Protocol (Pangea ID 2024-14140) Development of Algorithms to Identify Intracerebral Hemorrhage Greater Than 1 cm and Amyloid-Related Imaging Abnormalities Using Electronic Medical Records in Select Populations of Alzheimer's Disease and Related Dementias and Mild Cognitive Impairment Patients in the United States

First published: 13/10/2025

Last updated: 13/10/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000501

Study ID

1000000501

DARWIN EU® study

No

Study countries

United States

Study description

Develop algorithms to identify intracerebral hemorrhage (ICH) greater than 1 cm and amyloid-related imaging
abnormalities (ARIA) using Natural Language Processing (NLP) of unstructured radiology reports from
Electronic Health Record data among patients with Alzheimer’s disease and mild cognitive impairment. Algorithms will be validated using medical chart review.

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Premier Healthcare Solutions, Inc.

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Krista Schroeder 0000-0002-0589-2613

Primary lead investigator

ORCID number:

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Study timelines

Date when funding contract was signed

Actual: 27/09/2024

Study start date

Planned: 01/01/2026

Date of final study report

Planned: 30/01/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & Co.

Study protocol

LY3002813 2024-14140 NI PASS Algorithm Development Protocol_ENCePP (PI only)_Redacted.pdf (1019.5 KB)

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 topic, other:

Algorithm development

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Kisunla

Anatomical Therapeutic Chemical (ATC) code

(N06DX05) donanemab

donanemab

Medical condition to be studied

Dementia Alzheimer's type

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

Healthix HIE Data

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown