

Expanding clinical trial access to underrepresented populations in the US: Findings from the Alzheimer’s disease pre-screener study

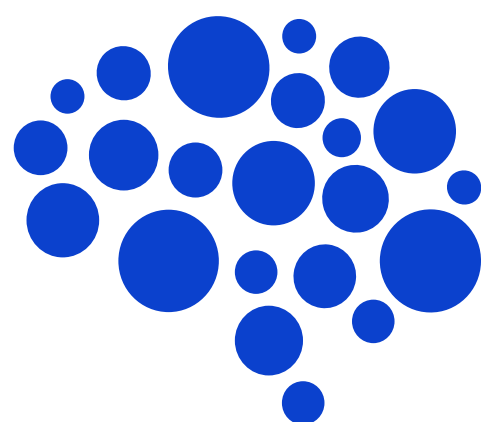
Roche

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

- The historic lack of diversity in AD clinical trials can be addressed by strategically selecting sites and using community-based education
- This BP45085 pilot study led to the creation of the Site Alliance for Understudied Communities (SAUC) in February 2026. The SAUC transitioned 22 clinical trial sites into a formal network, dedicated to improve representation of diverse communities, provide education and resources, foster collaboration and establish key metrics to measure the impact of inclusive initiatives across AD trials. This initiative ensures that "underrepresented" does not remain "understudied"

Background

Access for underrepresented populations (URP) to clinical trials

- Historically, AD clinical trials predominantly enrolled White participants, with <10% from URP<sup>2</sup>
- Increasing access to URP is critical to ensure that studies reflect the broader population that may benefit from scientific advances<sup>1,3</sup>
- As part of the global cognitive pre-screener study in collaboration with the Global Alzheimer's Platform Foundation (GAP), we intentionally selected sites from diverse areas in the US and confirmed these selections using the US Census data
- This focused approach provided broader access to underrepresented and underserved communities willing to participate in research when it is made available

Methodology

Site identification and selection

- The pilot study took place at 12 US sites (urban, suburban and two rural) across eight US states that were predominantly located in diverse communities
- Community-based education and inclusive recruitment practices were included

Assessments

- Assessments included:
  - Race and ethnicity
  - Medical and medication history
  - Mini-Mental State Examination (MMSE)
  - Clinical Dementia Rating scale (optional; n=4)
- Principal Investigators completed a survey on whether participants met key clinical inclusion/exclusion criteria of upcoming Phase III studies based primarily on age, ability to complete study procedures, medical and medication history, and cognitive criteria

Acknowledgements

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Results

- The 4-month pilot (September–December 2024) enrolled 1,215 participants aged 60–84 years in the US (**Table 1**)

Table 1. Participant characteristics.

|                                            | 1,215 participants      |
|--------------------------------------------|-------------------------|
| <b>Diagnosis status*</b>                   |                         |
| No AD diagnosis                            | 84.4% (n=1,030)         |
| Cognitively unimpaired at risk for AD      | 2.5% (n=30)             |
| MCI due to AD                              | 5.7% (n=69)             |
| AD dementia                                | 7.1% (n=86)             |
| <b>Age (mean [SD], range, years)</b>       | 70.5 ± 6.1†<br>60–84‡   |
| <b>Sex</b>                                 |                         |
| Female                                     | 67.2% (n=817)           |
| Male                                       | 32.8% (n=398)           |
| <b>Race / ethnicity group</b>              |                         |
| WH                                         | 39.2% (n=476)           |
| Black                                      | 33.1% (n=402)           |
| Asian                                      | 4.1% (n=50)             |
| Others§                                    | 6.3% (n=76)             |
| WNH                                        | 17.4% (n=211)           |
| <b>Education (mean [SD], range, years)</b> | 13.6 ± 3.0†<br>8 to 18‡ |
| <b>MMSE score (mean [SD], range)</b>       | 25 ± 4.1†<br>3–30‡      |

\*Participants did not require a confirmed AD diagnosis to be enrolled. †Values represent mean ± standard deviation. ‡Refers to full range from minimum to maximum. §Includes individuals with single race other than White, Black or Asian, and those with mixed races. MCI, mild cognitive impairment.

Disclosures

- IK, EG, KC, NM, JT** and **RT** are employees of and shareholders in F. Hoffmann-La Roche Ltd
- TMR, JF**, and **MC** are employees of The Global Alzheimer's Platform Foundation
- LG** is an employee of Genentech and shareholder in F. Hoffmann-La Roche Ltd
- TC, CL** and **RC** are employees of Roche Products Ltd and shareholders in F. Hoffmann-La Roche Ltd
- LS** is a former employee of F. Hoffmann-La Roche Ltd

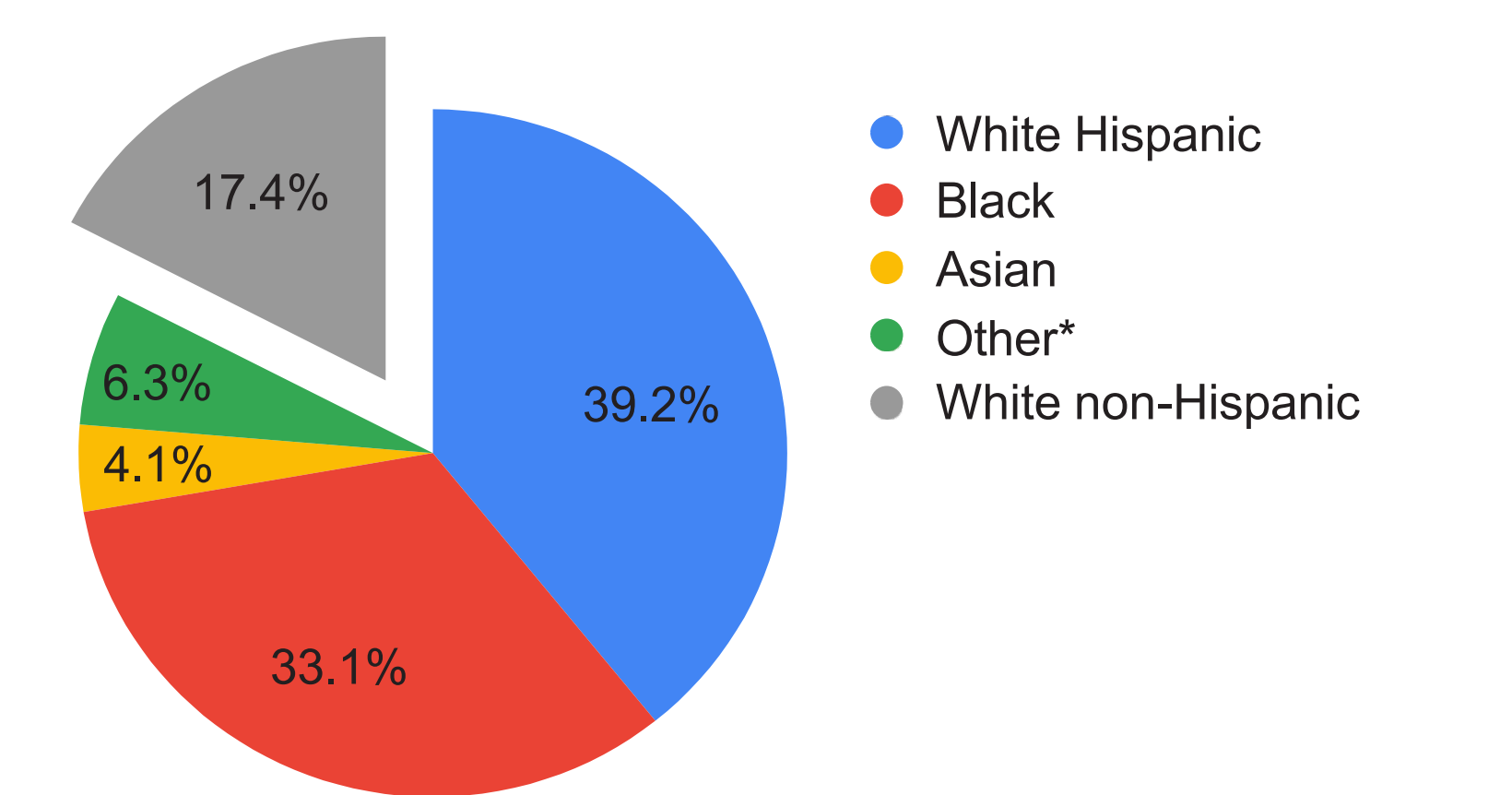
Conclusions

- The proportion of individuals recruited from historically understudied populations within the short timeframe is exceptionally high, illustrating that underrepresented and underserved communities are willing to participate in research when it is made available in their communities
- These learnings are being built upon in Roche's TRAVELLER prescreening study, with the goal to broaden representativeness of upcoming Phase III studies and improve generalisability of results

Results cont.

- A high proportion of participants (82%; n=1,004) were from URP (**Figure 1**)
  - This diverse group was mainly composed of White Hispanic (WH) and Black participants

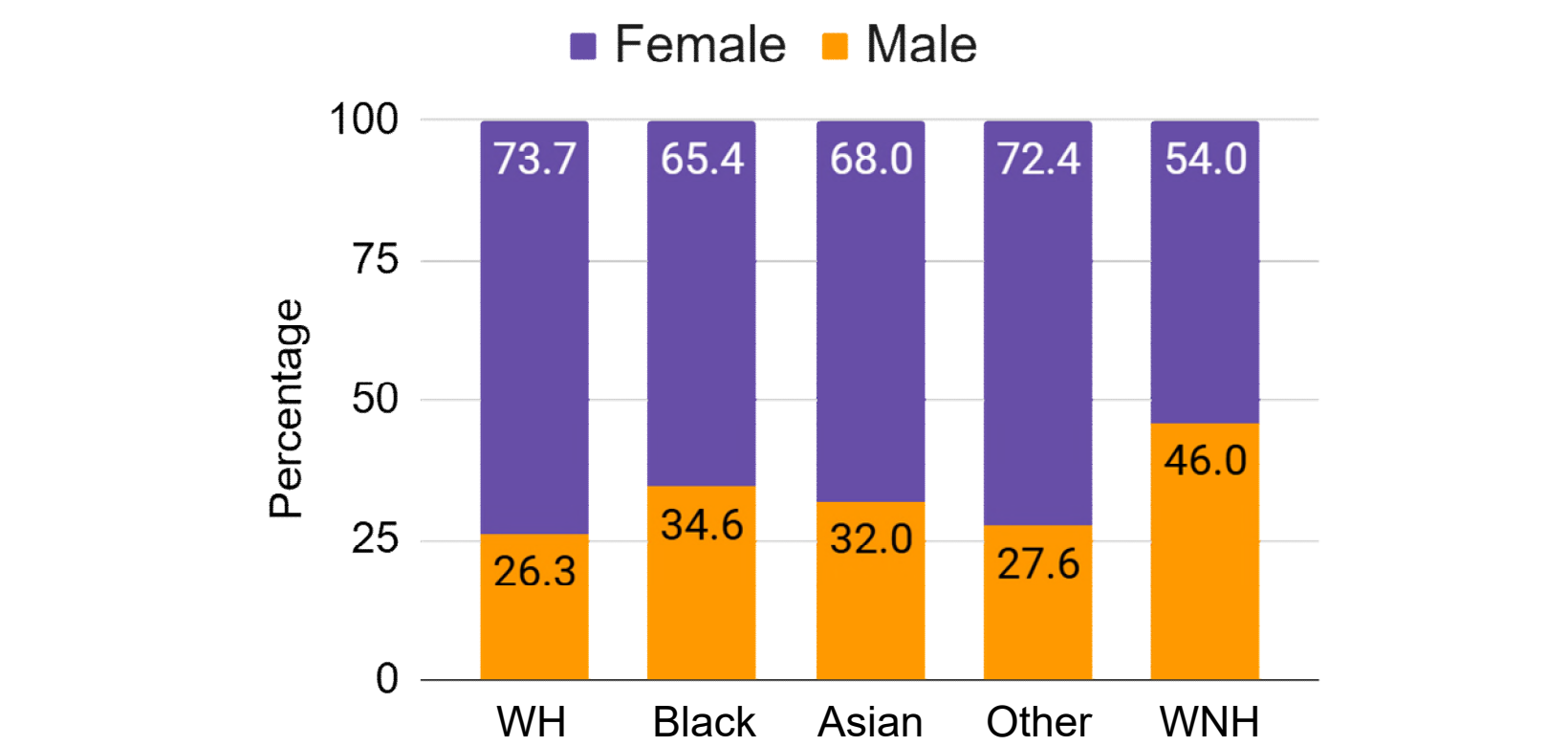
Figure 1. Proportion of race and ethnicity groups.



\*Includes individuals with single race other than White, Black or Asian, and those with mixed races.

- Females were more common, particularly in URP groups compared to White non-Hispanic (**Figure 2**)

Figure 2. Percentage of females and males in each group.



- The mean MMSE scores and years of education were somewhat lower in WH and Black participants compared to WNH participants (**Table 2; Figure 3**)

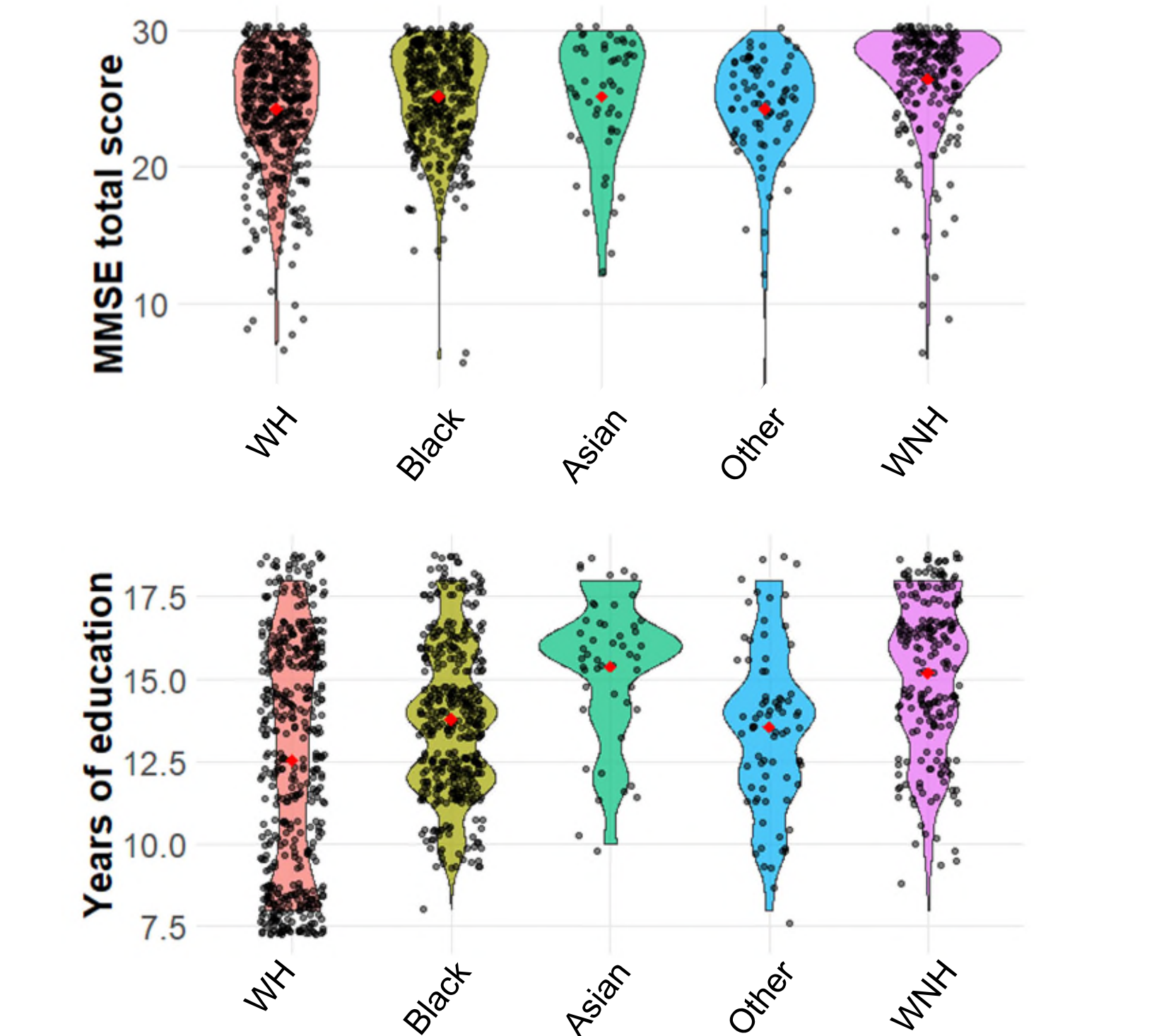
Results cont.

Table 2. MMSE and education across groups.

|                    | MMSE score | Education (years) |
|--------------------|------------|-------------------|
| WH                 | 24.3 ± 4.2 | 12.5 ± 3.5        |
| Black              | 25.2 ± 3.6 | 13.8 ± 2.3        |
| Asian              | 25.1 ± 4.5 | 15.4 ± 2.1        |
| Other              | 24.2 ± 4.3 | 13.6 ± 2.5        |
| White non-Hispanic | 26.4 ± 4.0 | 15.2 ± 2.3        |

Values represent mean ± standard deviation.

Figure 3. Violin plots of MMSE and education.



Width of the shaded area represents kernel probability density; black dots represent individual data points; red dots represent group mean.

- Of all participants, 66% were considered as meeting key clinical eligibility criteria for upcoming Phase III studies

References

- Langbaum JB, et al. Alz Dement 2022;7:696–707
- Lin, Z. et al. JAMA Netw Open 2026;9:3:e262427
- Raman R, et al. JAMA Netw Open 2021;4:e2114364

Abbreviations

- AD, Alzheimer's disease; GAP, Global Alzheimer's Platform Foundation; MCI, mild cognitive impairment; MMSE, Mini-Mental State Examination; URP, underrepresented populations; WH, White Hispanic; WNH, White non-Hispanic