Patient Registry workshop on Alzheimer's disease

15 December 2025, 09:00 – 17:30 (CET/CEST)
In-person at the EMA building, Amsterdam (Room 1D) + virtual enabled

Objectives of the workshop

This joint hybrid HMA/EMA workshop on Patient Registries follows on the successful disease-specific workshops held between 2017 and 2019, as well as the EMA multi-stakeholder workshop on qualification of Patient Registries held in 2024.

The event brings together representatives of registry holders, regulatory agencies, pharmaceutical companies, patients, healthcare professionals, academia and non-for-profit research organisations, health technology assessment bodies and payers to explore how we can work all together to foster the use of registry data for regulatory decision-making in the field of Alzheimer's Disease.

More specifically, the main objectives of the workshop are to agree on recommendations for optimising stakeholders' collaboration to **facilitate the long-term follow-up of patients using registries**[1], and **enable the generation of meaningful evidence** on the safety and effectiveness of medicines using patient registries. These objectives will be addressed by:

- Raising awareness of the evidence gaps related to current and upcoming therapies that could potentially be addressed using real-world data (RWD).
- Identifying core data elements to be collected in registries to enable the evaluation of therapies, and the effectiveness of their risk minimisation measures.
- Aligning on recommendations regarding patient consent, governance for accessing and sharing data, quality assurance and registry interoperability.

[1] In according with the EMA Guideline on registry-based studies, "Patient registry" (referred to as "registry" in the rest of the agenda) is defined as: Organised system that collects uniform data (clinical and other) to identify specified outcomes for a population defined by a particular disease, condition or exposure. The term 'patient' highlights the focus of the registry on health information. It is broadly defined and may include patients with a certain disease, pregnant or lactating women or individuals presenting with another condition such as a birth defect or a molecular or genomic feature.

Co-Chaired by **Ewa Balkowiec-Iskra** (URPL, CNS WP Chair, SAWP Vice-Chair, member of CHMP, ETF, and PCWP) and **Peter Arlett** (EMA, Head of Data Analytics and Methods Task Force)

08:30 Joining and technical checks

09:00 Welcome and opening remarks

Welcome to the workshop **5'**
Co-Chairs of the event

Opening remarks from EMA Executive Director **5'**
Emer Cooke (EMA Executive Director)

Opening remarks from the CHMP Chair **5'**
Bruno Sepodes (CHMP Chair, Infarmed, Portugal)

Opening remarks from the European Commission **5'**
Tim Raemaekers (Directorate-General Research & Innovation, Belgium)

09:20 Session 1: Current evidence gaps and potential of real-world data

Co-Chairs: Ulla Wandel Liminga (PRAC Chair, MPA, Sweden), Francesca Day (Head of Therapeutics Area Department, EMA)

Introduction on Alzheimer's Disease and current therapies **20'**
Marion Haberkamp (CNS WP, BfArM, Germany)

Stakeholders' perspectives on real-world evidence generation **70'**

- **Healthcare professional** – *Kristian Steen Frederiksen (Danish Dementia Research Centre, Denmark)*
- **Patient** – *Stuart Dougall (EWG PWD)*
- **Regulator in the European Economic Area** – *Peter Mol (CHMP, MEB, The Netherlands)*
- **Non-EU Regulator** - *Teresa Buracchio (Office of Neuroscience, CDER, FDA)*
- **Health Technology Assessment Body** - *Niklas Hedberg (TVL, Sweden)*
- **Payer** - *César Hernández (Ministerio de Sanidad, Spain)*
- **Industry** – *Elsie Grace (Eli Lilly), Pamela Dobay (Biogen)*

10:50 Coffee Break

11:20 Session 1 (continued): Current evidence gaps and potential of real-world data

Registry holders' perspectives on real-world evidence generation **60'**

- Experience and lessons learnt from a network of registries in another therapeutic area, **Big MS Network** – *Jan Hillert (Big Multiple Sclerosis Data Network, Swedish Neuro Registries, Karolinska Institutet, Sweden)*
- **SveDem**: Swedish registry for cognitive / dementia disorders - *Dorota Religa (Department of Neurobiology, Care Sciences and Society, Karolinska Institutet, Sweden)*
- **InRAD**: International Registry for Alzheimer's Disease and Other Dementias - *Robert Hyde (InRAD CoFounder and Consultant for TW1 Healthcare and GWS GmbH, Switzerland), Robert Perneczky (Department of Psychiatry and Psychotherapy, Ludwig-Maximilians-Universität Hospital München, Germany)*

12:20 Lunch break

13:10 Session 2: Parallel break-out sessions (no live broadcast)

The participants will be divided into three parallel breakout sessions to discuss research questions, core data elements, challenges, opportunities for collaboration **140'**

Breakout session A – Room 1A

Breakout session B – Room 1B

Breakout session C – Room 2A

15:30 Coffee break and move back to plenary room 1D

16:00 Session 3: Panel discussion

Co-Chairs: Bruno Sepodes (CHMP Chair, Infarmed, Portugal), Patrice Verpillat (Head of Real-World Evidence, EMA)

Feedback from breakout sessions, recommendations on next steps **80'**

17:20 Closing remarks

Wrap up **10'**

Peter Arlett (Head of Data Analytics and Methods Task Force, EMA)

Acronyms

Acronyms	
AD	Alzheimer's Disease
BfArM	Federal Institute for Drugs and Medical Devices, Germany
Big MS Network	Big Multiple Sclerosis Data Network
CDER (US-FDA)	Center for Drug Evaluation and Research
CNS WP	Central Nervous System Working Party
CHMP	Committee for Medicinal Products for Human Use
EC	European Commission
ETF	Emergency Task Force
EMA	European Medicines Agency
EWG PWD	European Working Group of People with Dementia
HMA	Heads of Medicines Agencies
INFARMED	Autoridade Nacional do Medicamento e Produtos de Saúde I.P., Portugal
InRAD	International Registry for Alzheimer's Disease and Other Dementias
MEB	Medicines Evaluation Board, The Netherlands
Ministerio de Sanidad	Common Portfolio of the NHS and Pharmacy at the Spanish Ministry of Health
MPA	Medical Products Agency, Sweden
MWP	Methodology Working Party
NDSG	Network Data Steering Group
PCWP	Patient and Consumer Working Party
PRAC	Pharmacovigilance Risk Assessment Committee
RWD	Real-World Data
RWE	Real-World Evidence
SAWP	Scientific Advice Working Party
SveDem	Swedish registry for cognitive / dementia disorders
TDA	Data Analytics and Methods Task Force
TVL	Dental and Pharmaceutical Benefits Agency, Sweden
URPL	Office For Registration Of Medicinal Products Medical Devices And Biocidal Products, Poland
US FDA	Food and Drug Administration of the Unites States of America