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Long-Term Trends in Racial and Ethnic Reporting and Representation in US Alzheimer's Clinical Trials

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Abstract

Alzheimer's disease (AD) disproportionately burdens racial and ethnic minority populations, yet the extent to which US clinical trials reflect this burden remains poorly understood. We conduct a systematic review of all 88 completed US-based Phase III AD drug trials between 1997 and 2023, using a multi-source approach that integrates the Trialtrove clinical trial database with PubMed, ClinicalTrials.gov, pharmaceutical reports, and conference abstracts. We document three main findings. First, nearly half of published trials (49.3%) reported no data on patient race or ethnicity. Among trials that did report, practices were highly inconsistent in terminology, categorization, and analytical depth. Second, White patients constituted a median of 91.3% of enrollment, while Black patients represented 4.5%–7.2%, Hispanic patients 5.2%, and Asian / Pacific Islander and Native American patients less than 1% - shares that are grossly disproportionate to AD prevalence rates, which are approximately twice as high among nonHispanic Black older adults and 1.5 times as high among Hispanic older adults relative to nonHispanic Whites. Third, only 3 trials (4.2%) conducted any subgroup analyses by race or ethnicity, and none reported treatment safety or efficacy stratified by demographic group. Critically, regression models find no evidence of improvement in reporting or representation from 1997 to 2023. These patterns limit the generalizability of existing AD treatment evidence and raise fundamental concerns about health equity. Our findings support strengthening mandatory reporting standards, broadening eligibility criteria, and diversifying trial site selection to ensure emerging AD treatments are evaluated equitably across the populations most affected.

JEL classification

I14, I18, J15, J14, L65, I11

Keywords

Alzheimer's disease, dementia, clinical trials, racial and ethnic disparities, health equity, underrepresentation, diversity in clinical research

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Introduction

Alzheimer's disease (AD) affects more than 7 million Americans and disproportionately impacts racial and ethnic populations underrepresented in clinical research in the US.[1] Non-Hispanic Black and Hispanic older adults are nearly twice and 1.5 times more likely, respectively, to have AD than non-Hispanic White older adults,[1–5] yet face substantial barriers to participation in clinical trials.[6–9] As the US population ages and becomes more diverse, these disparities are expected to widen, further intensifying the burden of AD and pointing to the urgency of addressing inequities in disease burden and research representation.[1–5]

These growing disparities highlight the need to assess whether emerging treatments are safe and effective across diverse groups.[10,11] Clinical trials, particularly Phase III trials, provide the foundation for clinical guidelines and regulatory decisions and are critical for establishing the safety and efficacy of new AD treatments.[6,12,13] However, Phase III trials have often fallen short of enrolling racial and ethnic underrepresented populations, including non-Hispanic Black, Hispanic, and Native American individuals, and frequently fail to reflect the racial and ethnic diversity of the US population.[9,11,14–16] Such underrepresentation limits the generalizability of trial findings and may exacerbate disparities in care, as well-documented differences in genetic, behavioral, and clinical factors of AD across racial and ethnic groups can influence therapeutic safety and efficacy.[17–21] For example, prior research has demonstrated racial and ethnic differences in APOE prevalence, burden of vascular and cardiometabolic conditions, health behaviors, healthcare access and utilization, and clinical presentation of cognitive symptoms, all of which may affect AD risk and treatment response.[1,22–24] Despite these concerns, reporting and inclusion by race and ethnicity remain limited and inconsistent.[6]

Previous reviews of AD trials often did not distinguish between trial phases, combined US and non-US trials, or relied primarily on selected bibliographic databases or trial registries, limiting their applicability and policy relevance to the US context.[6,19] Moreover, the extent to which US-based AD trials have achieved meaningful racial and ethnic representation remains unclear, particularly given rapid demographic shifts in which racial and ethnic underrepresented groups constitute the fastest-growing segments of the older adults population.[11,25] Focusing on US-based Phase III trials is therefore critical to ensuring that trial findings are directly relevant to the populations most affected by AD.[9,11,17,25,26]

Using comprehensive trial databases, we characterized the trends to date in how patient race and ethnicity have been reported, analyzed, and represented in US-based Phase III AD trials from 1997 to 2023. We assessed the extent to which racial and ethnic differences were considered in trial design and analysis and evaluated changes in reporting and representation over time.

Methods

This systematic review was determined non-human subjects research and we followed the PRISMA reporting guidelines.

Data Sources and Trial Identification

We conducted a systematic review of US-based Phase III AD clinical trials of drug treatment using a multi-source approach. AD trials were identified primarily through the Trialtrove clinical trial database, which provides comprehensive tracking of clinical trials from initiation through completion. Trialtrove aggregates information from a wide variety of sources, including

pharmaceutical companies, regulatory agencies, trial registries, conference proceedings, press releases, and peer-reviewed publications.[27–29] The database has been validated in prior research,[28,29] and offers detailed information on trial design, enrollment characteristics, study timelines, and reported outcomes, enabling precise identification, selection, and analysis of clinical trials.[27–29]

In this study, Trialtrove was queried to identify all Phase III AD clinical trials as of April 21, 2023. To ensure completeness and accuracy, identified trials were cross-referenced with PubMed, trial registries, and other public sources. This approach enabled inclusion of both published and unpublished trials and supported comprehensive identification regardless of registration and publication status.

Eligibility Criteria and Study Selection

Trials were eligible for inclusion if they met the following criteria: (1) designated as Phase III drug trials; (2) targeted Alzheimer's disease; (3) considered as completed; and (4) recruited patients exclusively in the US. Trials were excluded if they were ongoing, planned, terminated, or suspended without publicly available data; were not Phase III drug trials; or included non-US populations.

The initial search identified 484 Phase III AD trials. After excluding trials that were open or planned (67 trials), lacked US populations (178 trials), or recruited patients outside the US (136 trials), 103 US-based Phase III trials remained for further review.

Two reviewers (K.L., S.S.) independently screened the 103 trials by examining associated publications, registries, or public sources. We excluded 15 trials that were incomplete with no publicly available records (10 terminated, 1 suspended), not Phase III (2 trials), or not fully US-

based (2 trials) after the review. The final analytic sample included 88 completed US-based Phase III AD trials. The sample selection process is presented in the Supplementary eFigure 1 and the list of 88 trials is provided in Supplementary eReferences (see Supplementary eFigure 2 for the distribution of trials over publication years).

Data Extraction and Quality Assurance.

We followed a two-stage process to extract data on patient race and ethnicity reporting and representation. In the first stage, the two reviewers (K.L., S.S.) independently extracted all reported racial and ethnic data from available sources. For each trial with published reports, the data source and publication date were documented. Publication dates in our sample ranged from 1997 to 2023. In the second stage, the reviewers cross-checked their extracted data and resolved discrepancies through consensus. A third reviewer (Z.L.) then performed a final quality check. Data collection was completed in May 2024.

Outcome Measures

The primary outcomes were measures of patient racial and ethnic reporting and representation in US-based Phase III AD trials, including whether race and ethnicity were reported, the number of racial and ethnic groups reported, the terminology used, and the proportion of patients from each racial and ethnic group.

Secondary outcomes included whether trials reported sample characteristics, subgroup analyses or differences in safety or efficacy by race and ethnicity, and whether trial reports discussed the racial and ethnic representation of enrolled patients.

Terminology used to describe racial and ethnic groups varied widely and was often inconsistent with existing reporting guidelines.[30–34] Because Hispanic ethnicity were frequently unspecified, racial and ethnic categories were analyzed separately for White (ethnicity unspecified) and White (non-Hispanic) patients, as well as for Black (ethnicity unspecified) and Black (non-Hispanic) patients. Additional categories included Hispanic, Asian or Pacific Islander, and Native American patients, as documented in trial reports.

Statistical Analysis

Trials were considered published if trial data appeared in peer-reviewed journals, ClinicalTrials.gov, pharmaceutical reports, or conference abstracts. Our analyses focused on all published trials, with additional emphasis on trials reported in peer-reviewed publications. When multiple reports were available for a single trial, the report containing the most complete information was selected.

Descriptive statistics were used to summarize trial characteristics, reporting practices, and patient composition. Time trends in racial and ethnic reporting were assessed by estimating changes over time in the proportion of trials reporting race and ethnicity and the number of racial and ethnic groups reported. Time trends in representation were evaluated by examining changes in the percentage of enrolled patients across racial and ethnic categories over time. Linear regression models with robust standard errors were used to estimate temporal trends, with statistical significance assessed at 5% level. Analyses were conducted using R (version-4.5.0) and STATA (version-17.0).

Results

Table 1 presents the characteristics of US-based Phase III AD clinical trials. Of the 88 Phase III AD clinical trials reported from 1997-2023, 71 trials (80.7%) had published data available, while 17 (19.5%) had no publications. Among trials with available data, 52 (59.1%) were published in peer-reviewed journals, the remaining trials reported results through ClinicalTrials.gov, pharmaceutical company reports, or conference abstracts.

Racial and Ethnic Reporting in AD Trials

Among the 71 published trials, nearly half (49.3%) did not report any data on patient race or ethnicity. Only 35.2% trials reported White patients (ethnicity unspecified), and 15.5% reported White (non-Hispanic) patients. Reporting of other racial and ethnic groups was limited. Specifically, only 15.5% of trials reported data on Asian/Pacific Islander patients, 14.1% on Black (ethnicity unspecified) patients, 14.1% on Black (non-Hispanic) patients, 18.3% on Hispanic patients, and 2.8% on Native American patients (**Table 1**).

Reporting proportions were modestly higher among trials published in peer-reviewed journals; however, substantial underreporting persisted. The median number of patient racial and ethnic groups reported was 1 (IQR: 0-3) across all published trials, and 1 (IQR: 0-3.5) among peer-reviewed trials, with most trials reporting only the number/proportion of White patients (**Table 1**).

Trials differed in whether they reported race, ethnicity, or both; whether Hispanic ethnicity was clearly distinguished from race; and how racial and ethnic categories were defined (Supplementary eTable 1).

No trials reported sample characteristics (e.g., demographic or clinical characteristics) stratified by race or ethnicity. Only 3 trials (4.2%) conducted any subgroup analyses by race or

ethnicity, and none reported detailed treatment efficacy or safety outcomes stratified by racial or ethnic group or provided sufficient information to assess differential treatment effects (**Table 1**).

Racial and Ethnic Representation in AD Trials

When racial and ethnic composition was reported, White patients constituted the majority of enrolled populations. The median proportion of White patients was 91.3% (IQR: 87.3%-93.6%) among trials reporting White race, and 84.1% (IQR: 80.1%-93.4%) among trials reporting non-Hispanic White ethnicity.

In contrast, patients from racial and ethnic underrepresented groups accounted for a small proportion of trial enrollment. Median enrollment populations were 0.9% (Interquartile Range [IQR]: 0.6-1.6) for Asian or Pacific Islander, 4.5% (IQR: 3.6-6.6) for Black (unspecified ethnicity), 7.2% (IQR: 3.7-9.1) for Black (non-Hispanic), 5.2% (IQR: 3.1-6.6) for Hispanic, and 0.4% (IQR: 0-0.8) for Native American patients. No trials acknowledged underrepresentation in enrollment, discussed its implications for generatability, or proposed strategies to improve representation (**Table 1**).

Trends in Racial and Ethnic Reporting and Representation

Figure 1 illustrates trends in racial and ethnic reporting. Over time, the proportion of trials reporting any patient race or ethnicity data did not improve, though the number of racial and ethnic groups reported slightly increased. Among all published trials, there was a nonsignificant decline in the proportion reporting racial and ethnic data (slope: -1.0%; 95% CI: -3.4%, 1.4%), while reporting remained stable among trials published in peer-reviewed journals (slope: 0.02%; 95% CI: -3.7%, 3.7%). The number of racial and ethnic groups reported showed an increasing

trend among peer-reviewed trials, although this trend was not statistically significant (slope: 0.12; 95% CI: -0.01, 0.26).

Figure 2 presents trends in racial and ethnic groups representation among trial patients (see Supplementary eFigure 3 for more detailed breakdowns). White patients consistently constituted nearly 90% of trial enrollment over time, with a slight but nonsignificant increasing trend. In contrast, enrollment of racial and ethnic underrepresented groups remained persistently low, with no evidence of improvement over time. Among peer-reviewed trials, Hispanic representation showed a modest and statistically significant decline (slope: -1.3%; 95% CI: -2.4%, -0.19%).

Discussion

This systematic review of US-based Phase III AD clinical trials reported between 1997 and 2023 reveals persistent and substantial gaps in both reporting of patient race and ethnicity and representation. Despite decades of recognition that AD disproportionately affects certain racial and ethnic groups, including non-Hispanic Black and Hispanic populations,[1,2] nearly half of trials failed to report any information on patient race or ethnicity, with little evidence of improvement over time. Among trials that did report these data, enrollment of racial and ethnic underrepresented populations remained consistently low, and few trials conducted subgroup analyses by patient race or ethnicity. As a result, the ability to assess treatment safety or efficacy across diverse populations remains constrained.[6,11,35] These patterns raise important concerns about the generalizability of trial findings and the extent to which current evidence can support equitable treatment decisions for populations most affected by AD.[6,17]

Inadequate reporting of race and ethnicity represents a fundamental limitation of current clinical evidence to inform AD treatment. Even when demographic information was reported, we found that practices were often inconsistent, with wide variation in terminology, categorization, and distinctions between race and ethnicity. Reporting frequently focused on White patients, with limited attention to other racial and ethnic groups and little clarity regarding how categories were defined or used in analyses. These inconsistencies limit transparency and hinder meaningful comparisons across trials. More importantly, incomplete reporting constrains the ability to assess the generalizability and evaluate whether treatment safety and efficacy may differ across populations, despite well-documented differences in genetic risk profiles, comorbidity burden, and social determinants of health across racial and ethnic groups.[1,17,20,21,36] The persistence of these reporting gaps highlights the importance of further strengthening and consistently implementing race and ethnicity reporting standards, including recent initiatives by federal agencies and academic journals.[30–34]

Meanwhile, our findings reveal a persistent mismatch between AD disease burden and trial enrollment. In the US, non-Hispanic Black older adults experience nearly twice the prevalence of AD compared with non-Hispanic White older adults, and Hispanic older adults face approximately 50% higher prevalence than non-Hispanic White older adults.[1] Notably, in 2020, non-Hispanic Black individuals accounted for 17.5% of all people living with AD, while Hispanic individuals accounted for 11.7%, proportion projected to increase to 24.5% for Black and 26.8% for Hispanic individuals respectively by 2060.[37] Yet Phase III AD trials have continued to enroll disproportionately few patients from these groups. From 1997-2023, we showed that median enrollment remained approximately 4% to 7% for Black patients, about 5% Hispanic patients, and less than 1% for Native American patients, while White patients

consistently comprised nearly 90% of trial populations. This marked imbalance has important implications for both equity and scientific validity. When trial populations do not reflect those most affected by AD, the resulting evidence may inadequately capture variation in treatment response, adverse events, and real-world effectiveness.[6] This concern is particularly salient for AD, given well-established differences in disease progression, comorbid conditions, and access to diagnosis and care across populations.[1,11]

The limited progress observed in reporting and representation likely reflects broader structural and trial-level barriers.[6–11,14,19,35,38–46] Restrictive eligibility criteria, including exclusions related to comorbidities or cognitive screening thresholds, may disproportionately exclude individuals from populations with higher disease burden.[9,19,47] Trial sites are often concentrated in locations that are less accessible to individuals living in disadvantaged or underserved communities, further limiting participation by racial and ethnic underrepresented groups. In addition, investigators may face practical constraints, including limited time, funding, expertise, and access to culturally appropriate resources, which may challenge effective engagement with underrepresented communities.[48] Recruitment strategies also often lack partnerships with community organizations and fail to address limited awareness of AD and research opportunities, language barriers, cultural relevance, stigma, logistical challenges, and longstanding mistrust of research instiutions.[6–11,14,19,35,38–45,49] These factors, together, help explain why improvements in enrollment and reporting have remained limited despite increased attention to diversity in clinical research.

Addressing these challenges will require coordinated multilevel efforts.[6,10,11,14,19,35] First, standardized race and ethnicity reporting, with consistent definitions and mandatory registry fields, provides a necessary foundation for improving transparency, comparability, and

accountability.[17,19,21] This should follow established guidance from federal agencies and journals, including separate collection of race and ethnicity, consistent use of predefined categories, explicit distinction of Hispanic ethnicity from race, allowance for multiple racial identifies, and clear reporting of missing or unknown responses.[30–34] Consistent application of these standards across trial registries and publications would improve comparability and interpretability across AD trials. Second, beyond reporting, meaningful progress in representation will depend on intentional trial design choices, including more inclusive eligibility criteria, broader and more diverse site selection, and recruitment strategies that actively engage racial and ethnic populations disproportionately affected by AD. [7,19] Financial supports such as transportation assistance or patient compensation may help mitigate socioeconomic barriers that disproportionately limit participation among underrepresented populations.[19,26,41] In addition, partnerships with local advocacy groups and healthcare providers, use of bilingual and culturally concordant research staff, and tailored outreach materials for underserved communities may further reduce barriers, strengthen trust, and improve accessibility.[7,18,20,21,41,43] These approaches should be adopted more widely to ensure inclusive and generalizable AD research.[6,10,11,14,19,35]

Strengths

This study has several notable strengths. First, by leveraging multiple complementary data sources, including Trialtrove, PubMed, ClinicalTrials.gov, conference abstracts, and pharmaceutical reports, we identified a comprehensive list of US-based AD trials conducted between 1997 and 2023. Second, our exclusive focus on US-based Phase III trials elevates both clinical and policy relevance, as these trials provide the highest level of evidence for treatment efficacy and play a central role in regulatory decision-making for the US population. Third, our

assessment of racial and ethnic reporting and representation was both thorough and comprehensive. We examined not only whether demographic data were reported, but also how they were reported and the quality of reporting. Additionally, by analyzing trends over time, we identified persistent gaps and highlighted the need for more systematic oversight and regulatory efforts.

Limitations

This study also has limitations. Although focusing on US-based trials strengths relevance for domestic US policy and practice, it excludes large multinational trials in which underrepresentation is also a significant concern. The issue of racial and ethnic underrepresentation persists even in broader global trials.[11] Second, trials that fail to report any racial or ethnic data may be more likely to have enrolled few patients from racial and ethnic underrepresented groups, potentially leading to underestimation of the full extent of these disparities. Finally, while we discuss several contributing factors, the underlying causes of underreporting and underrepresentation, as well as the reasons for their persistence over time, warrant further investigation. Future research, particularly using mixed methods, is needed to better understand the mechanisms and identify effective interventions.

Conclusion

This study highlights the persistent challenges in providing equitable access to clinical research and the critical need for more inclusive and representative AD trials. To ensure that the benefits of emerging AD treatments are equitably distributed, clinical trials must better reflect the diverse demographics of the US population. Policy initiatives, such as those proposed in the bipartisan

Equity in Neuroscience and Alzheimer's Clinical Trials (ENACT) Act may play an important role in addressing these disparities by expanding outreach, strengthening recruitment infrastructure, and promoting a more representative clinical research workforce.[7,50] Effective and persistent efforts are needed to reduce health disparities and improve outcomes for all individuals affected by AD.

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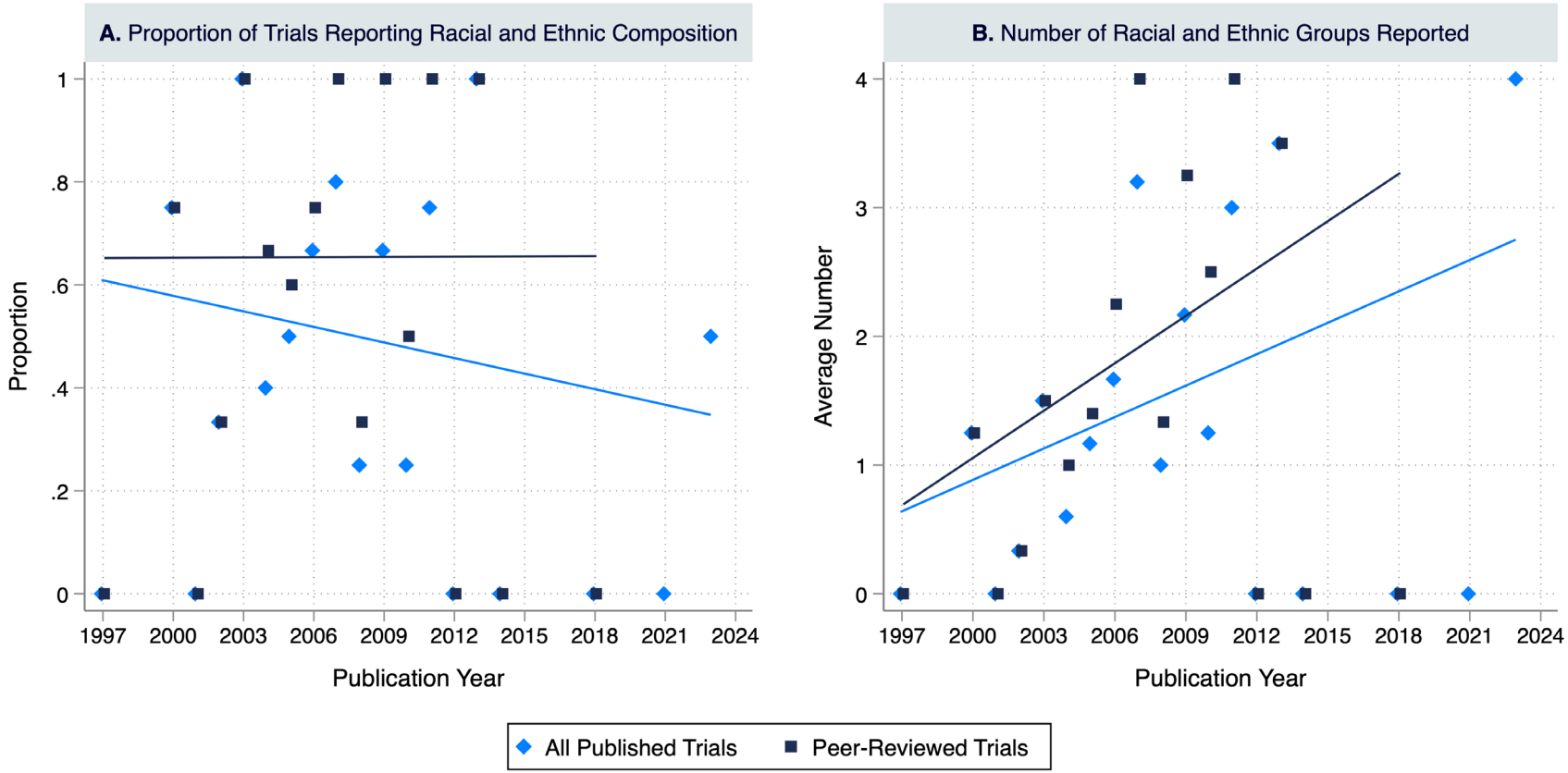
Table 1. Characteristics and Racial/Ethnic Reporting and Representation in Phase III Alzheimer's Disease Clinical Trials in the US, 1997-2023 (N=88)

Characteristics	No. of trials (%)	
	All trials (N=88)	**Trials with peer-reviewed publications (N=52)**
Data source		
Peer-reviewed publications	52 (59.1)	52 (100)
ClinicalTrials.gov registries	8 (9.1)	0 (0)
Trial reports of the pharmaceutical companies	2 (2.3)	0 (0)
Conference abstracts	9 (10.2)	0 (0)
No publication	17 (19.3)	0 (0)
Year of publications among published [a]		
≤ 2000	5 (7.0)	5 (9.6)
2001-2005	24 (33.8)	19 (36.5)
2006-2010	29 (40.8)	20 (38.5)
2011-2015	9 (12.7)	7 (13.5)
2016-2023	4 (5.6)	1 (1.9)
Sample size [a], median (IQR)	191 (85-433)	324 (134-525)
Race and ethnicity reported [a]		
No race and ethnicity reported	35 (49.3)	18 (34.6)
Reported Asian/Pacific Islander	11 (15.5)	10 (19.2)
Reported Black (ethnicity unspecified)	10 (14.1)	9 (17.3)
Reported Black (non-Hispanic)	10 (14.1)	10 (19.2)
Reported Hispanic	13 (18.3)	12 (23.1)
Reported Native American	2 (2.8)	1 (1.9)

Reported White (ethnicity unspecified)	25 (35.2)	23 (44.2)
Reported White (non-Hispanic)	11 (15.5)	11 (21.2)
No. of racial and ethnic group reported [a], median (IQR)	1 (0-3)	1 (0-3.5)
Percentage of Asian/Pacific Islander patients [b], median (IQR)	0.9 (0.6-1.6)	0.9 (0.6-1.6)
Percentage of Black (ethnicity unspecified) patients [b], median (IQR)	4.5 (3.6-6.6)	4.6 (4.1-6.6)
Percentage of Black (non-Hispanic) patients [b], median (IQR)	7.2 (3.7-9.1)	7.2 (3.7-9.1)
Percentage of Hispanic patients [b], median (IQR)	5.2 (3.1-6.6)	5.6 (2.5-6.6)
Percentage of Native American patients [b], median (IQR)	0.4 (0-0.8)	0.8 (0.8-0.8)
Percentage of White (ethnicity unspecified) patients [b], median (IQR)	91.3 (87.3-93.6)	91.3 (87.3-93.6)
Percentage of White (non-Hispanic) patients [b], median (IQR)	84.1 (80.1-93.4)	84.1 (80.1-93.4)
Reporting sample characteristics by racial and ethnic groups [a]		
No	71 (100)	52 (100)
Yes	0 (0)	0 (0)
Reporting detailed trial outcomes (e.g., safety, efficacy) by racial and ethnic groups [a]		
No	71 (100)	52 (100)
Yes	0 (0)	0 (0)
Analyzing/discussing heterogeneity or differences across racial and ethnic groups [a]		
No	68 (95.8)	49 (94.2)
Yes	3 (4.2)	3 (5.8)
Discussing the racial and ethnic representation of enrolled trial patients [a]		
No	71 (100)	52 (100)
Yes	0 (0)	0 (0)

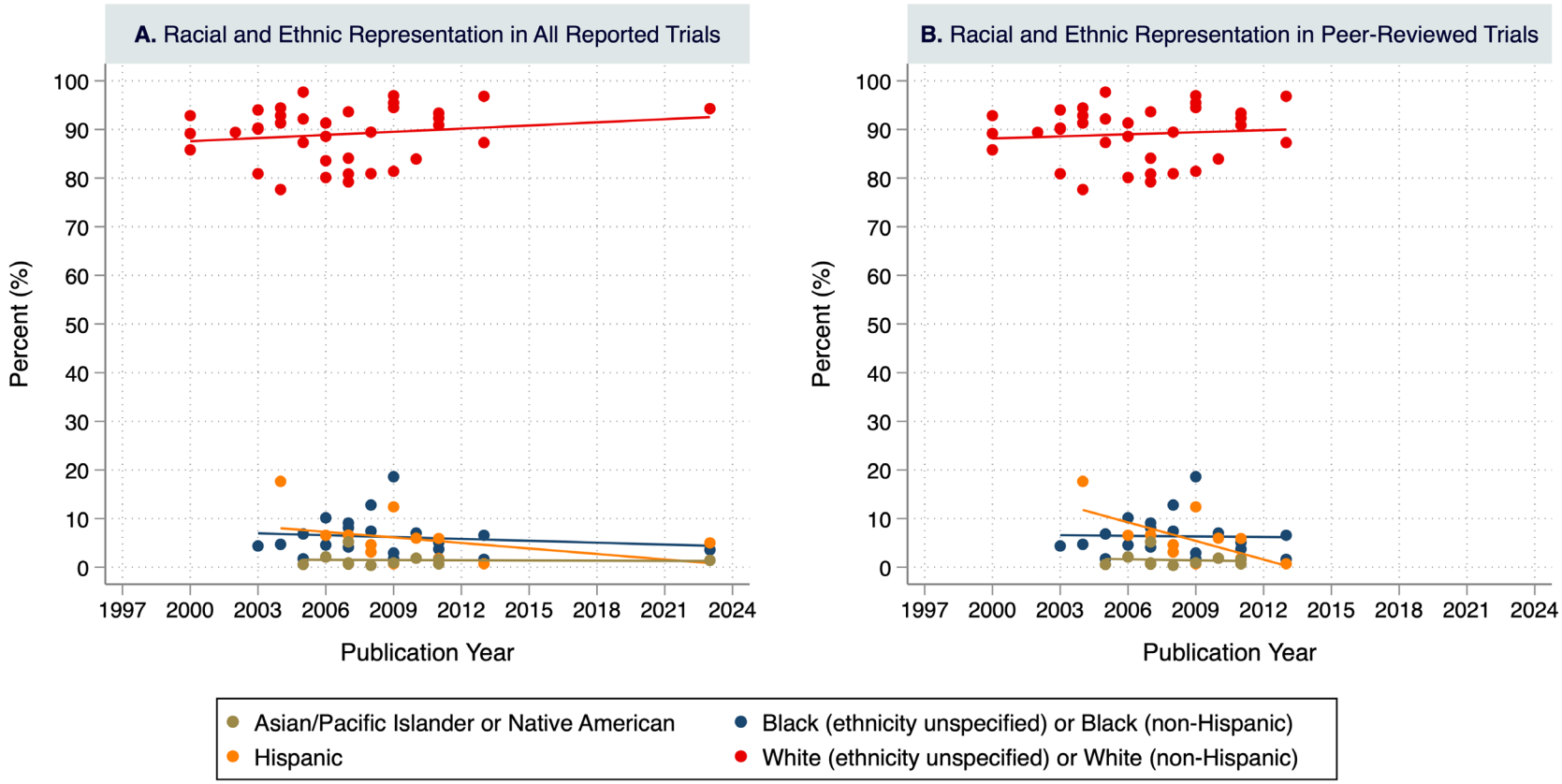
Abbreviation: IQR, Interquartile Range.
[a] Among trials with any published data, N=71 for column 2 (any publications), N=52 for column 3 (peer-reviewed publications)
[b] Among trials with reported data on race and ethnicity. The sample size for each reported race and ethnicity is provided above in the table under the variable “Race and ethnicity reported”.

Figure 1. Trends in Racial and Ethnic Reporting Among US-based Phase III Alzheimer's Disease Trials, 1997-2023



Notes: Panels A and B present the time trend of race and ethnicity reporting over years. Panel A presents the proportion of trials that reported racial and ethnic composition of the study patients. Each dotted points represent the proportion for each year, with light blue representing the proportion among all published trials, and dark blue representing the proportion among trials with peer-reviewed publications. Linear time trends were fitted respectively for all published trials (light blue line) and all peer-reviewed trials (dark blue line). Panel B presents the average number of racial and ethnic groups reported for each year among trials with published data. Estimate for each year were provided as dotted points and linear time trends were fitted respectively for all published trials (light blue color) and peer-reviewed trials (dark blue color). No statistically significant linear trends were observed.

Figure 2. Trends in Racial and Ethnic Representation Among US-based Phase III Alzheimer's Disease Trials, 1997-2023



Notes: Panels A and B present the racial and ethnic representation among all published trials (Panel A) and peer-reviewed trials (Panel B). Each dotted point represents the percentage of patients from a specific racial and ethnic group in individual clinical trials that reported data on that group. Green dots represent the reported percentages of Asian or Pacific Islander or Native American patients; blue dots represent the reported percentages of Black (ethnicity unspecified) or Black (non-Hispanic) patients; orange dots represent the reported percentages of Hispanic patients; and red dots represent the reported percentages of White (ethnicity unspecified) or White (non-Hispanic) patients. Linear time trends were fitted for each racial and ethnic groups with consistent colors as the dotted points. No

statistically significant linear trends were observed, except for a significant decline in Hispanic representation in peer-reviewed trials. Further breakdowns of racial and ethnic groups are shown in Supplementary eFigure 3.

Supplementary Online Content

Title: Long-Term Trends in Racial and Ethnic Reporting and Representation in US Alzheimer's Clinical Trials

Supplementary eFigure 1. Study Sample Selection Process

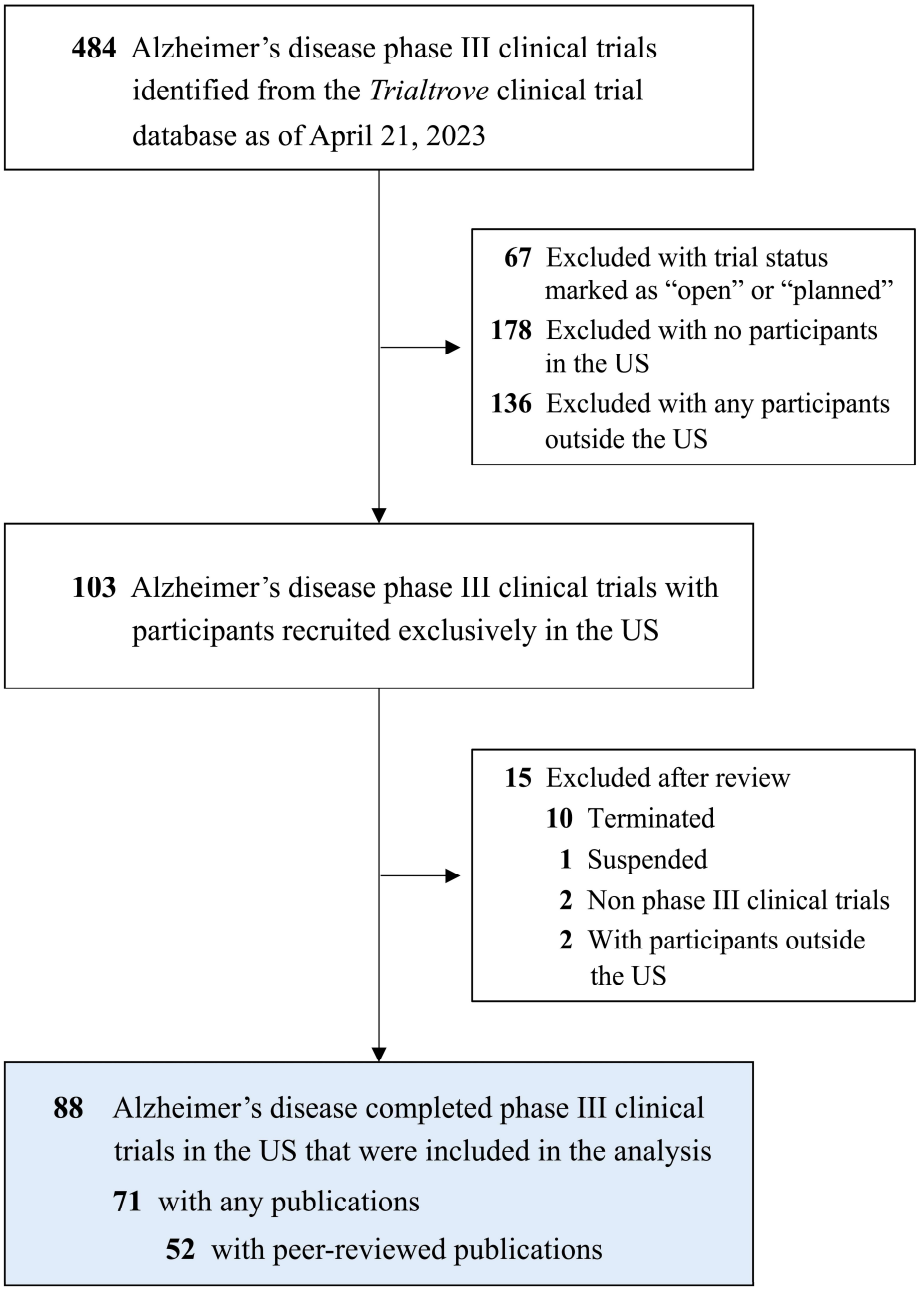
Supplementary eFigure 2. Number of US-based Phase III Alzheimer's Disease Trials Over Publication Years, 1997-2023

Supplementary eFigure 3. Trends in Representation of All Reported Racial and Ethnic Groups Among US-based Phase III Alzheimer's Disease Trials, 1997-2023

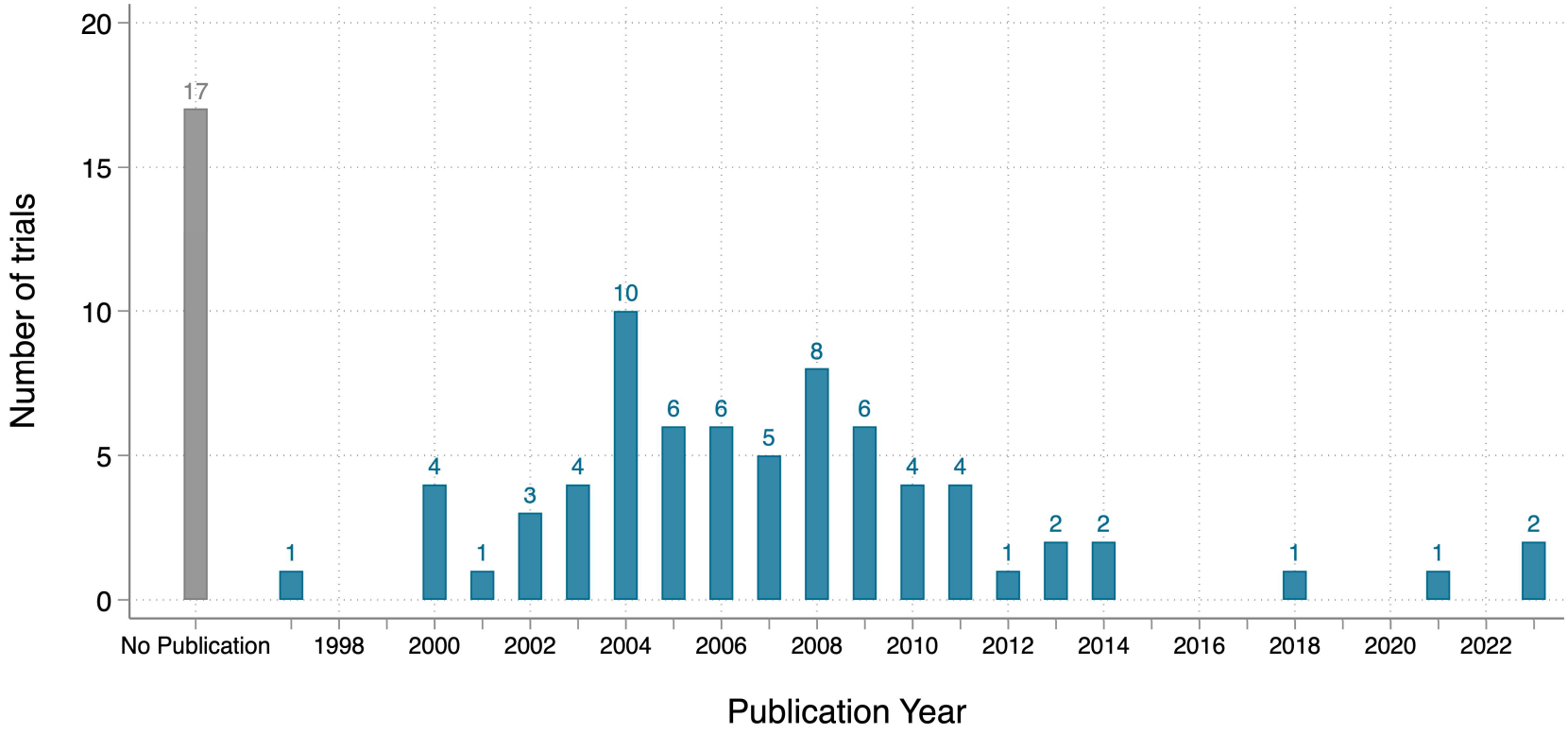
Supplementary eTable 1. Terminology Used for Racial and Ethnic Group Reporting Among All Published US-based Phase III Alzheimer's Disease Trials, 1997-2923

eReferences

Supplementary eFigure 1. Study Sample Selection Process

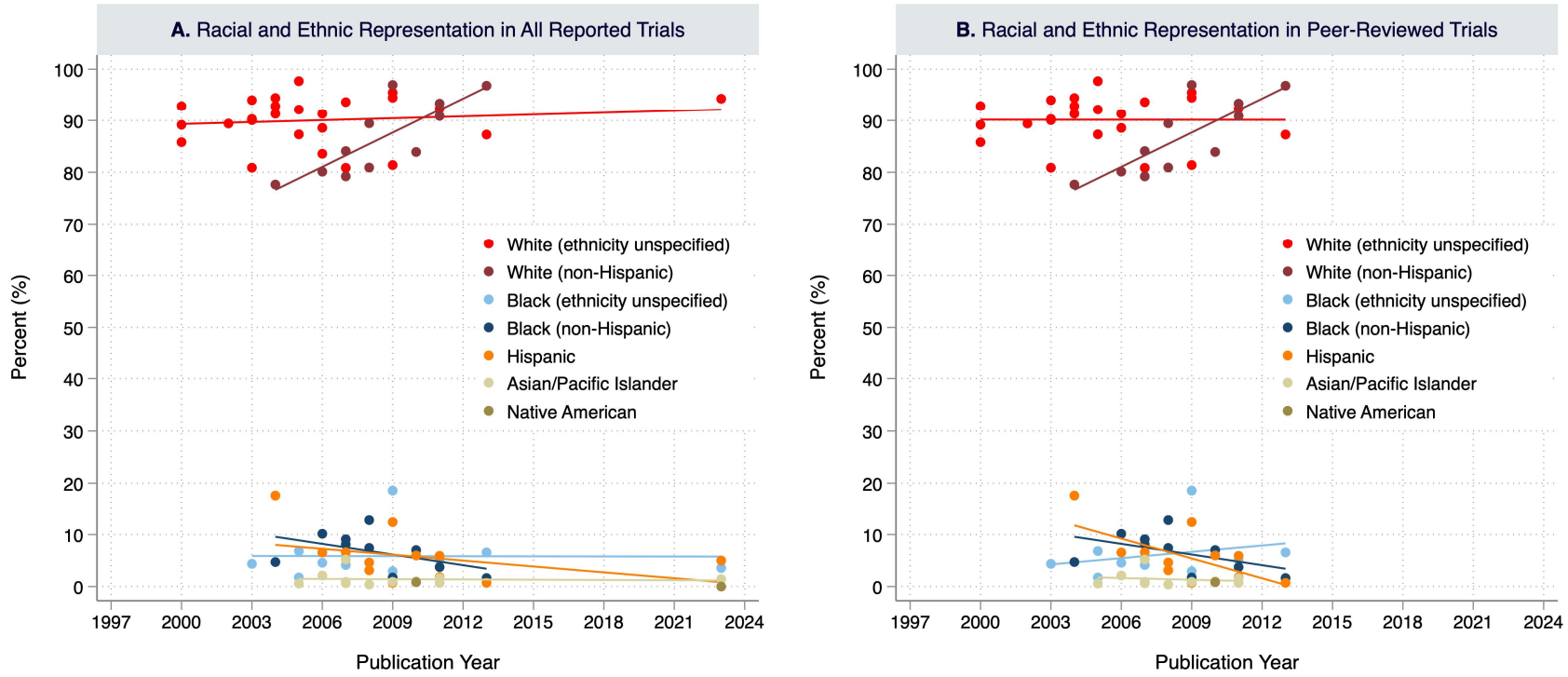


Supplementary eFigure 2. Number of US-based Phase III Alzheimer's Disease Trials Over Publication Years, 1997-2023



Notes: In the figure, the gray bar represents the number of trials with no publications, and the blue bars represent the number of trials published in each year.

Supplementary eFigure 3. Trends in Representation of All Reported Racial and Ethnic Groups Among US-based Phase III Alzheimer's Disease Trials, 1997-2023



Notes: Panels A and B present the racial and ethnic representation among all published trials (Panel A) and peer-reviewed trials (Panel B). Each dotted points represent the percentage of patients of certain race and ethnicity in each clinical trial published with reported data on that race and ethnicity. Red dots represent the reported percentages of White (ethnicity unspecified) patients; dark red dots represent the reported percentages of White (non-Hispanic) patients; light blue dots represent the reported percentages of Black (ethnicity unspecified) patients; dark blue dots represent the reported percentages of Black (non-Hispanic) patients; orange dots represent the reported percentages of Hispanic patients; light green dots represent the reported percentages of Asian or Pacific Islander patients; and dark green dots represent the reported percentages of Native American patients. Linear time trends were fitted for each racial and ethnic groups with consistent colors as the dotted points. Linear trends for Native American patients were not fitted because only one clinical trial had reported data on the percentage of Native Americans.

Supplementary eTable 1. Terminology Used for Racial and Ethnic Group Reporting Among All Published US-based Phase III Alzheimer's Disease Trials, 1997-2923

	No. of studies (%)	
Terms used in racial and ethnic reporting	**Trials with publications (n=71)**	**Trials with peer-reviewed publications (n=52)**
No Race/Ethnicity Reported	35 (49.3)	18 (34.6)
White	10 (14.1)	10 (19.2)
Caucasian	2 (2.8)	1 (1.9)
Minorities	1 (1.4)	1 (1.9)
White, Other	1 (1.4)	1 (1.9)
Caucasian, Hispanic/Latino	1 (1.4)	1 (1.9)
White, African American or Other	1 (1.4)	1 (1.9)
White, Black, Other	1 (1.4)	1 (1.9)
White, Hispanic, Black	1 (1.4)	1 (1.9)
Caucasian, Black, Asian	1 (1.4)	1 (1.9)
Caucasian, Black, Other	1 (1.4)	1 (1.9)
White/Caucasian, Black, Other	1 (1.4)	1 (1.9)
African American, Caucasian, Other	1 (1.4)	1 (1.9)
White, Black, Hispanic, Other	2 (2.8)	2 (2.8)
White, African-American, Hispanic, Other	1 (1.4)	1 (1.9)
White, Black, Asian/Pacific Islander, Hispanic/Latino	1 (1.4)	1 (1.9)

White, African-American, Asian/Pacific Islander, Other	1 (1.4)	1 (1.9)
White, Black/African American, Hispanic/Latino, Not Hispanic/Latino+	1 (1.4)	1 (1.9)
White, Black, Hispanic, Asian, Other	2 (2.8)	2 (3.8)
Unknown, Asian, Black, White, more than 1 race	1 (1.4)	1 (1.9)
Caucasian, African-American, Hispanic, Asian, Other	1 (1.4)	1 (1.9)
Caucasian, Hispanic, African American, Asian, Other	1 (1.4)	1 (1.9)
Caucasian (White), Non-Caucasian, Black, Asian, Other	1 (1.4)	1 (1.9)
African-American, Asian, White (non-Hispanic), White (Hispanic), Native American	1 (1.4)	1 (1.9)
American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Black or African American, White, More than one race, Unknown or not reported, Hispanic	1 (1.4)	0 (0.0)

Notes: Terms are ordered by the number of racial and ethnic groups reported. All terminology shown reflects the exact wording used in the original publications.

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