DARWIN EU® - Alzheimer’s Disease: Incidence, Prevalence, and Individuals' Characteristics

First published: 10/11/2025

Last updated: 18/12/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000826

Study ID

1000000826

DARWIN EU® study

Yes

Study countries

- [ ] Croatia
- [ ] Denmark
- [ ] Germany
- [ ] Netherlands

United Kingdom

Study description

Alzheimer’s disease (AD) is the most common cause of dementia, characterised by progressive cognitive
decline and loss of independence. Its burden is rising globally due to population ageing, with substantial
implications for healthcare systems and society. Recent therapeutic advances, such as the approval of anti
amyloid monoclonal antibodies, are reshaping AD management but also highlight the need for
comprehensive and updated real-world evidence on the epidemiology and characteristics of affected
populations.
This DARWIN EU® study will provide contextual information through a comprehensive overview of the
incidence and prevalence of AD in the general adult population in European countries, as well as
demographic and clinical characteristics of individuals with AD.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

- [ ] Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution | Educational Institution | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal

- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

Natasha Yefimenko study@darwin-eu.org

Study contact

study@darwin-eu.org

Primary lead investigator

Rana Jajou

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/10/2025

Actual: 07/10/2025

Study start date

Planned: 06/11/2025

Actual: 06/11/2025

Date of final study report
Planned: 30/01/2026

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-021_Alzheimer's - burden and characteristics _V3.0.pdf (1.97 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

• Population level cohort study (objective 1)

• Patient level cohort study (objective 2)

Main study objective:

1. To estimate overall incidence and prevalence of Alzheimer's disease in the general population and stratified by calendar year, sex, and age.
2. To describe the demographic characteristics, diagnostic procedures, and clinical profile of individuals with newly-diagnosed AD.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Dementia Alzheimer's type

Population studied

Short description of the study population

Objective 1: All individuals aged 18 years or older present in the data sources during the study period from
01/01/2014 to 31/12/2024, or earliest date of loss to follow-up, death, end of the observation period or
data availability, or the earliest date of AD diagnosis with at least 365 days of database history.
Objective 2: All individuals with newly (incident) diagnosed AD aged 18 years or older, diagnosed with AD
during the study period from 01/01/2014 to 31/12/2024, with at least 365 days of database history.

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)

Study design details

Data analysis plan

Objective 1: Yearly incidence rates per 100,000 person-years and prevalence of AD will be estimated,
overall and stratified by calendar year, sex, and age categories. Incidence rates and prevalence will be
reported with 95% confidence intervals.
Objective 2: Demographic characteristics, pre-specified comorbidities, concomitant medications, diagnostic
procedures, and prior cognitive diagnosis will also be described and will be reported as counts and
proportions. For MCI, time from MCI recording to AD diagnosis will be described as well.
A minimum cell count of 5 will be used when reporting results, with any smaller count reported as “<5” and
zero counts as “0”.

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)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Danish Health Data Registries

InGef Research Database

IQVIA Disease Analyzer Germany

Integrated Primary Care Information (IPCI)

Clinical Practice Research Datalink (CPRD) GOLD

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No