-Public European partnership for Brain Health



Joint Research Centre

- CHIEF initiative (Collaborative Health Information European Framework)



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Health Cluster **call topic**

HORIZON-HLTH-2022-TOOL-11-02

New methods for the effective use of **real-world data** and/or synthetic data in **regulatory decision-making** and/or in health technology assessment

MetReal cluster of funded projects

- **More-EUROPA**
More Effectively Using Registries to support Patient-centered Regulatory and HTA decision-making
2023-2027, RIA, EU contrib. €7 million
- **ONCOVALUE**
Implementing value-based oncology care at European cancer hospitals: An AI-based framework for assessing real-life effectiveness of novel cancer therapies in real-time
2022-2026, RIA, EU contrib. €6,9 million
- **Real4Reg**
Development, optimisation and implementation of AI methods for RWD analyses in regulatory decision-making and HTA along the product lifecycle
2023-2026, RIA, EU contrib. €7 million
- **REALM**
RWD Enabled Assessment for health regulatory decision-Making
2023-2026, RIA, EU contrib. €6,7 million
- **REDDIE**
RWE for decisions in diabetes
2023-2026, RIA, EU contrib. €4,8 million
- **INSAFEDARE**
Innovative applications of assessment and assurance of data and synthetic data for regulatory decision support
2023-2026, RIA, EU contrib. €2,9 million



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Health Cluster **call topic**

HORIZON-HLTH-2021-TOOL-06-03

Innovative tools for use and re-use of **health data** (in particular of **electronic health records** and/or **patient registries**)

InToEHR cluster
of funded projects

- [AIDAVA](#)
AI powered Data Curation & Publishing Virtual Assistant
2022-2026, RIA, EU contrib. €7,7 million
- [RES-Q PLUS](#)
Comprehensive solutions of healthcare improvement based on the global Registry of Stroke Care Quality
2022-2026, RIA, EU contrib. €7,7 million
- [IDEA4RC](#)
Intelligent Ecosystem to improve the governance, the sharing and the re-use of health Data for Rare Cancers
2022-2026, RIA, EU contrib. €8,2 million
- [DataTools4Heart](#)
A European Health Data Toolbox for Enhancing Cardiology Data Interoperability, Reusability and Privacy
2022-2026, RIA, EU contrib. €7,7 million
- [eCREAM](#)
enabling Clinical Research in Emergency and Acute care Medicine through automated data extraction
2022-2027, RIA, EU contrib. €7,3 million



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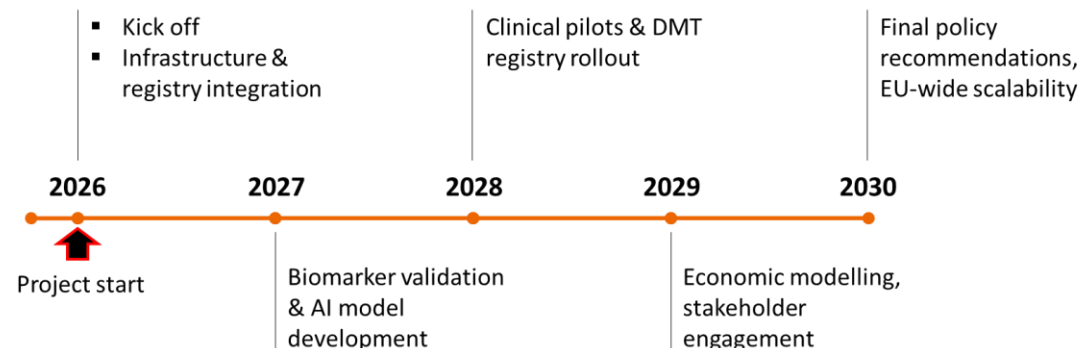
- Public-Public European partnership for Brain Health



Innovative Health Initiative's ACCESS AD project

- under signature, start Jan 2026
- Aims to create a pan-European **framework** for optimised Alzheimer's care
- Will establish a **pan-European registry** for patients treated with DMT via integration and expansion of available sources (e.g InRAD)
- Plans to generate **harmonised RWE** on DMTs & emerging therapies
- Will deliver flexible analytical tools to evaluate impact of emerging technologies across the AD care pathway, adaptable to different countries & settings

ACCESS AD Timeline



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Objectives of ACCESS-AD



Regulatory Need	How ACCESS-AD Delivers It
Evidence gaps for current and upcoming therapies	WP5 real-world cohorts (500+ pts), multimodal data, treatment monitoring; WP4 predictive models.
Use of real-world data (RWD) from registries	WP2 federated data infra; WP5 DMT registry; harmonized clinical + PRO datasets.
Core data elements definition	WP2 data standards + WP6 regulatory engagement; multimodal biomarkers (MRI, PET, BBM, digital).
Long-term follow-up of patients	WP5 longitudinal cohorts; digital IADL monitoring; decentralized follow-up.
Data governance, consent, interoperability	WP2 governance framework, FAIR compliance, federated architecture matching EHDS.
Quality assurance for evidence generation	WP3 standardized imaging/biomarker workflows; WP6 QA processes; harmonized site protocols.
Stakeholder collaboration	WP7 multi-stakeholder engagement + WP6 regulatory/HTA alignment + WP1 coordination.



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- **Public-Public European partnership for Brain Health**



launch: 1 Jan 2026

European partnership for Brain Health

- Largest co-funded partnership in Health Cluster
EU contrib.: €~150 M; Total €~500 M
- Start: Jan 2026
Duration: 10 years
- Builds on previous EU-supported initiatives
- Align efforts & funding under a strategic research & innovation agenda (**SRIA**)
- By connecting stakeholders, it could **facilitate** the follow-up of patients using registries

<https://www.brainhealth-partnership.eu/resources/sria/>



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Collaborative Health Information European Framework (CHIEF)

Published deliverables:

- Process towards agreement, definition, and contextual description of indicators using diabetes registries as a case study. doi: [10.3389/fpubh.2025.1685731](https://doi.org/10.3389/fpubh.2025.1685731)
- Data and indicator standardised contextualisation ontology incorporating a data quality description framework. doi's: [10.3389/fcomp.2024.1463989](https://doi.org/10.3389/fcomp.2024.1463989); [10.3390/data10090136](https://doi.org/10.3390/data10090136)
- Data protection, interoperability and governance assessment tool.
doi: [10.3389/fdgth.2025.1685774](https://doi.org/10.3389/fdgth.2025.1685774)

Deliverables shortly to be published addressing:

- Federated process to avoid centralised collection of personal data
- Patient involvement in registry networks

*Featured in special issue of **Frontiers in Public Health**:*

<https://www.frontiersin.org/research-topics/70015/the-design-of-collaborative-frameworks-for-sustainable-health-indicators-in-europe-using-diabetes-and-its-complications-as-a-scalable-model-across-disease-domains/articles>



Thank you



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