

BACKGROUND

- Black, Indigenous, and people of color (BIPOC) are disproportionately affected by autoimmune connective tissue diseases (AICTD)¹
- Clinical trials can help to address this disparity
 - Provide knowledge of disease processes
 - Direct future investigational strategies
 - Provide access to novel and potentially life-saving therapy for those with refractory disease
- Underpowered or absent groups in clinical trials can be significantly harmed²
- Research question: How well are racial and ethnic minorities represented in clinical trials for novel AICTD therapies?

METHODS

- Query: Randomized clinical trials in human subjects with biologics or small molecule drugs for lupus, dermatomyositis, systemic sclerosis, or morphea
 - MEDLINE (Ovid)
 - Embase (Ovid)
 - Web of Science
 - Cochrane Library via Wiley
 - Global Index Medicus
 - ClinicalTrials.gov
 - WHO ICTRP
- Three independent reviewers performed title and abstract screening followed by full text screening

RESULTS

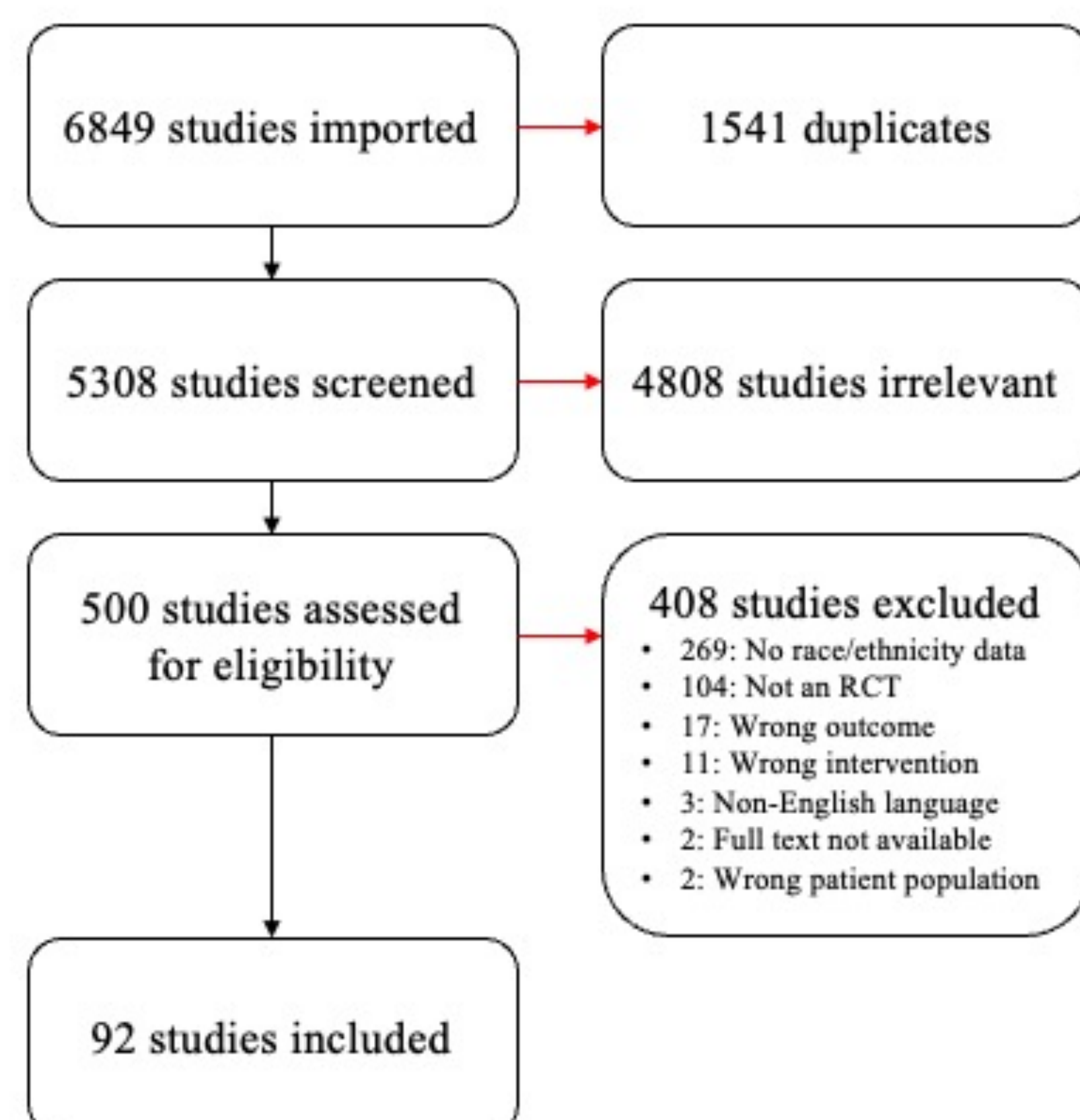


Figure 1: PRISMA Diagram

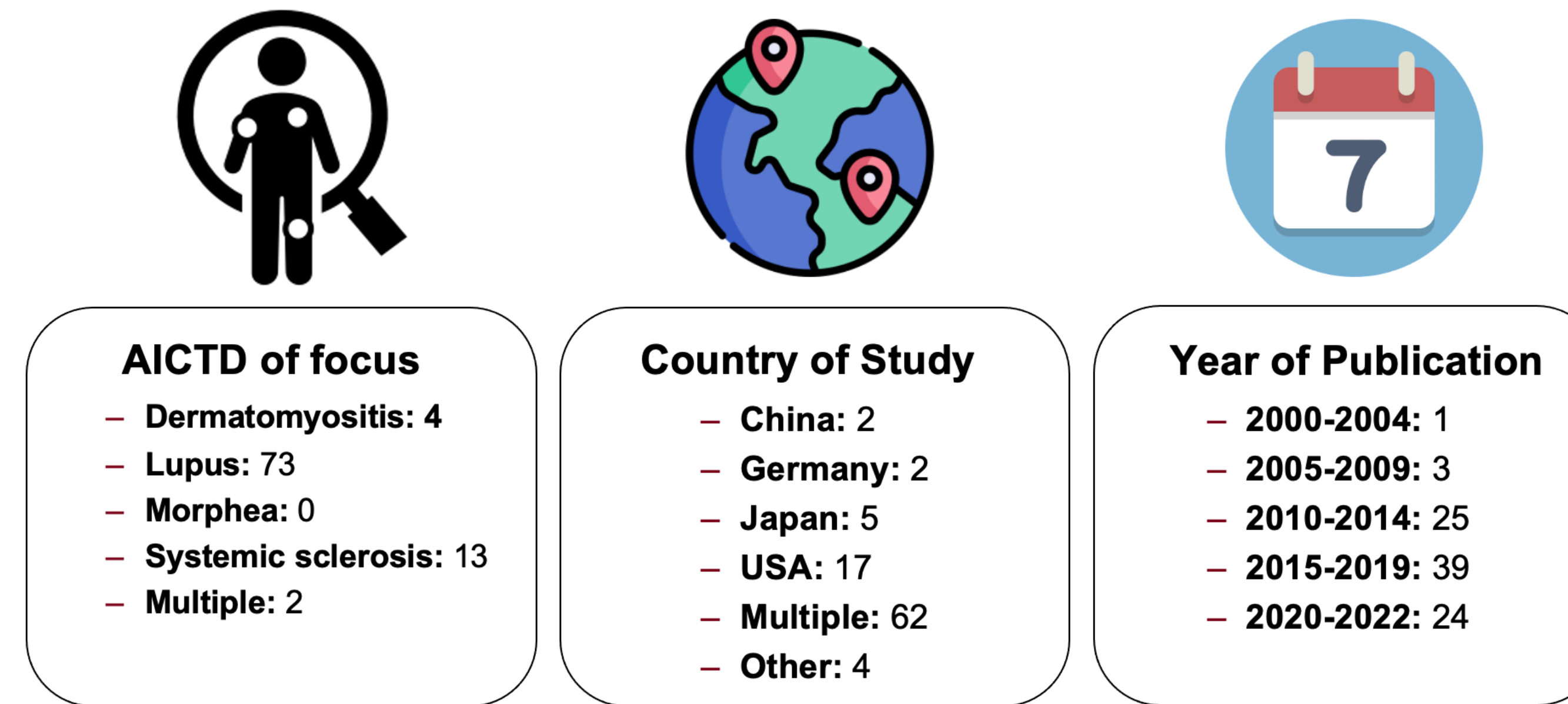


Figure 2: Focus, country of study, and year of publication for included clinical trials

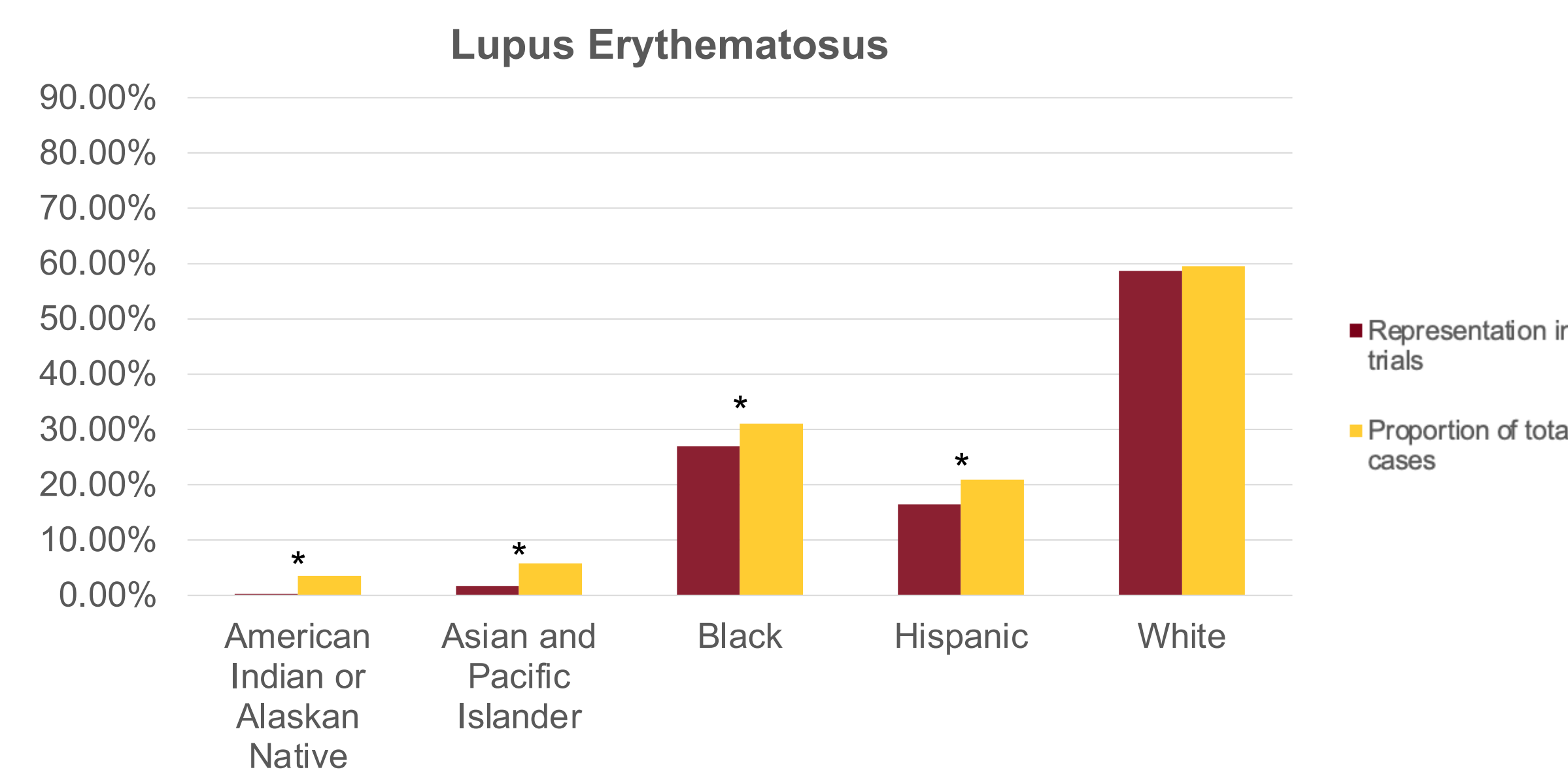


Figure 3: Racial and ethnic representation in lupus erythematosus RCTs based in the United States. Data is from 13 United States-based clinical trials involving 1240 patients with lupus erythematosus. United States epidemiological data was based on previously reported meta-analyses of the CDC's National Lupus Registries.² *p<0.05

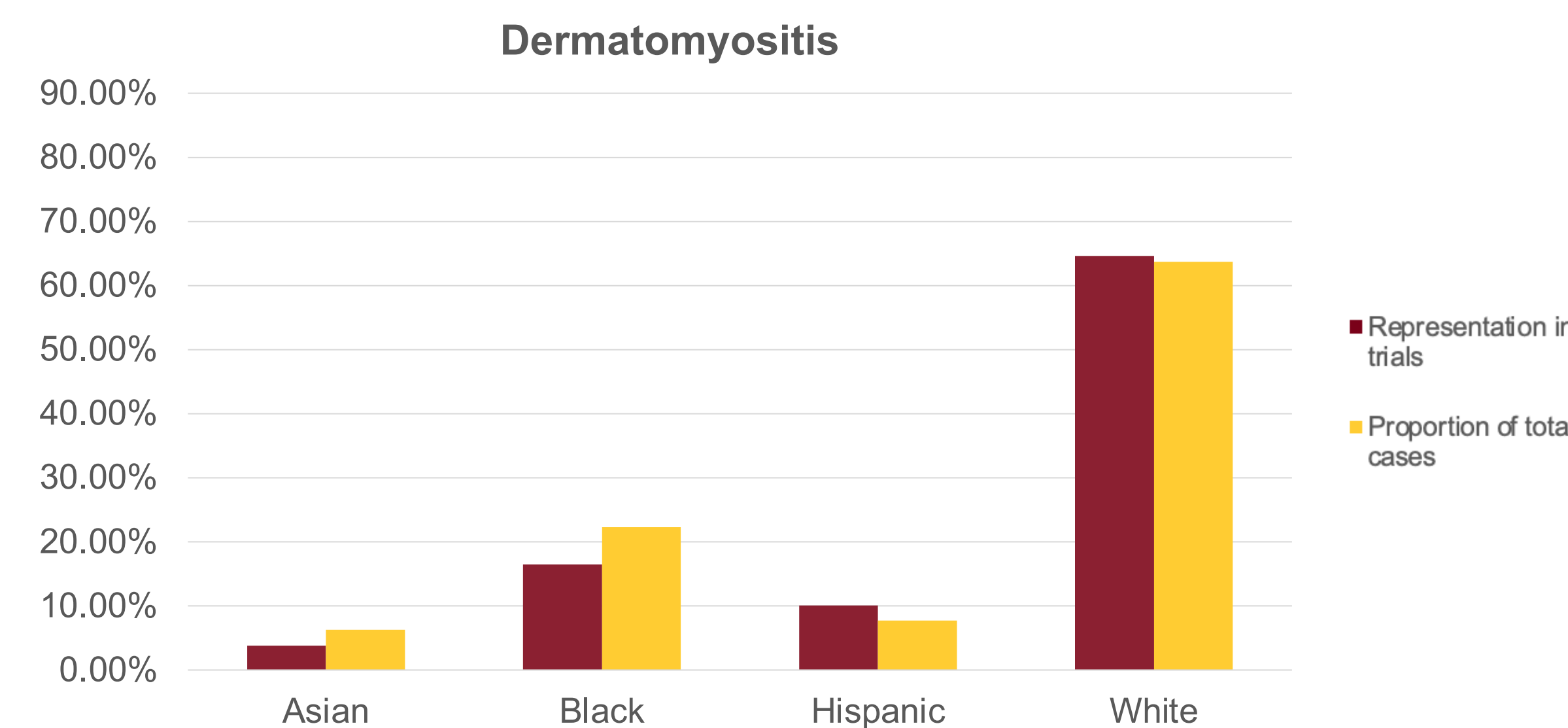


Figure 4: Racial and ethnic representation in dermatomyositis RCTs based in the United States. Data is from 3 United States clinical trials involving 79 patients with dermatomyositis or polymyositis. United States epidemiological data was based on 2020 prevalence mapped onto corresponding US census data.^{3,4} *p<0.05

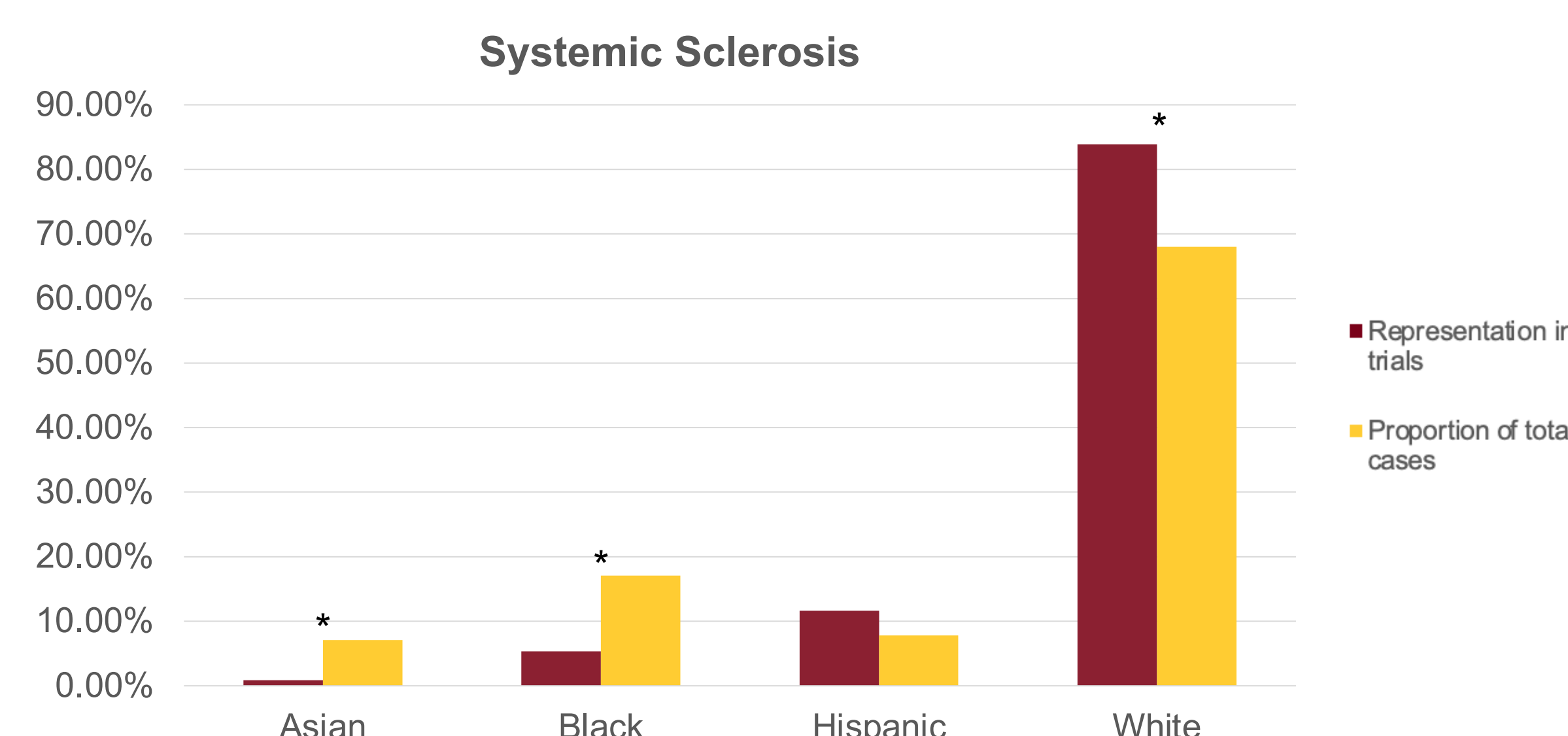


Figure 5: Racial and ethnic representation in systemic sclerosis RCTs based in the United States. Data is from 4 United States clinical trials involving 112 patients with systemic sclerosis. United States epidemiological data was based on 2020 prevalence mapped onto corresponding US census data.^{3,4} *p<0.05

Race/Ethnicity	≤ 2017 N = 16479	2018-2022 N = 6069	χ^2	p
American Indian or Alaskan Native	7.6%	2.2%	221.97	<0.00001
Asian	19.2%	18.2%	3.04	0.08
Black	10.3%	16.8%*	178.33	<0.00001
Hispanic	17.3%	13.7%	42.00	<0.00001
Native Hawaiian or Other Pacific Islander	0.1%	0.2%	1.49	0.23
Other	4.0%	6.5%	59.05	<0.00001
White	56.0%	55.3%	0.88	0.35
BIPOC [†]	58.6%	57.3%	3.26	0.07

Figure 6: Race and ethnicity in US AICTD RCTs over time, comparing the past 5 years to all prior trials. * Includes EMBRACE study, accounting for over 40% of Black trial participants 2018-2022. † American Indian/Alaskan Native, Asian, Black, Hispanic, Native Hawaiian/Other Pacific Islander, Other.

CONCLUSIONS

- Inclusivity in RCTs for AICTDs remains problematic, even despite recent pushes for greater diversity in participants.
- BIPOC patients are underrepresented in trials of novel therapies for lupus and systemic sclerosis
- In AICTD RCTs in the last 5 years:
 - American Indian/Alaskan Native and Hispanic involvement has declined.
 - Black involvement has significantly increased due to the EMBRACE trial.
 - Without the EMBRACE trial, BIPOC inclusion overall would have seen a significant decline.
- Lack of diversity in trials serves to exacerbate disparities for BIPOC patients with AICTDs.
- Further targeted efforts are needed to increase inclusivity in RCTs for novel AICTD therapies.

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