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European Medicines Agency

Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on Patient Registries for Alzheimer's disease – 15 December 2025

Summary

On 15 December 2025, the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) organised a multistakeholder workshop to explore how to best use registries to collect data that can help fill evidence gaps on Alzheimer's disease, its prevention and its treatments.

Dementia is the leading cause of disability and dependency in older adults, affecting almost 8 million people in the EU. Alzheimer's disease is the most common form of dementia and is thought to account for 60-80% of cases. While a diagnosis of Alzheimer's disease changes a person's life and that of their relatives, a very active research ecosystem feeds substantial hopes for improved outcomes in the near future.

Clinical evidence is at the heart of well-informed decisions on the development, authorisation, reimbursement, use and monitoring of medicines. Patient registries play a key role in collecting data, including long-term data, to support some of these decisions. Stronger collaboration across stakeholders is needed to ensure data collected are of high quality, and meaningful for patients, healthcare professionals, but also for regulators, research groups and pharmaceutical industry to address evidence needs.

The currently fast-evolving treatment landscape for Alzheimer's disease creates a unique momentum and opportunity for a smarter and better coordinated data collection that will meet the needs of all stakeholders.

After listening to the perspectives from all stakeholder groups, and learning about the evidence gaps, challenges, but also opportunities offered by existing patient registries such as Svedem and InRAD, the participants agreed on a series of key principles.

- It is important to work together to define a core dataset for Alzheimer's disease registries that would be acceptable for all stakeholders and fit-for-use in multiple contexts. This should meet the immediate and future needs of patients, healthcare professionals, research groups as well as those of the regulators, especially in terms of data quality. Participants agreed that this is a key aspect which should be guided by EMA's data quality framework.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- Patients and caregivers must be involved in defining this core dataset to ensure the collected data reflect outcomes that matter to them and ultimately bring them a benefit, through better treatments, better care and better information.
- The collection and sharing of data should be handled in a secured, trusted and transparent way to ensure patients' confidence and engagement.
- Efforts should be made to progress towards large disease-based registries designed to capture data on all treatments allowing comparisons 1) between treated and untreated patients, 2) across treatments and 3) across countries, to avoid fragmented data collection and underpowered studies.
- There is a need for a sustainable support through permanent funding under clear governance principles from multiple interested parties, including public institutions (e.g., governments) and pharmaceutical industry, rather than relying only on project-based funding. This would help patient registries to collect high-quality and meaningful data, adapt as treatment landscape evolves, and better integrate into healthcare systems.
- The use of digital tools and possibility of data linkage should be further investigated to supplement registry data and reduce the burden on clinicians and patients.

Several EU-wide initiatives were highlighted, namely the upcoming European Partnership for Brain Health, and the ACCESS-AD project, aiming to create a pan-European registry for Alzheimer's disease and to facilitate dialogue between all stakeholders.

The output of this HMA/EMA workshop will serve as a catalyst for stronger collaborative effort between all stakeholders to move forward on the development of useful Alzheimer's disease registries.

A full report will be published in the first quarter of 2026. It will include further information about the next steps and way forward.