

## ABSTRACT

Vitiligo is a depigmenting autoimmune skin condition that impacts individuals of all races and ethnicities.<sup>1</sup> However, the visibility and stigma associated with vitiligo varies by the affected individual's race/ethnicity, skin tone, and culture.<sup>1,2</sup> Underreporting of participant demographic data and underrepresentation of racial/ethnic minority groups are prevalent issues across dermatology research, including vitiligo research, and this affects the generalizability of findings to the diverse population of affected individuals.<sup>3,4,5</sup> This study assessed US vitiligo clinical trials from 2006-2023 to determine trends in demographic reporting, and to assess whether trial participants were representative of the US population as measured by the 7/2022 US Census Population Estimates. Fifteen trials were included in our analysis, of which 60% (n=9) disclosed participant race/ethnicity. We found that industry-funded studies and studies after 2017, when reporting became mandated by the NIH, were significantly more likely to report participant race/ethnicity (p=0.028).<sup>5</sup> The 9 trials reporting participant race/ethnicity had 1,510 participants total, of which only 25.43% (n=384) participants were non-White and 20.40% (n=308) were Hispanic. Black, Native American, and Native Hawaiian individuals were the most underrepresented racial groups. We found appropriate representation of Hispanic participants in US vitiligo trials in accordance with US Census estimates; however, the US Census undercounts minority groups, particularly Hispanics. Our results indicate that vitiligo clinical trial reporting of participant race/ethnicity has significantly improved in recent years, coinciding with the 2017 NIH mandates for demographic reporting.<sup>5</sup> However, racial minority groups continue to be underrepresented, and investigators must aim to increase racial/ethnic diversity in US vitiligo trials.

## METHODS

- A search for "vitiligo" was performed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).
  - 2006 to September 5, 2023
  - All U.S. clinical trials, published and unpublished, are recorded on this database.
  - Inclusion criteria: Completed or terminated U.S. clinical trials with results, focused on treatment of vitiligo
  - Exclusion criteria: trials not focused on vitiligo, non-interventional trials, and duplicate trials
- Participant demographic data, including race, ethnicity, and age were collected and analyzed. Information on study funding, trial start year, and intervention type were also collected. Statistical analyses were performed using Fischer exact tests.

**Table 1: Vitiligo Clinical Trial Characteristics**

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

<sup>+</sup>: P-values were calculated using Fischer exact test.

<sup>\*</sup>: Reached statistical significance with p < 0.05

**Table 2: Racial/Ethnic Diversity in Vitiligo Clinical Trials**

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

Table 2 compares the racial and ethnic makeup of U.S. vitiligo clinical trial participants to that of the United States population.

\*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.

## RESULTS/DISCUSSION

- 15 clinical trials met inclusion criteria
  - 1,510 total enrolled participants
  - Both pediatric and adult patient populations were studied
- 60% (n=9) trials reported participant race:
  - Industry-funded studies and studies after 2017 were significantly more likely to report participant data regarding race/ethnicity (Table 1)
  - Of trials reporting participant race/ethnicity: 0.331% American Indian, 9.93% Asian, 0.132% Native Hawaiian, 6.62% Black, 74.75% White, 3.31% more than one race, and 5.10% unknown (Table 2)
  - 20.40% of participants were Hispanic (Table 2)

## CONCLUSION

- Amongst participants of clinical trials providing participant demographic data, Black, Native American, and Native Hawaiian individuals were the most underrepresented groups.
- We found adequate representation of Hispanic participants, although Census counts of Hispanic Americans may be inaccurate due to undercounting of minority groups.
- 40% (n=6) of trials did not provide data on participant race/ethnicity, limiting our assessment.
- Since 2017, 100% of trials have disclosed participant race/ethnicity, likely due to the 2017 NIH mandate.<sup>5</sup>
- Creating a more representative sample and performing subgroup analyses by race/ethnicity allows for results to be more generalizable to the diverse patient population.

## REFERENCES

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