REACHED: Participant characteristics from a pilot pre-screening study designed to diversify clinical trial recruitment in understudied populations in Alzheimer's disease

Alexandria Wise-Brown, PhD[1], Frank Boess, PhD[2], Frank Perilli, BS[3], Ira Goodman, MD[3], Erin Beck, MPH, MBA[3], Karra D. Harrington, PhD[4], Nicklas Linz, PhD[5], Alison Buick, PhD[5], Nicola Maiorano, PhD[2], Ruth Croney, MSc[6], Kelly Coultes, PMP[7], Janice Smith, PhD[6]

[1]Genentech, Inc., South San Francisco, CA, USA; [2]F. Hoffmann-La Roche Ltd, Basel, Switzerland; [3]SiteRx, New York, NY, USA; [4]CogState Ltd, New Haven, CT, USA; [5]Ki:elements GmbH, Saarbrücken, Germany; [6]Roche Products Ltd, Welwyn Garden City, UK; [7]F. Hoffmann-La Roche Ltd, Mississauga, ON, Canada

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What does this mean for the Alzheimer's disease (AD) community?

- Findings further establish remote cognitive assessments as feasible tools for research in AD across diverse populations and clinical disease severity
- Artificial intelligence (AI)-assisted review of Electronic Medical Records (EMRs), remote consent, and digital assessments may help identify people with early symptomatic AD (eAD) from understudied populations for scientifically representative research
- Understanding operational barriers and digital assessment performance may inform approaches to improve identification and recruitment of understudied populations in future clinical trials

Conclusions

- The REACHED study used a feasible, efficient, and well-received approach for identifying and recruiting diverse participants in AD research, yielding an enrollment cohort with 82.0% participants from understudied populations
- In the era of FDA-approved disease-modifying therapies that require demonstrated amyloid pathology for access, these data suggest that underrepresented and socioeconomically disadvantaged communities may face barriers to standard care pathways before clinical trial enrollment begins. These findings suggest a need for more equitable access to biomarker testing
- Future approaches could pair decentralized digital screening (LILA™ application/SB-C) with at-home or local blood collection for blood-based biomarker testing (e.g. plasma p-tau217), potentially enabling more comprehensive remote pre-screening

Background

- In the US, ~7.4 million people live with clinically diagnosed AD, with varying risk per race and ethnicity[1]
  - Black or African American and Hispanic/Latinx populations face a higher risk of developing AD and other dementias than non-Hispanic White Americans[1,2]
- Underrepresentation of populations across clinical research reflects a multitude of interconnected barriers, specifically:[3,4]
  - A shortage of research-active specialists providing care for diverse populations
  - Protocols creating participation burdens for those facing socioeconomic challenges
  - Gaps in non-English language support
- Reduced therapeutic access and greater social determinants of health burden disproportionately affect populations understudied in clinical trials[3,5]
- Initial barriers to clinical trial participation impact translatability of findings and may confound efficacy and safety expectations when treatment becomes available to the diverse, heterogeneous population[3,6]
  - Understanding neighborhood-level socioeconomic disadvantage may help to inform recruitment initiatives for reaching understudied populations[7]

REACHED aimed to evaluate the utilization, feasibility, and performance of remote digital cognitive assessments in a diverse eAD cohort, examining assessment completion across participant subgroups and potential downstream clinical trial eligibility

Methodology

- REACHED methodology has been presented previously[8]

Study design and population

- REACHED was a US-based observational, prospective database study conducted via a centralized virtual research site between December 2024−April 2025 (13 US states)
- Participants were aged 50–90 years with eAD (mild cognitive impairment [MCI] due to AD or mild AD dementia), mostly from understudied populations (Black/African American, Asian American, Native American, or Hispanic/Latinx ethnicity regardless of race), alongside a reference group of 10 non-Hispanic White participants

Participant identification and enrollment

- Participants were identified using an AI-assisted search of a real-world database, based on study-defined inclusion/exclusion criteria and International Classification of Disease billing codes (ICD-9 or ICD-10) from EMRs
- Individuals recommended to take part via a treating physician received a Health Insurance Portability and Accountability Act (HIPAA) release of information (ROI) authorization
  - Those who signed the ROI were invited to complete a web-based eligibility questionnaire; completed questionnaires and medical records were reviewed by the Principal Investigator
- Upon signing an electronic informed consent form (eICF), participants were enrolled

Remote data collection and assessments

- Remote participant characteristic data collection included:
  - Area Deprivation Index ([ADI]; categorized into low [1–4], moderate [5–6] and high [7–9] deprivation ranks per state deciles)[7]
  - self-reported education
  - living arrangements
  - transportation barriers
- Participant characteristics included medical history, including prior AD biomarker (amyloid or tau) testing, clinically significant disease history, and medication use
- Cognitive performance was assessed using two remote neurocognitive tests: an automated phone-based voice assessment (Speech Biomarker for Cognition [SB-C])[9,10] and a smartphone-based List Learning and Memory Assessment (LILA™) application[11–13]
- Following remote assessment completion, an exit survey was provided and potential participant Phase III eligibility was assessed

Results

Participant characteristics

- Overall, 61 participants, aged 53–89 years, were enrolled; 50 (82.0%) participants were from understudied populations (**Table 1**)
  - Most participants were retired (n=50; 82.0%), and 36 (59.0%) had foundational educational experience (i.e., some college [non-graduate], some high school/high school graduate, or elementary school)
  - Most participants lived with others; among those living alone (n=7), median ADI score was 7, indicating high neighborhood deprivation
  - A total of 33 (54.1%) individuals were classified within the moderate-to-high ADI deciles, regardless of race/ethnicity
  - Most (n=42) participants had prior documented cognitive testing. Of those with a documented instrument, 18 had a Mini-Mental State Examination, 11 had a Montreal Cognitive Assessment and 1 had a St Louis University Mental Status examination
- Primary ICD-10 diagnostic codes were MCI (n=26), mild AD (n=16), other amnesia (n=15), and unspecified dementia (n=4)

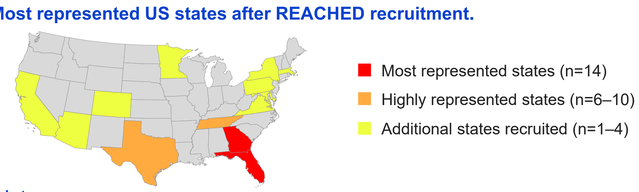
Table 1. Baseline demographic and clinical characteristics.

	White, non-Hispanic (n=10)	Black or African-American (n=26)	Hispanic /Latinx (n=17)	American Indian or Alaska Native (n=3)	Asian (n=4)	Unknown (n=1)	Total (N=61)
Sex; female, n (%)	3 (30)	18 (69)	10 (59)	3 (100)	1 (25)	0	35 (57)
Age, years							
<65	5 (50)	2 (8)	1 (6)	1 (33)	0	0	9 (15)
≥65	5 (50)	24 (92)	16 (94)	2 (67)	4 (100)	1 (100)	52 (85)
Social determinants							
Median education (years)	17	14	13	14	16.5	NA	14
Living arrangements, n (%)							
Living alone	0	4 (15)	2 (12)	0	1 (25)	0	7 (12)
Transportation barriers, n (%)*							
Barrier reported	0	0	3 (18)	0	0	0	3 (5)
Area Deprivation Index ranks							
1–4 [low]	8 (80)	12	3 (18)	2 (67)	3 (75)	0	28 (46)
5–6 [moderate]	0	10	6 (35)	0	1 (25)	1 (100)	18 (30)
7–9 [high]	2 (20)	4	8 (47)	1 (33)	0	0	15 (25)
Medical history, n (%)†							
Diabetes mellitus	2 (20)	9 (35)	7 (41)	1 (33)	1 (25)	0	20 (33)
Cardiovascular disease	3 (30)	3 (12)	5 (29)	1 (33)	1 (25)	0	13 (21)
Cancer	2 (20)	4 (15)	3 (18)	1 (33)	1 (25)	0	11 (18)
Prior cognitive testing†	7 (70)	16 (64)‡	11 (61)‡	3 (100)	4 (100)	1 (100)	42 (70)
Mini-Mental State Examination	1 (10)	6 (24)‡	8 (44)‡	1 (33)	1 (25)	1 (100)	18 (30)

*In the past 12 months †Percentage calculated using available data (n=1, not reported); ‡Percentages calculated out of n=25 Black or African-American and n=18 Hispanic/Latinx, due to one participant belonging to both ethnicities self-reporting as Hispanic/Latinx rather than Black for cognitive testing record.

- Overall, 13 US states were represented in REACHED, with Florida and Georgia (both 14 participants) comprising the most represented states, followed by Texas and Tennessee (**Figure 1**)

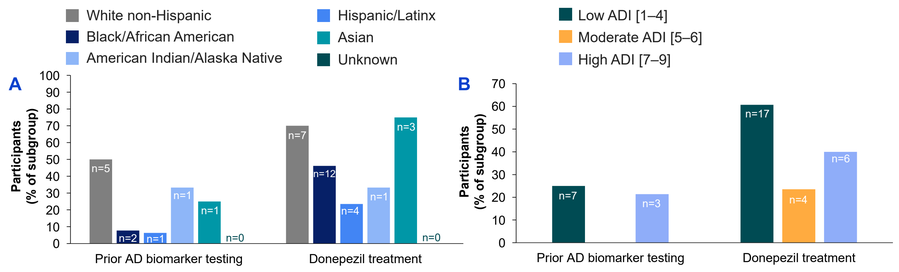
Figure 1. Most represented US states after REACHED recruitment.



Medical history

- Most (n=50, 83%) participants had no AD biomarker testing prior to enrollment (**Figure 2**)
  - Prior AD biomarker testing was more common among non-Hispanic White participants (n=5, 50%), while Hispanic/Latinx participants were least likely to have prior testing (n=1, 6.3%)
  - The likelihood of prior formal AD biomarker testing was higher in participants residing in low ADI areas; participants from mid-to-high ADI areas had no documented amyloid testing

Figure 2. Prior AD biomarker testing and donepezil use per A) race and ethnicity and B) ADI rank.



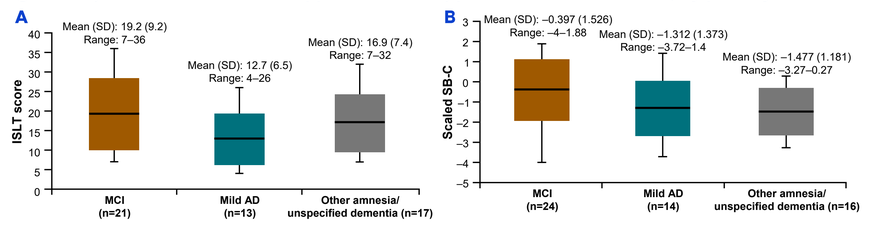
AD, Alzheimer's disease; ADI, Area Deprivation Index.

Results (cont.)

Digital assessment feasibility and completion

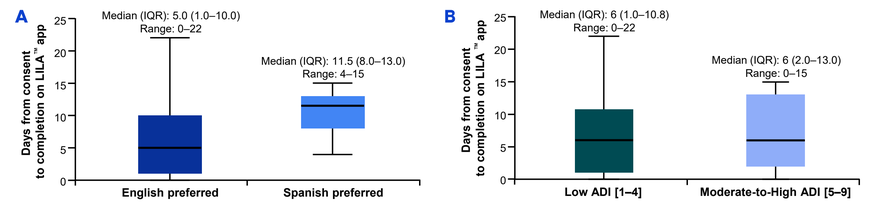
- Cognitive assessments determined via the LILA™ application and the phone-based SB-C captured clinical severity gradients within the expected range[14,15] across diagnostic groups (**Figure 3**)
- Observable trends emerged in time from consent to remote assessment completion via LILA™ application
  - Primary Spanish speakers experienced longer delays downloading and opening the application (median: 5 vs. 2 days) and longer overall completion times (**Figure 4**), compared with primary English speakers
  - Median completion time was 7.0 days for both White non-Hispanic and Black/African American cohorts, and 9.0 days for the Hispanic/Latinx cohort, while the Asian and Native American cohorts recorded the longest times at 13.0 and 16.0 days, respectively
  - Observed latencies were driven by language preference and structural access. These remain descriptive operational trends patterns, across very small subgroups without formal statistical hypothesis testing

Figure 3. A) ISLT score via LILA™ application and B) phone-based SB-C score, by primary ICD-10 code.



Horizontal center lines denote means; box limits denote the standard deviation; whiskers denote ranges.
AD, Alzheimer's disease; ICD, International Classification of Disease; International Shopping List Test; MCI, mild cognitive impairment; SB-C, Speech Biomarker for Cognition; SD, standard deviation.

Figure 4. Time from consent to completion of assessment via the LILA™ application by A) primary preferred language and B) ADI rank.



Horizontal center lines denote medians; box limits denote the IQR; whiskers denote ranges. ADI, Area Deprivation Index; IQR, interquartile range.

Study completion and exit survey

- Study completion was **80.3% (n=49/61)** overall, and **86.0% (n=49/57)** among those who initiated cognitive testing. Remote eICF introduced minimal latency: same-day signature (median: 0.0 days; mean: 1.3±2.6 days)
- In total, **63.9%** (n=39/61) of participants completed all assessments within the protocol-defined study timelines. Mean overall time from eICF to final assessment completion was **8.5 days**
- Descriptively, completion was higher for the phone-based SB-C assessment than for the LILA™ application (91.8% [n=56/61] versus 83.6% [n=51/61]), respectively (**Table 2**)
- Exit surveys demonstrated high participant acceptability, with most (n=43; 87.8%) participants reporting satisfaction with the study participation process

Table 2. Completion of phone-based SB-C and LILA™ application assessments.

	n	Phone-based SB-C*	LILA™ application
<70 years	21	21	20
70–79 years	30	27	23
≥80 years	10	8	8
ADI ranks 1–4	28	26	24
ADI ranks 5–6	18	15	12
ADI ranks 7–9	15	15	15
≤12 years of education	19	17	15
>12 years of education	41	39	36
English preferred	51	47	43
Spanish preferred	9	9	8
Black or African American	26	23	21
Hispanic/Latinx	17	17	15
White, non-Hispanic	10	9	9
Total completion, n (%)		56 (92)	51 (84)

*Includes two participants who completed the SB-C but for whom an SB-C score could not be generated. ADI, Area Deprivation Index.

Potential eligibility for Phase III trials

- When mapped against publicly available study criteria for early AD trials, a subset of participants (n=15–21; 24.6%–34.4%) shared baseline age, diagnostic, and preliminary cognitive characteristics consistent with cohorts evaluated in trial pre-screening; biomarker status confirmation would help determine eligibility

Discussion

- REACHED provides a broad view of greater diversity of participants with eAD, identified through AI-assisted EMR review and enrolled through a centralized virtual research site. Cognitive assessments captured expected clinical severity gradients across diagnostic groups, while self-administered smartphone and voice-based tools were feasible in this diverse cohort
- REACHED demonstrates that AI EMR phenotyping must search broad amnestic umbrellas, rather than narrow AD codes, to successfully capture underrepresented groups
  - In real-world community clinics, these codes frequently capture vascular cognitive impairment, nutritional deficiencies, medication-induced delirium, or psychiatric pseudodementia, and primary care providers serving underserved populations frequently avoid specific AD codes due to diagnostic uncertainty and lack of specialist access[16]
- Findings highlight potential barriers to clinical trial participation related to socioeconomic context, language, digital workflow, and prior access to biomarker testing that may be relevant when considering decentralized or digitally enabled trial methodology. Further inquiry is required to evaluate potential barriers to remote assessment completion, ranging from digital literacy to workflow timing, to inform evidence-based solutions
- Learnings may inform recruitment strategies of understudied populations in future clinical trials

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NB: There may be associated costs for downloading data. These costs may vary depending on your service provider and may be high if you are using your smartphone abroad. Please check your phone tariff or contact your service provider for more details Copies of this poster obtained through QR (Quick Response) code are for personal use only and may not be reproduced without written permission of the authors. In order to use the QR code, please use or download an app called "QR code reader" from the Apple App Store™ or Android Play Store™.

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