**Methods**

The numbers of scleroderma patients in the U.S. and Southeastern U.S. in total and by race were estimated based on the estimated U.S. population provided by the [United States Census Bureau](https://www.census.gov/quickfacts/fact/table/US) as of July 1st, 2024; the estimated scleroderma prevalence among adults in the United States of 25.9 per 100,000 people [(Fan, et al. 2020)](https://www.jmcp.org/doi/10.18553/jmcp.2020.20136); and the scleroderma prevalence estimates among White and Black populations based on prevalence estimates from [(Mayes, et al. 2003)](https://onlinelibrary.wiley.com/doi/10.1002/art.11073).

To estimate the total number of White and Black scleroderma patients in the U.S. and Southeast U.S., the current study weighted the scleroderma prevalence of the general U.S. population from Fan, et al. for White and Black individuals in the U.S. based on each race’s proportion of the total prevalence estimates from Mayes, et al. The prevalence estimates of scleroderma among White and Black individuals in the U.S. were assumed to be the same for their respective populations in the Southeast U.S.. For example,

These estimates were then used to calculate the numbers of scleroderma patients overall and within each regional and racial group using the following methods:

The number of unrepresented Black scleroderma patients were calculated by multiplying the number of scleroderma patients for both regions by the observed proportion of Black participants in U.S. clinical trials (8.9%) and subtracting this “represented” population from the total estimated Black scleroderma patient population in the region:

To investigate whether the demographics of scleroderma clinical trial participants are reflective of the the United States’ scleroderma patient population, two one-sample z-tests were conducted in R 4.5.0 to compare the observed proportions of White and Black participants in U.S. clinical trials to their respective estimated proportions within the United State’s scleroderma patient population. Furthermore, we quantified this disparity by estimating the number of all Black scleroderma patients who are unrepresented in clinical trials in the United States and Southeastern U.S. (defined as AL, AR, FL, GA, KY, LA, MS, NC, SC, and TN), which is home to about half of the United States’ total Black population.

**Results**

Table 1. Reporting of Race and Ethnicity in Scleroderma Clinical Trials

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Counts (percentages)** | | | | | | | |
| **Participant Information** | | | | **Ethnicity** | | | |
| Total number of participants in clinical trials | Female Participants | Male Participants | | Total number of participants reporting ethnicity | Hispanic or Latino | Not Hispanic or Latino | |
| 691 | 580 (83.9%)  (580/691) | 111 (16.1%)  (111/691) | | 436 | 31 (7.1%) (31/436) | 405 (92.9%)  (405/436) | |
| **Race** | | | | | | | |
| aTotal number of participants reporting race | American Indian or Alaska Native | Asian | Native Hawaiian or Other Pacific Islander | | Black or African American | White | More than one race |
| 673 | 1 (0.15%)  (1/673) | 15 (2.2%)  (15/673) | 2 (0.30%)  (2/673) | | 60 (8.9%)  (60/673) | 570 (84.7%)  (570/673) | 25 (3.7%)  (25/673) |

Based on Census data and race-specific prevalence estimates, we estimate that 29.1% of SSc patients in the Southeast are Black (95% CI: 28.7%–29.7%), which is 63.2% higher than the national proportion of 17.8%. In absolute numbers, we estimate there are 88,089 SSc patients in the entire U.S. (95% CI: 86,728–89,789), of whom 15,714 are Black (95% CI: 15,471–16,017). In the Southeastern region, that implies 5,932 Black scleroderma patients (95% CI: 5,840–6,046). Because only 60 Black patients appeared in trials, we estimate that 7,874 Black SSc patients nationwide remain unrepresented in trials (95% CI: 5,936–9,769), and 5,404 unrepresented Black patients in the Southeast (95% CI: 5,273–5,531).

The proportion of Black participants enrolled in U.S. scleroderma clinical trials was 8.9% (60/673; 95% CI: 6.8%–11.1%). This was significantly lower than our estimated proportion of Black individuals in the general U.S. scleroderma population (17.8% [95% CI: 16.8%–18.9%]; see Methods for how this CI was derived). A one-sample z-test comparing 8.9% to 17.8% yielded z = –7.72, p < 0.001. The absolute difference between trial versus population was –8.9 percentage points (95% CI: –11.1% to –6.8%), corresponding to an observed-to-expected ratio (OER) of 0.50 (95% CI: 0.37–0.62).

Table 2. Scleroderma Clinical Trial Underrepresentation in the Southeastern U.S. States

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Region** | **aPercent of Population Identifying as Black** | **Estimated Total Scleroderma Patients (95% CI)** | **Estimated Black Scleroderma Patients (95% CI)** | **Percent of Scleroderma Patients who are Black (95% CI)** | **Estimated Unrepresented Black Patients (95% CI)** | **Percent of Patients Unrepresented (95% CI)** |
|  |
| United States | 13.7% | 88,089 (86,728-89,789) | 15,714 (15,471-16,017) | 17.8% (17.6%-18.2%) | 7,874 (5,936-9,128) | 50.1% (37.8%-62.2%) |
| Southeast US | 22.4% | 20,378 (20,064-20,772) | 5,932 (5,840-6,046) | 29.1% (28.7%-29.7%) | 5,404 (5,273-5,531) | 69.4% (61.9%-76.8%) |

aNational and state population data were provided by the U.S. Census Bureau. U.S. clinical trial demographics were sourced from publicly available NCBI clinical trial data available on ClinicalTrials.gov.

In contrast, White participants made up 84.7% of clinical trial enrollees (570/673; 95% CI: 82.0%–87.4%), which was significantly higher than the estimated proportion of White patients in the U.S. scleroderma population (69.9% [95% CI: 68.1%–71.7%]). The one-sample z-test comparing 84.7% vs. 69.9% gave z = 8.64, p < 0.001. The absolute difference was +14.8 percentage points (95% CI: 12.0%–17.5%), with an OER of 1.21 (95% CI: 1.17–1.25). Together, these results indicate that Black individuals are markedly underrepresented and White individuals are overrepresented in clinical trials relative to their disease burden in the overall U.S. scleroderma population. This underrepresentation may have implications for the generalizability of clinical trial findings and highlights a need for targeted efforts to improve racial equity in scleroderma research participation.

**References**

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