

# Racial and Ethnic Diversity in Vitiligo Clinical Trials: A Retrospective Cross-Sectional Study Assessing Demographic Reporting of Participants

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## ABSTRACT

**Background:** While the prevalence of vitiligo is similar across racial and ethnic groups, the effects of vitiligo vary by demographic group, culture, and skin color, with darker-skinned individuals facing greater stigma due to increased visibility of the disease.<sup>1,2</sup> The recruitment of diverse participants that are representative of the United States (US) population is crucial to ensuring the generalizability of findings and understanding the impacts of vitiligo across diverse patient groups.

**Objectives:** This study aimed to determine demographic reporting trends in US vitiligo clinical trials and to determine whether participants are representative of the US population.

**Methods:** A search for US vitiligo clinical trials was conducted on clinicaltrials.gov. Trials conducted between 2006 to September 5, 2023, were included if they intended to treat vitiligo, were conducted in the US, and were completed or terminated.

**Results:** Of the 15 trials meeting inclusion criteria, only 60% (n=9) reported participant race/ethnicity. These 9 studies included 1,510 participants, of which only 25.43% (n=384) were non-White and 20.40% were Hispanic. There was disproportionately low representation of racial minorities, particularly Black, Native American, and Native Hawaiian groups.

**Limitations:** Limitations of our study include small sample size, variations in demographic reporting between trials, and undercounting of minority groups by the US Census.

**Conclusions:** Racial and ethnic minority groups remain underrepresented in US vitiligo clinical trials. Given that the impact of vitiligo can vary by the affected individual's demographic group and skin color, investigators must be intentional about including a more diverse and representative population in vitiligo clinical trials.

*J Drugs Dermatol.* 2024;23(7):164-166. doi:10.36849/JDD.8117e

## INTRODUCTION

Vitiligo is a chronic, depigmenting, autoimmune skin condition with a similar prevalence across all racial and ethnic groups.<sup>1</sup> Despite this equal prevalence, the degree to which quality of life is impaired by vitiligo has been shown to vary by the affected individual's race, ethnicity, culture, and skin color.<sup>1,2</sup> Darker-skinned individuals affected by vitiligo may experience more concern and stigma regarding their appearance due to the increased visibility of the condition.<sup>1</sup> Studies have found that the stigma surrounding vitiligo varies by the affected individual's cultural background and level of assimilation into Western culture.<sup>2</sup> Given these differences, recruiting racially and ethnically diverse participants who are representative of the United States (US) population is crucial to ensuring the generalizability of vitiligo research. However, it

has been demonstrated that racial and ethnic minority groups are underrepresented in dermatology research studies.<sup>3</sup>

A previous analysis of vitiligo studies found underreporting of demographic data and underrepresentation of participants with Fitzpatrick skin types V-VI.<sup>4</sup> These issues are prevalent across dermatology research for most disorders.<sup>5</sup> A review of clinical trials for acne, atopic dermatitis, and psoriasis found that less than 25% of trials reported both participant race and ethnicity. Furthermore, white participants were overrepresented, constituting 77.5% of total participants.<sup>5</sup> To address demographic underreporting, the NIH mandated that NIH-funded trials report participant demographics on clinicaltrials.gov in 2017.<sup>5</sup> This study aims to determine the racial/ethnic demographic

TABLE 1.

Vitiligo Clinical Trial Characteristics			
	Number of Trials	Trials Reporting Race/Ethnicity N (%)	P-Value*
Total	15	9 (60%)	--
Funding	--	--	0.041*
Industry	8	7 (87.5%)	--
Academic	7	2 (28.6%)	--
Age Group	--	--	0.23
Adult Only	12	6 (50.0%)	--
Adult & Pediatric	3	3 (83.3%)	--
Intervention Type	--	--	0.33
Topical	6	5 (83.3%)	--
Photodynamic	5	2 (40%)	--
Procedure	1	0 (0%)	--
Oral	2	1 (50%)	--
Other	1	1 (100%)	--
Trial Start Year	--	--	0.028*
Before 2017 <sup>#</sup>	9	3 (33.3%)	--
After 2017 <sup>#</sup>	6	6 (100%)	--

\*P-values were calculated using the Fisher exact test. A limitation of our analysis is the small sample size (n = 15).

<sup>#</sup>In 2017, the NIH began to mandate that NIH-funded clinical trials report demographic characteristics on clinicaltrials.gov.<sup>5</sup>

\*Reached statistical significance with  $P < 0.05$

reporting trends in US vitiligo clinical trials and to determine whether participants are representative of the US population.

A search for US vitiligo clinical trials was conducted on clinicaltrials.gov on September 5, 2023. Trials from 2006 to 2023 were included if they intended to treat vitiligo, were conducted in the US, and were completed or terminated. Exclusion criteria were trials with non-interventional study designs, trials conducted outside of the US, and duplicate trials. From included clinical trials, data on trial year, funding source, intervention type, and participant demographic data was collected. Given that vitiligo affects individuals of all races and ethnicities equally, these values were compared to the overall US population as measured by the 07/2022 US Census Population Estimates.<sup>1</sup> Fisher exact tests were used to assess for associations between study year, funding source, and intervention type and reporting of participant demographics.

Of the 15 trials meeting inclusion criteria, only 60% (n=9) disclosed participant race/ethnicity. Trials with industry funding and studies starting after 2017 were significantly more likely to report demographic data (Table 1). The nine studies disclosing participant race/ethnicity had 1,510 participants in total. Only 25.43% (n=384) of these participants were non-White, and 20.40% (n=308) of participants were Hispanic (Table 2). Only 26.7% (n=4) trials reported Fitzpatrick skin type.

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TABLE 2.

Racial/Ethnic Diversity in Vitiligo Clinical Trials		
	Vitiligo Trial Subjects N (%)	US Census* Population N (%)
Total	1510	333,287,557
Race		
White	1126 (74.57%)	75.5%
Asian	150 (9.93%)	6.3%
Black	100 (6.62%)	13.6%
American Indian/ Alaska Native	6 (50.0%)	--
Alaska Native	5 (0.331%)	1.3%
Native Hawaiian/ Pacific Islander	2 (0.132%)	0.3%
More Than One	50 (3.31%)	3%
Unknown/Not Reported	77 (5.10%)	--
Ethnicity		
Hispanic**	308 (20.40%)	19.1%

\*07/2022 U.S. Census Population Estimates

\*\*For trials reporting "Hispanic" in the race category, participants documented as Hispanic were recorded as "Hispanic" in our ethnicity analysis, and "unknown/not recorded" in our race analysis.

Limitations of our study include a small sample size (n=15), of which only 60% (n=9) of studies disclosed demographic data, further limiting our analysis. Additionally, there was variation in how race/ethnicity was reported between trials. Finally, the US Census undercounts minority groups, particularly Hispanics, which potentially masks the degree of underrepresentation in our analysis.

Our results indicate that the reporting of demographic data in US vitiligo clinical trials has significantly increased following the 2017 NIH mandate ( $P=0.028$ ).<sup>5</sup> However, participants in vitiligo trials are not yet fully representative of the US population. Amongst the trials that disclosed participant race/ethnicity, White participants comprised the majority of participants. There was disproportionately low representation of racial minorities, particularly Black, Native American, and Native Hawaiian participants, consistent with previous findings in dermatology research for other conditions.<sup>5</sup> We found that US vitiligo trials include appropriate representation of Hispanic participants according to the US Census, although Census numbers may not be accurate due to the undercounting of Hispanics.

Possible reasons for insufficient racial and ethnic diversity in vitiligo trials include a lack of diversity in the dermatology workforce, mistrust regarding clinical research amongst minority populations, and a need for improved cultural competence amongst researchers.<sup>3</sup> Given that the impact of vitiligo varies by demographic group and skin color, investigators must aim to include a more diverse and representative population in future vitiligo clinical trials to allow for better generalizability of results to all affected individuals.<sup>2,3</sup>

**DISCLOSURES**

Dr. Elbuluk has served as a consultant, advisory board member, and/or speaker for for Avita, Incyte, VisualDx, La Roche Posay, Beiersdorf, Unilever, Allergan, Eli Lilly, Galderma, Pfizer, Takeda, Abbvie, La Roche Posay, L'Oreal, McGraw Hill, Dior, Medscape. She has received royalties from McGraw-Hill. She has stock options in VisualDx. Dr Pandya serves as a consultant for Abbvie, Arcutis, Avita, Immune Tolerance Network, Incyte, Pfizer, Thalocan, WCG/Trifecta, Twi, Villarís, Vimela, and Vyne. He has served as an investigator for Incyte. He has stock options in Tara Medical and Zerigo Health. The other authors have no conflicts of interest to declare.

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