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Feasibility Of Using Secondary Databases For Observational Research On Amyloid-Targeting Therapies

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OBJECTIVE

- To identify **secondary real-world data** (RWD) in three geographies (United Kingdom (UK), Brazil, and the European Union (EU)) and evaluate the identified RWD's fit for purpose for conducting **real world evidence** (RWE) studies on **amyloid-targeting therapies** (ATTs).

CONCLUSION

- Existing secondary RWD are available and could be used to support research on persons using ATTs, with limitations due to data structure or availability.
- This structured, multi-step assessment framework provides a **systematic evaluation** of data availability, completeness, and suitability for ATT research across diverse healthcare systems globally.

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BACKGROUND

- Secondary **real-world data** (RWD), such as electronic medical records (EMR), patient registry data or claims data, can be used to **complement the evidence from clinical trials** and fill knowledge gaps.
- These data sources are often large and readily available but can have limitations such as variable availability and limited clinical interpretation.
- Secondary RWD could generate RWE to support ATT research needs, such as:
  - **Safety** risk from rarer outcomes, such as anaphylaxis and intracerebral haemorrhage.
  - Receipt of **pre-treatment evaluations** such as APOE4 genetic testing, amyloid testing and MRI screening.
  - Receipt of post-dosing MRI **monitoring.**
  - **Patient demographics** and baseline clinical characteristics.
  - **Treatment characteristics**, such as treatment duration and treatment dose.
- This work utilized a structured framework to identify secondary RWD in the UK, Brazil, and EU and evaluate which were **fit-for-purpose** for research into RWE needs of ATT therapies.

STUDY DESIGN

The RWD identification and evaluation involved three-steps:

- ***Step 1 Data landscaping***: identification of potentially relevant RWD and shortlist sources.
- ***Step 2 Qualitative assessment***: evaluation against three critical go/no-go criteria.
- ***Step 3 Quantitative assessment***: quantify Alzheimer's disease (AD) or mild cognitive impairment (MCI) person counts and completeness of key treatment, monitoring (e.g., MRI), and safety event capture using analog products (matched on administration route, setting, monitoring requirements, and frequency of use). Analogs were used as proxies for ATTs due to the absence of ATTs in the data at the time of evaluation.

RWD feasibility assessment

Step 1: Data landscaping

a) **Search strategy**: combine disease, geographical, and data source specific terms in PubMed for the last 10 years
b) **Desk-based research**: identify conference publications, disease-specific registries, claims data, and national health databases that may not have been published
c) **Full-text review** exclusions: geographical scope, lack of RWD and/or secondary data, study types (e.g., clinical trials, chart reviews ,etc.) or non-English publications
d) **Select RWD sources** for the respective markets for a pre-specified qualitative in-depth assessment based on their suitability for safety studies

Step 2: Qualitative assessment

Critical criteria (go/no-go):
a) Data source captures **sufficient public and/or private healthcare data** in line with assumptions on national **reimbursement** for the ATT
b) Ability to **identify administration** of the ATT within the data source and study period
c) **Key variables** are captured, including patient profile and demographics, clinical characterization, treatment characteristics, dates of drug administration, receipt of imaging tests and records of safety events

Enhancement criterion:
d) **Imaging results** are available to support amyloid positivity and amyloid-related imaging abnormality assessments

Step 3: Quantitative assessment

a) Number of persons with **AD/MCI** in the data source
b) Number of persons with a record for an **antithrombotic** medication
c) Number of persons with a record for a list of predefined **safety events**
d) Number of persons treated with **analog products similar to the ATT** with the following data included:
- Drug name recorded
- Dose of first administration recorded
- Repeated infusions recorded
- Follow-up data at 6, 12, and 18 months after analog initiation

RESULTS

Available | Partially available | Not available

United Kingdom

- CPRD-HES and the Arcturis RWD Network were evaluated under the assumption of eventual public reimbursement in this region. CPRD-HES did not progress beyond *Step 2*, as administration of ATTs could not be identified due to missing drug names.
- The Arcturis RWD Network met all criteria at the time of assessment for the UK (Table 1).

Brazil

- TriNetX and DATASUS were assessed with the assumption that a private care source was required. DATASUS, representing the public healthcare system, failed *Step 2* due to reimbursement coverage limitations.
- TriNetX met all criteria for Brazil (Table 1).

European Union

- France (SNDS, HUGO), Germany (GePaRD, InGef, NTD), the Netherlands (PHARMO), Sweden (SveDem + Swedish Health Registries), Spain (VID, SIDIAP), and TriNetX (EU-wide) were assessed with the assumption of public reimbursement. HUGO, GePaRD, NTD, PHARMO, VID and TriNetX (EU) failed *Step 2* due to long data lag time or insufficient coverage balance. SIDIAP was not progressed beyond *Step 2*, as it cannot identify ATTs and safety events in secondary care.
- SNDS, InGef, and SveDem met all criteria (Table 1).

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Table 1. RWD sources that passed *Step 1* and were selected for qualitative and quantitative evaluation

	UK	Brazil	France	Germany	Sweden
Step 1:	Arcturis RWD Network	TriNetX	SNDS	InGef	SveDem + Swedish Health Registries
Data type	EMR (secondary care)	EMR (secondary care)	Claims	Claims	EMR/disease registry
Size	>12 million unique longitudinal patient records	19 million patients (~10% of population)	67 million (99% of population)	Data from ~50 statutory health insurance companies	Data from 100% of memory clinics and 78% primary care
***Step 2*: Key PASS variables**					
Patient demographics (e.g., age, sex)	Available	Available	Available	Available	Available
Medical history (e.g., Down syndrome)	Available	Available	Available	Available	Available
APOE testing observed	Currently not routine practice	Currently not routine practice	Not available	Not available	Available
APOE testing results	Currently not routine practice	Currently not routine practice	Not available	Not available	Available
***Step 2*: Clinical characteristics, imaging and biomarkers**					
MRI/CT/PET scan observed	Available	Available	Available	Available	Available
MRI/CT/PET scan results	Unstructured format	Unstructured format	Not available	Not available	Study-specific
CSF test observed	Available	Available	Available	Available	Available
CSF test results	Unstructured format	Unstructured format	Not available	Not available	Study-specific
***Step 2*: Treatment characteristics**					
Able to identify ATT infusion	Available	Available	Available	Available	Available
ATT administration dates*	Available	Available	Available	Available	Available
ATT dose	Available	Unstructured format	Available	Via procedure codes	Available
***Step 2*: Safety events**					
Intracerebral haemorrhage	Available	Available	Available	Available	Available
Hypersensitivity	Available	Available	Available	Available	Available
ARIA-E/ARIA-H	Unstructured format	Unstructured format	Not available	Not available	Study-specific
Date of event	Available	Available	Available	Available	Available
***Step 3*: Quantitative assessment**					
Counts of persons with AD/MCI	Available	Available	Available	Available	Available
Counts of antithrombotic use	Secondary care only	Secondary care only	Available	Available	Available
Counts of safety events	Available	Available	Available	Available	Available
Counts of patients with analog medication	Available	Available	Available	Available	Available

*Discontinuation dates can be estimated based on treatment gap rules, but reason for discontinuation is unavailable.

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