German Dementia Registry (DEMREG)

First published: 29/05/2026

Last updated: 29/05/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000913

Study ID

1000000913

DARWIN EU® study

Yes

Study countries

Germany

Study description

The aim of the German Dementia Registry is to prospectively collect longitudinal real-world data on all consenting patients diagnosed in clinical routine with SCD, MCI, and early dementia of different etiologies in Germany, independent of their actual treatment regimen. For this purpose, an online

platform will be provided.
Data are collected during patient visits and items for data collection are aligned with diagnostic/treatment guidelines and clinical procedures. The disease specific registry will be conducted to prospectively follow the natural course of dementia and to differentiate e.g. patients with Alzheimer’s dementia from patients with dementia of other etiology.
The data collected will provide prospective and longitudinal data demonstrating the natural course of disease and the current diagnostic and treatment behavior in clinical routine in the German healthcare system. Prospective monitoring of dementia patients is expected to lead to a better understanding of the natural history of dementia and the changes in biomarker values within different etiologies of dementia. This can help to improve and adapt the early diagnostic criteria regarding biomarkers and real-world data for patients on newly approved treatments (e.g. amyloid antibodies).

Study status

Ongoing

Research institutions and networks

Institutions

Uniklinik RWTH Aachen: University Hospital Aachen, Department of Neurology

University Hospital Magdeburg (OVGU)

Germany

First published: 26/11/2025

Last updated: 26/11/2025

Institution | Hospital/Clinic/Other health care facility

Deutsches Zentrum für Neurodegenerative Erkrankungen e. V. (DZNE)

Germany

First published: 20/11/2025

Last updated: 20/11/2025

Institution | Hospital/Clinic/Other health care facility

1. Department of Neurology, University Hospital Ulm, Germany

2. Department of Neurology, University Hospital Bremen-Ost, Germany

3. Department of Neurology and Policlinic, University Hospital Heidelberg, Germany

4. Psychiatric and Psychotherapeutic Clinic, University Hospital Erlangen, Germany

5. Clinic for Geriatrics, University Medical Center Göttingen, Germany
6. Department of Neurology, University Hospital Essen, Germany
7. Psychiatry and Psychotherapy, University Hospital Tübingen, Germany
8. Center for Mental Health, Immanuel Hospital Rüdersdorf, Brandenburg Medical School Theodor Fontane, Germany
9. Psychiatric and Psychotherapeutic Clinic, Hospital Frankfurt (Oder), Germany
10. Department of Neurology, University of Leipzig Medical Center, Germany
11. Psychiatric and Psychotherapeutic Clinic, Charité University Medicine Berlin, Germany
12. Clinic and Polyclinic for Neurology, University Hospital Hamburg Eppendorf, Germany
13. Clinic for Geriatric Psychiatry, Psychosomatics and Psychotherapy, Pfalzklinikum Klingenmünster,

Germany
14. Clinic for Neurology Campus Kiel, University Hospital Schleswig-Holstein, Germany
15. University Hospital Magdeburg, Germany
16. Central Institute for Mental Health, Clinic for Geriatric Psychiatry, Mannheim, Germany
17. Clinic for Psychiatry and Psychotherapy, Homburg, Germany
18. Memory Clinic, Clinic for Gerontopsychiatry, Asklepios Klinik Nord, Ochsenzoll, Germany
19. Clinic for Psychiatry and Psychotherapy, Charité University Medicine Berlin, Germany
20. Department of Neurology, Faculty of Medicine and University Hospital Cologne, University of Cologne, Cologne, Germany
21. Department of Neurology, Technical University of Munich, School of Medicine and Health, TUM University Hospital, Munich, Germany
22. University Medical Centre of Johannes

Gutenberg University Mainz, Department of Psychiatry and Psychotherapy, Mainz, Germany

23. Augsburg University Hospital, Department of Neurology, Augsburg, Germany

24. University Hospital Jena, Department of Neurology, Jena, Germany

25. German Center for Neurodegenerative Diseases (DZNE), Greifswald, Germany

26. Martin-Luther-University Halle-Wittenberg, Department of Neurology, Halle (Saale), Germany

Networks

German Network of Memory Clinics (Deutsches Netzwerk Gedächtnisambulanzen; DNG)

Contact details

Study institution contact

Jennifer Michels jmichels@ukaachen.de

Study contact

jmichels@ukaachen.de

Primary lead investigator

Jörg B. Schulz 0000-0002-8903-0593

Primary lead investigator

ORCID number:

0000-0002-8903-0593

Study timelines

Date when funding contract was signed
Actual: 23/02/2021

Study start date
Actual: 16/05/2022

Date of final study report
Planned: 01/01/2050

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

DEMREG was funded by Biogen (2021–2022) and is currently supported by Eisai (since 2022) and Lilly (since 2023), as well as private donations.

Study protocol

GDR Protocol v2.0 16.12.2021_signed.pdf (14.71 MB)

19-050_Protocol_Dementia_Registry_v6.0_clean_signed.pdf (1.06 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

DRKS00027547 - 01.04.2022

https://drks.de/search/en/trial/DRKS00027547

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study topic, other:

Dementia, Registry, Biomarkers, Neurodegeneration, Natural history, Treatment, Mild cognitive impairment

Study type:

Not applicable

Scope of the study:

Disease epidemiology

Drug utilisation

Evaluation of patient-reported outcomes

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is an open-ended prospective longitudinal multicenter registry in adult patients with SCD, MCI or early dementia of different etiology with fluid biomarkers such as cerebrospinal fluids (CSF).

Main study objective:

The primary goal of the DEMREG is to establish a register for the collection of data and biomarkers related to amyloid-beta (Aβ) and tau pathology of cognitive impairment and early dementia in Germany. This also includes patients with anti-amyloid or other treatments.
The central task of the DEMREG is to systematically collect longitudinal data on demographics, clinical and neuropsychological characteristics, as well as imaging, blood, and cerebrospinal fuid markers in patients with subjective

cognitive decline (SCD), mild cognitive impairment (MCI) or mild dementia to measure the natural course and therapeutic effects.
It is designed to investigate the natural course of cognitive disorders, while also capturing the effects of therapeutic interventions and identifying risk factors that may infuence disease progression. By integrating longitudinal clinical, biomarker, and treatment data from clinical routine, the registry aims to uncover patterns that contribute to a better understanding of disease dynamics. Ultimately, the fndings are intended to support the development of targeted strategies to improve patient care and optimize treatment pathways.

Study drug and medical condition

Medicinal product name

LEQEMBI

Medicinal product name, other

Donanemab - Kisunla®

Study drug International non-proprietary name (INN) or common name

LECANEMAB

Anatomical Therapeutic Chemical (ATC) code

(N06DX05) donanemab

donanemab

Medical condition to be studied

Dementia

Cognitive disorder

Population studied

Short description of the study population

Participating patients must have a level of cognitive decline of SCD, MCI or early dementia with a clinical diagnosis of i.e. Alzheimer’s Disease, Frontotemporal Dementia, Parkinson’s Disease, Lewy-Body Dementia, Progressive Supranuclear Palsy, Corticobasal Degeneration, Normal Pressure Hydrocephalus, Major Depression; Vascular Dementia; TDP-43 associated limbic encephalopathy (LATE), Mixed Dementia AD + VaD, Prion Associated Dementia together with biomarkers such as cerebrospinal fluids (CSF) amyloid beta 1-42, amyloid beta 1-40, amyloid beta 1-42/amyloid beta 1-40 ratio, total tau and phosphorylated tau, amyloid or tau imaging.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Cognitive impairment

Estimated number of subjects

5000

Study design details

Setting

All memory clinics within the German Network of Memory Clinics (Deutsches Netzwerk Gedächtnisambulanzen [DNG]; www.gedaechtnisambulanzen.de) are eligible to participate in this registry.

Patients are eligible as participants if: (a) they (or their legally authorized representative) are able to understand the purpose and risks of the registry and provide written informed consent and authorization to use protected health information in accordance with national and local privacy regulations; (b) they have received a diagnosis of subjective cognitive decline (SCD), mild cognitive impairment (MCI), or mild dementia, irrespective of etiology; (c) they have available results of neurodegeneration biomarkers (i.e., cerebrospinal fuid (CSF) Aβ1-42, Aβ1-40, Aβ1-42/Aβ1-40 ratio, total tau, and phosphorylated tau, and/or Aβ-PET or tau- PET imaging); and

(d) they are 18 years of age or older.

Study partners are eligible if: (a) they are 18 years of age or older, (b) they are study partners of a patient who has been included in the registry, (c) they have regular contact with the patient (according to the patient’s statement), and (d) they can understand the purpose and risks of participating in the study and provide written informed consent.

Most of the data (e.g. demographics, medical history, medication, cognitive assessments) are collected from routine clinical records. Additional diagnostic parameters, such as biomarkers, imaging and laboratory results, will also be documented if they are available as art of the clinical routine. Existing neuropsychological data from routine clinical assessments that are no older than six months will also be included. If consented to, blood samples will be collected for biobank storage. Follow-up visits are conducted on an annual basis (±3 months).

Data analysis plan

The registry’s primary goal is to evaluate current diagnostic and treatment practices in terms of their efectiveness and infuence on disease progression, and to monitor the natural course of disease progression in a cohort of patients with cognitive impairment and dementia in Germany. The statistical analysis plan (SAP) includes an initial analysis of baseline characteristics of a German memory clinics’ cohort, which will be primarily descriptive, and with larger datasets enabling advanced statistical methods—such as linear mixed-efects models to assess progression rates and the validity of outcomes (e.g. responsiveness) on longitudinal assessments. Continuous variables will be reported using measures like mean, standard deviation, range, and quantiles, with categorical data presented as counts and percentages of valid responses. The study evaluates real-world data regarding treatment effectiveness and ARIA management.

Documents

Abstract of study report

The German Dementia Registry (DEMREG) - study protocol of a biomarker-based national registry for cognitive impairment and dementia (1).pdf (1.14 MB)

https://doi.org/10.1186/s42466-025-00433-9

https://doi.org/10.1186/s42466-025-00433-9

https://www.ukaachen.de/kliniken-institute/klinik-fuer-neurologie/forschung-1/k…

Study publications

https://doi.org/10.1186/s42466-025-00433-9

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Libre Clinica (open source electronic data capture (EDC) system for clinical trials)

Data sources (types)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction

after creation of study variables

Data characterisation details

Study variables and their implementation in the EDC system were reviewed as part of the system validation process.

Data exports are reviewed on a risk-based basis after they are generated.