



Addressing Disparities in Clinical Trial Participation: A Comparative Analysis of Cardiovascular and Oncology Studies

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Abstract

This poster examines disparities in minority representation in U.S. clinical trials for cardiovascular disease and cancer, two leading causes of death. Analyzing data from 5,492 cardiovascular and 10,328 oncology studies involving over 30.6 million participants, we found significant underrepresentation of Black and Hispanic Americans, despite their higher disease burden. Socioeconomic factors and historical distrust of the medical community contribute to these disparities, creating a cycle of exclusion. Improving enrollment practices and fostering community trust are essential to enhance diversity in trials, and ensure more reliable and applicable outcomes for all populations.

Introduction

Regulatory authorities, such as the FDA, have increasingly emphasized the critical importance of enhancing the representativeness of clinical trial populations. This push aims to ensure that trial findings more accurately reflect the demographics of potential medication users, which is essential for developing effective and equitable healthcare solutions. Diversity and representation in clinical trials are not just ethical imperatives but are also crucial for the scientific validity and applicability of trial outcomes across various population groups.

Recent FDA guidance on diversity action plans highlights the urgent need to improve the enrollment of participants from underrepresented groups, particularly racial and ethnic minorities who have historically been overlooked in clinical research. These groups, including Hispanic/Latinx, Black/African American, Asian, and Native Hawaiian, American Indian, Alaska Native, and Other Pacific Islanders, are significantly underrepresented in clinical trials for cardiovascular diseases and oncology, despite bearing a disproportionate burden of these conditions.

Our analysis, which examines data from cardiovascular and oncology trials conducted between 2000 and 2023, reveals stark disparities in trial participation. These disparities not only challenge the validity of trial results but also exacerbate existing health inequities. By addressing these disparities through improved enrollment practices, we can foster more inclusive research, leading to reliable and applicable trial outcomes that benefit all population groups. This poster presents a comparative analysis of demographic representation in clinical trials and underscores the necessity of diversity initiatives to break the cycle of underrepresentation and distrust in the clinical trial process.

Materials and Methods

In this analysis focused on two leading causes of death among U.S. adults—cardiovascular disease and cancer—which disproportionately affect minority groups. We extracted demographic data from clinicaltrials.gov using its API, which stores trial information in the Fast Healthcare Interoperability Resource (FHIR) format, including anonymized participant data. Completed studies in cardiovascular disease and oncology with available results from 2000 to 2023 were analyzed. Demographic data from these studies were aggregated to calculate total N values and percentage breakdowns for each group, both annually and cumulatively. Customized fields were used to classify participants into the most fitting demographic categories.

The goal was to evaluate demographic representation within these clinical trials and compare it to U.S. Census data, identifying potential disparities and suggesting strategies for improving trial enrollment practices. Some studies provided limited demographic details, resulting in lower totals for certain groups due to incomplete data availability.

Results and Discussion

This analysis encompassed 5,492 cardiovascular and 10,328 oncology studies, involving over 30.6 million participants. Despite cardiovascular disease and cancer being leading causes of death in the U.S., disproportionately affecting minority groups, our findings reveal significant disparities in clinical trial participation.

Key Disparities:

- **Black/African Americans:** The heart disease death rate for Black non-Hispanic Americans is 1.3 times higher than for non-Hispanic White Americans. However, Black Americans remain underrepresented in both cardiovascular and oncology trials.
- **Hispanic/Latinx:** Hispanic Americans are the most underrepresented group in cardiovascular studies, constituting only 5.0% of participants compared to 18.73% of the U.S. population. To achieve representation, Hispanic participation would need to increase by 13%, more than tripling the current figure.
- **Asian Americans:** While Asian Americans are overrepresented in these trials, this trend is slightly decreasing.
- **White/Caucasians:** White participants continue to be overrepresented, although their percentage is also trending slightly downward.

These disparities emphasize the need for targeted interventions and public health policies to enhance trial inclusivity and better inform treatment strategies, ultimately improving outcomes for all demographic groups.

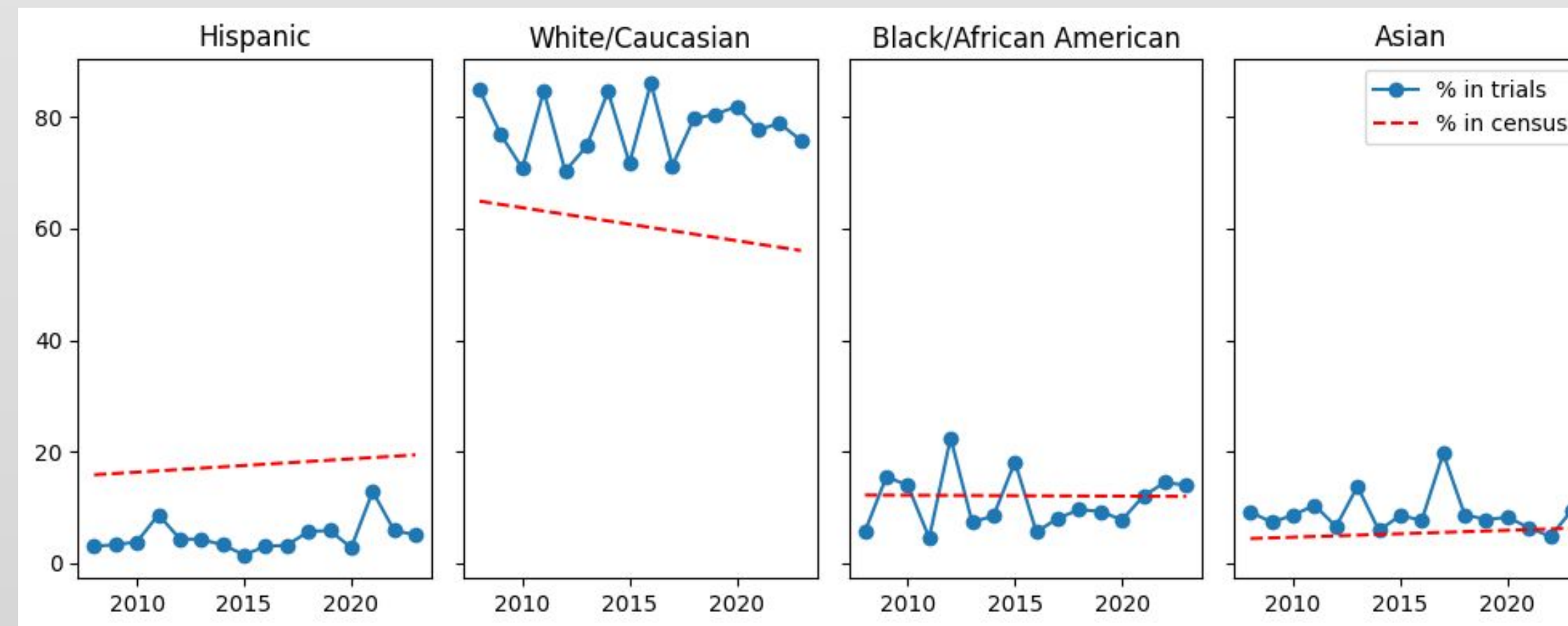


Figure 1: Percentage Over Time in Cardiovascular Studies

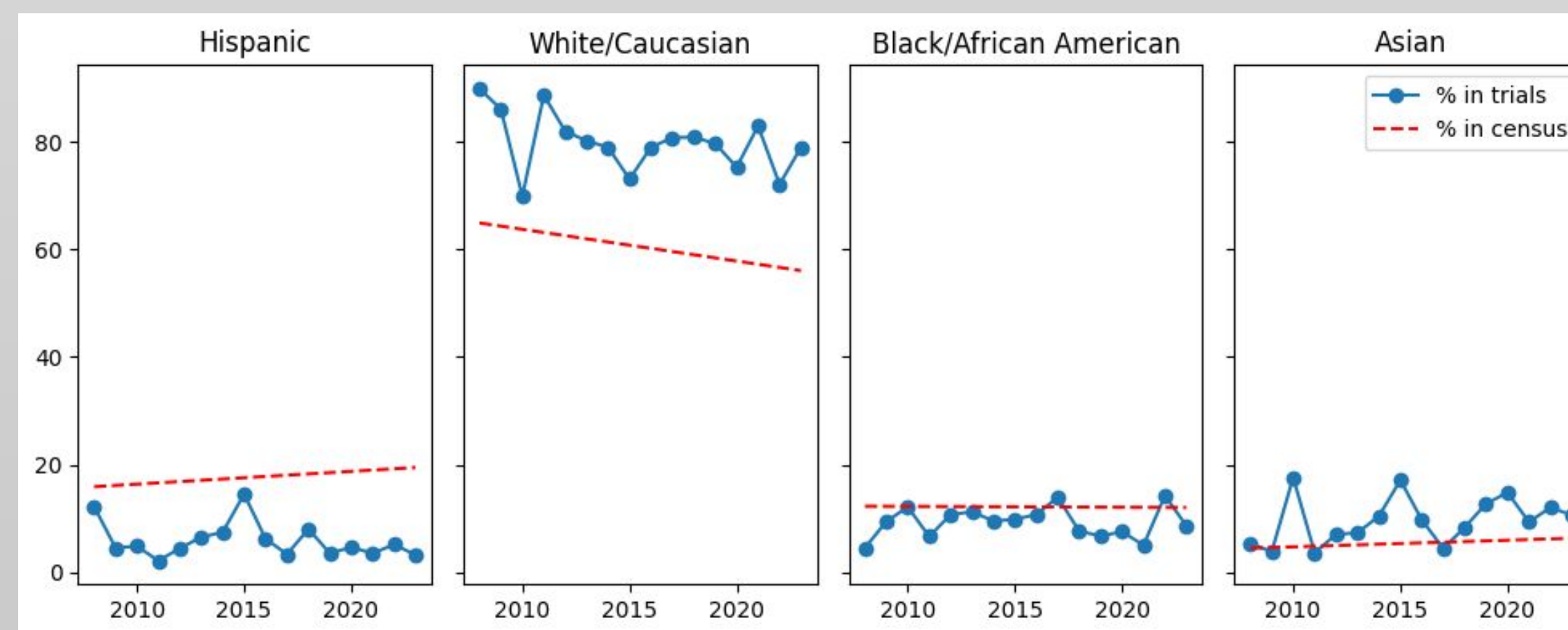


Figure 2: Percentage Over Time in Oncology Studies

Results and Discussion(continued)

	Cardiovascular	Oncology	Census Data
Hispanic	5.0%	10.1%	18.73%
White/Caucasian	79.2%	75.4%	57.84%
Black/African American	9.6%	9.7%	12.05%
Asian	9.3%	14.3%	5.92%
Native Hawaiian, American Indian, Alaska Native, and Other Pacific Islanders	1.2%	0.3%	0.87%
Two or More	0.7%	0.3%	4.09%

Table 1: Percentage by Race

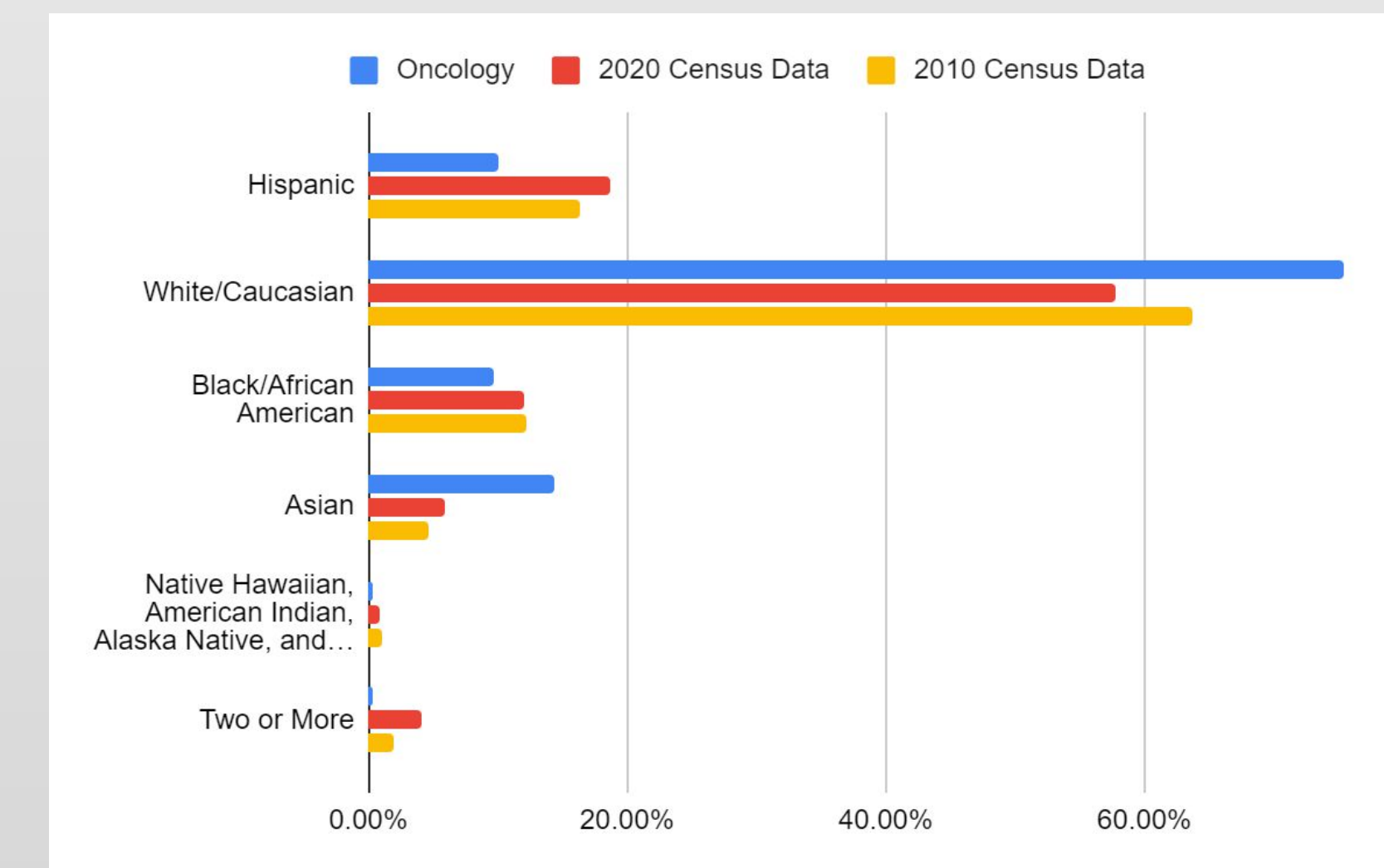


Figure 3: Percentage by Race in Oncology Studies

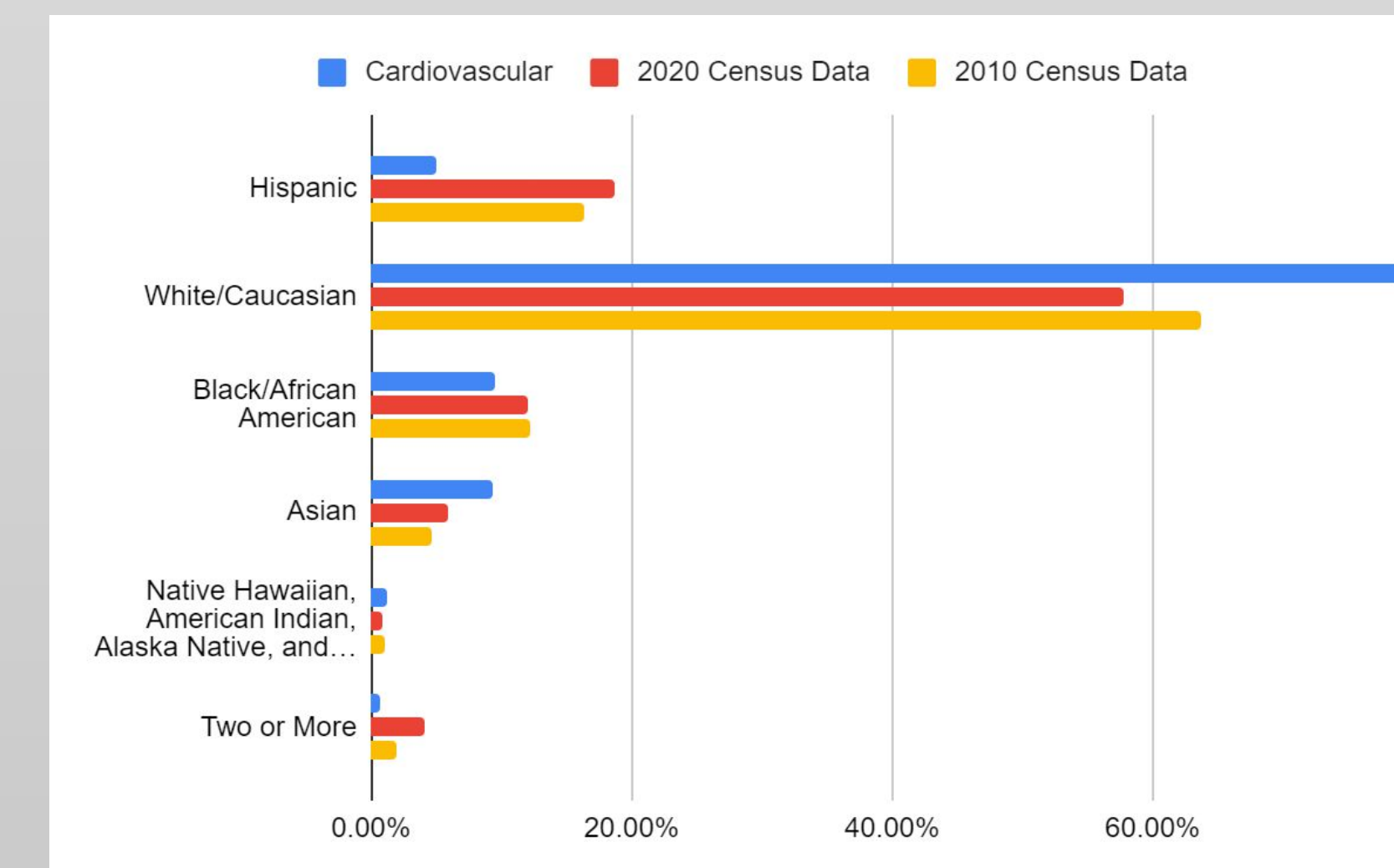


Figure 4: Percentage by Race in Cardiovascular Studies

Conclusion

The underrepresentation of minority groups in clinical trials is a multifaceted issue that may be influenced by socioeconomic factors such as income disparity. White and Asian Americans, who generally have higher average incomes, are more likely to participate in clinical trials than Black or Hispanic Americans. This disparity suggests that socioeconomic status may play a role in willingness to participate, with lower-income groups facing barriers such as limited access to healthcare or time constraints.

However, the issue goes beyond income. Historical wrongdoing by the medical community has led to deep-seated distrust among Black and Hispanic communities, resulting in a reduced propensity to participate in clinical research. This distrust perpetuates a vicious cycle where medical advancements are made with less input from these groups, further alienating them from the healthcare system and exacerbating existing health disparities.

Breaking this cycle requires intentional efforts to improve enrollment practices and build trust within these communities. Diversity initiatives must be prioritized, not only to rectify historical wrongs but to ensure that medical research is inclusive and reflective of all populations. By fostering more inclusive research, we can achieve more reliable and applicable trial outcomes, ultimately benefiting all demographic groups. Enhancing diversity in clinical trials is not merely an ethical obligation but a critical necessity for the future of equitable healthcare.

References

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