# EMPOWER AD: A NOVEL, PATIENT-CENTRIC, LONGITUDINAL, CLINICAL DATASET IN THE UNITED STATES

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## Background

- Medical records can provide real-world insights into Alzheimer's disease (AD); however, they are often fragmented and are not readily accessible to all patients.
- EMPOWER AD is an ongoing US observational study utilizing medical record data collection via a patient-centered electronic platform.
- Obtaining access to digitized records may empower patients and support shared decision-making with their healthcare providers.
- We aim to improve the collection, organization, and curation of medical record data to accelerate evidence generation, identify challenges in the patient care journey, and identify opportunities to improve outcomes for patients with AD.

## Methods

- Adult patients with diagnoses of mild cognitive impairment (MCI) or dementia with or without reference to AD were onboarded to the PicnicHealth medical record platform.
- Medical records are abstracted into a structured dataset to provide a longitudinal view of the disease course of patients with AD.
- Eligibility criteria include diagnoses of MCI or dementia with or without reference to AD.
- Diagnostic subgroups were determined using the most recent diagnosis date, which was a characteristic of the dataset. Patients who had multiple diagnoses on the same day were excluded from this interim analysis.
- Planned enrollment is 2500 (first participant enrolled January 2022). Our intention is to recruit a participant sample representative of US AD epidemiology.
- Demographic and clinical characteristics were compared using the Kruskal-Wallis test, Pearson's chi-squared test, and Fisher exact test.
- We compared cohorts using the gtsummary package (1.6.2). R software, version 4.2.1 was used to perform statistical analyses.

## Results

### *Participant Demographics*

- Of the 440 participants included in this interim analysis, 64.5% were diagnosed with AD dementia, 13% were diagnosed with MCI, and 22.5% were diagnosed with dementia.
- Participants were enrolled by self (48%) or via a care partner (52%).
- Demographics are comparable for participants with AD dementia, MCI, and dementia (**Table 1**).
- 1.6% of participants withdrew from the cohort; 6 due to participant choice and 1 participant is deceased.

**Table 1. Baseline characteristics**

| Characteristic | MCI N=57 | AD Dementia N=284 | Dementia N=99 | Overall N=440 | *P*-value* |
|---|---|---|---|---|---|
| **Age at recent dx, median (IQR)** | 71 (65, 75) | 71 (64, 77) | 73 (66, 78) | 71 (64, 77) | 0.2 |
| **Female, n (%)** | 30 (53%) | 157 (55%) | 51 (52%) | 238 (54%) | 0.8 |
| **Race and ethnicity, n (%)** | | | | | |
| White | 48 (84%) | 229 (81%) | 78 (79%) | 355 (81%) | |
| American Indian** | 0 (0%) | 2 (0.7%) | 1 (1.0%) | 3 (0.7%) | |
| Asian | 2 (3.5%) | 2 (0.7%) | 0 (0%) | 4 (0.9%) | |
| Black | 3 (5.3%) | 25 (8.8%) | 9 (9.1%) | 37 (8.4%) | |
| Hispanic or Latino | 1 (1.8%) | 16 (5.6%) | 8 (8.1%) | 25 (5.7%) | |
| More than one race | 1 (1.8%) | 1 (0.4%) | 2 (2.0%) | 4 (0.9%) | |
| Prefer not to say | 0 (0%) | 5 (1.8%) | 0 (0%) | 5 (1.1%) | |
| Unknown | 2 (3.5%) | 4 (1.4%) | 1 (1.0%) | 7 (1.6%) | |
| **APOE testing, n (%)** | 2 (3.5%) | 3 (1.1%) | 1 (1.0%) | 6 (1.4%) | 0.4 |
| APOE carrier† | 2 (3.5%) | 1 (0.4%) | 0 (0%) | 3 (0.7%) | |

*Kruskal-Wallis test; Pearson's chi-squared test; Fisher exact test. **American Indian or Alaska Native. †Participants with at least one E4 allele were considered APOE4 positive. AD, Alzheimer's disease; APOE, apolipoprotein E; dx, diagnosis; IQR, interquartile range; MCI, mild cognitive impairment, SD, standard deviation.

### *Participant Clinical Characteristics and Treatment Patterns*

- A significant difference in mean number of symptoms suggesting cognitive decline was exhibited by participants with AD dementia (3.5 [2.0]) compared with MCI (3.1 [1.8]) and dementia (2.6 [1.8]); *P*=0.001 (**Table 2**).
- Overall, the most prevalent symptoms were memory impairment (85%), mood disturbance (80%), and sleep disorder (47%). Symptoms occurring more frequently in AD dementia than in MCI or dementia were impaired executive function (*P*=0.020), disordered language (*P*=0.015), and visuospatial reasoning difficulty (*P*=0.007).
- Amyloid-PET imaging occurred in 9 (2.0%) participants overall and occurred more frequently in participants with MCI (3.5%) compared with AD dementia (2.5%) or dementia (0%).
- Overall, 306 (70%) of participants were evaluated with either the Mini-Mental State Examination (MMSE), Montreal Cognitive Assessment (MoCA), or Saint Louis University Mental Status Exam. Interestingly, the MMSE was used more frequently in participants with AD dementia, whereas the MoCA was used more in those with MCI.

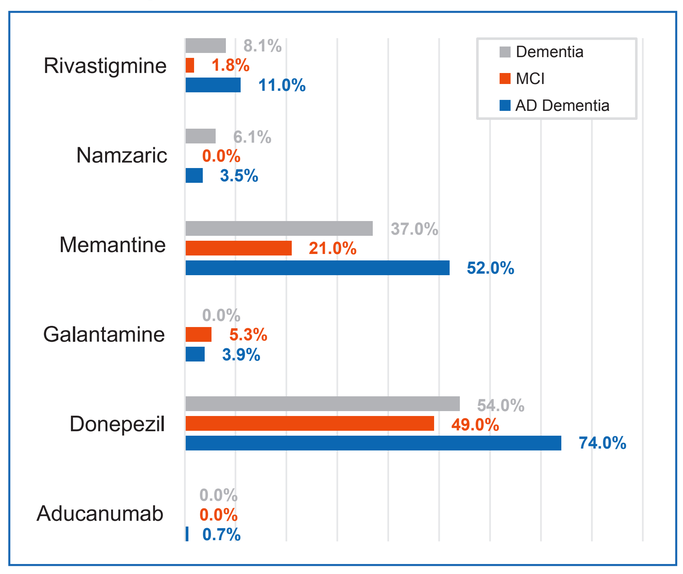
**Table 2. Participant Clinical Characteristics**

| Clinical Characteristic | MCI N=57 | AD Dementia N=284 | Dementia N=99 | Overall N=440 | *P*-value* |
|---|---|---|---|---|---|
| **No. of symptoms, mean (SD)** | 3.1 (1.8) | 3.5 (2.0) | 2.6 (1.8) | 3.2 (1.9) | 0.001 |
| **Symptom, n (%)**** | | | | | |
| Memory impairment | 46 (87%) | 237 (85%) | 69 (81%) | 352 (85%) | 0.6 |
| Mood disturbance | 40 (75%) | 228 (82%) | 66 (78%) | 334 (80%) | 0.4 |
| Sleep disorder | 29 (55%) | 128 (46%) | 37 (44%) | 194 (47%) | 0.4 |
| Impaired executive function | 15 (28%) | 93 (33%) | 15 (18%) | 123 (30%) | 0.020 |
| Disordered language | 12 (23%) | 71 (26%) | 9 (11%) | 92 (22%) | 0.015 |
| Agitation† | 6 (11%) | 61 (22%) | 15 (18%) | 82 (20%) | 0.2 |
| Altered appetite | 16 (30%) | 45 (16%) | 17 (20%) | 78 (19%) | 0.054 |
| Psychoses | 4 (7.5%) | 48 (17%) | 15 (18%) | 67 (16%) | 0.2 |
| Visuospatial reasoning difficulty | 3 (5.7%) | 44 (16%) | 4 (4.7%) | 51 (12%) | 0.007 |
| **Imaging test reported, n (%)** | | | | | 0.2 |
| Amyloid-PET | 2 (3.5%) | 7 (2.5%) | 0 (0%) | 9 (2.0%) | |
| MRI | 1 (1.8%) | 12 (4.2%) | 1 (1.0%) | 14 (3.2%) | |
| No imaging | 54 (95%) | 265 (93%) | 98 (99%) | 417 (95%) | |
| **CSF test performed, n (%)** | 1 (1.8%) | 26 (7.7%) | 1 (1.0%) | 28 (6.4%) | 0.003 |
| Normal finding | 0 (0%) | 5 (1.8%) | 1 (1.0%) | 6 (1.4%) | 0.4 |
| **No. of cognitive tests per participant (among those with a test), mean (SD)** | 1.9 (1.1) | 3.2 (2.8) | 2.3 (2.4) | 2.9 (2.6) | 0.006 |
| **Cognitive test performed, n (%)** | | | | | |
| MMSE | 18 (32%) | 119 (42%) | 26 (26%) | 163 (37%) | 0.014 |
| MoCA | 19 (33%) | 85 (30%) | 17 (17%) | 121 (28%) | 0.029 |
| SLUMS | 1 (1.8%) | 15 (5.3%) | 6 (6.1%) | 22 (5.0%) | 0.5 |
| **Cognitive test scores, median (IQR)** | | | | | |
| MMSE | 27.8 (23.6, 29.0) | 25.0 (20.0, 27.0) | 26.0 (21.0, 27.9) | 25.0 (20.8, 27.8) | 0.034 |
| MoCA | 24.0 (19.8, 25.0) | 19.3 (16.0, 23.0) | 21.0 (18.0, 23.4) | 20.0 (16.5, 23.7) | 0.069 |
| SLUMS | 25.0 (25.0, 25.0) | 18.0 (16.1, 21.5) | 17.2 (7.9, 24.0) | 19.0 (13.9, 21.8) | 0.4 |

*Kruskal-Wallis test; Pearson's chi-squared test; Fisher exact test. **Symptoms related to cognitive decline are reported here if the symptoms were experienced by >5% of patients examined. †Due to dementia. AD, Alzheimer's disease; CSF, cerebrospinal fluid; IQR, interquartile range; MCI, mild cognitive impairment; MMSE, Mini-Mental State Examination; MoCA, Montreal Cognitive Assessment; MRI, magnetic resonance imaging; PET, positron emission tomography; SD, standard deviation; SLUMS, Saint Louis University Mental Status.

- AD medication use was higher in participants with AD dementia than in those with MCI or dementia for symptomatic medications (specifically, donepezil, memantine, and rivastigmine) and aducanumab, of which 4 participants with AD dementia received from the overall study population (**Figure**).

**Figure. Alzheimer's Disease Medications Received by Participants**




AD, Alzheimer's disease; MCI, mild cognitive impairment.

## Limitations

- Given the early state of data collection, records are being continually updated. Completeness should improve over time.
- Cohort recruitment has targeted participants in the early stages of AD. This may skew the study population to underrepresent those in the later stages of the disease.
- Data are limited to available medical records. Patients may experience symptoms outside of those described. Similarly, drug usage data comes from reporting by healthcare providers and patients. Patients may not fully comply with prescribed regimens.

## Conclusions

- Medical record data can be used to understand disease journey, including symptom presentation.
- EMPOWER AD findings may deepen our understanding of the AD clinical trajectory and improve the standard of care for persons living with AD in the US.
- Obtaining access to digitized records may empower patients to make informed decisions about their health, and in turn creates new opportunities for shared decision-making with their healthcare providers.
- As we continue to build the dataset, we hope that EMPOWER AD will identify challenges in the patient care journey and identify opportunities to improve outcomes for patients with AD.

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## Disclosures

S Seleri Assunção, ES Mearns, K Raimundo, and C Wallick are employees of Genentech, Inc. and shareholders of F. Hoffmann-La Roche Ltd. K Belendiuk is an employee of Genentech, Inc. and a shareholder of F. Hoffmann-La Roche Ltd and Takeda. K Glockner, S Colbert-Pollack, J Xue, and H Patel are employees and shareholders of PicnicHealth. M Grundman is a consultant for Genentech, Inc. Medical writing and editorial support were provided by Health & Wellness Partners, LLC, Upper Saddle River, NJ, USA.

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