



Racial Bias in Clinical Trials: What You Need to Know



Significant work is needed to ensure that patients of all demographics are equally represented in our data.

BY JOSEPH M. CONEY, MD

Racial bias in health care is one of the underlying factors preventing diversity in clinical research. Implicit and racial biases affect all medical subspecialties, as do other systemic problems such as institutional racism, patient distrust, and a lack of minority physicians treating underserved populations.

For example, Black women have a 41% higher mortality rate from breast cancer compared with White women,^{1,2} but they represent only 5% of clinical trial participants.³ Likewise, Black men have a 76% higher incidence rate and 120% higher death rate from prostate cancer compared with White men,⁴ yet more than 96% of participants enrolled in these studies are White.⁵

In our own field of retina, although Blacks and Latinos are more likely than Whites to be diagnosed with or go blind from diabetic retinopathy, they are underrepresented in our pivotal diabetic macular edema trials with less than 12% of participants being Black.^{6,7}

The FDA recently released new guidance for industry sponsors to enhance the diversity of trial populations,⁸ but a holistic approach is needed to drive lasting and sustainable change. Physicians and researchers alike must understand and address clinical research disparities and racial bias to achieve greater health equity for all patients, regardless of race, ethnicity, gender, age, or other demographics.

BARRIERS TO RECRUITMENT

As a retina specialist who has served my community for 15 years, I've experienced fair success in recruiting patients to participate in clinical trials; however, I'm not immune to

biases—none of us are. The key is recognizing our biases so that we can alter our behavior. In particular, I've noticed several barriers we need to overcome to help mitigate racial bias and improve minority representation in clinical research.

Implicit Bias

Most often, patients consider taking part in a trial because a physician asked them to participate.⁹ If a physician makes a snap judgment about a patient based on race,

AT A GLANCE

- ▶ Although Blacks and Latinos are more likely to be diagnosed or go blind from diabetic retinopathy, they constitute less than 12% of trial populations.⁶
- ▶ Of the 2,400 retina specialists in the United States, fewer than 100 identify as an underrepresented minority.
- ▶ Today, 30% to 50% of minorities distrust the COVID-19 vaccine and aren't considering vaccination.¹⁵
- ▶ Genentech's External Council on Advancing Inclusive Research seeks to ensure that clinical trial participants represent broader patient populations so that those with serious and life-threatening diseases have the opportunity to benefit from investigational medicines.

ethnicity, gender, or other demographics and concludes that the patient isn't an ideal candidate for a clinical trial, it's a lost opportunity to potentially help the patient and advance medical research. If we don't ask our minority patients to participate, they won't. Trial participation should be offered to everyone.

However, an invitation to participate is not sufficient on its own. We must also be aware of, and address, our own biases that, when left unchecked, can disrupt the physician-patient relationship. Without a foundation of trust between patients and physicians, noncompliance is likely. We must be conscious that some minority patients are inherently apprehensive and distrusting. We must listen to patients and address their concerns in a culturally competent manner.

Lack of Minority Physicians

Patients often prefer to see a doctor with whom they can identify.¹⁰ Although there are approximately 40 million Blacks (13% of the population) in the United States, only 5% of physicians and 2.9% of ophthalmologists are Black—and the disparity is even greater for non-White Hispanics.¹¹

Even more challenging, of the 2,400 retina specialists in the United States, fewer than 100 are an underrepresented minority. We desperately need stronger efforts to enroll more underrepresented minorities into medical school, assist with matriculation into competitive residencies and fellowships, expose students to subspecialty societies, and encourage early participation in advisory boards and research.

Patient Distrust

Long-standing social injustices and prejudices have led to skepticism among people of color regarding health care. Numerous research abuses, such as the Tuskegee Syphilis Study,¹³ the story of Henrietta Lacks and HeLa cells,¹⁴ and radiation studies on prisoners, have left deep-seated doubt in the minds of many about the safety and benefits of research.¹² This sentiment persists today, during the pandemic, as 30% to 50% of minorities distrust the COVID-19 vaccine and aren't considering vaccination.¹⁵

Cost and Time Commitment

Out-of-pocket travel costs, travel time to trial sites, medical follow-up appointments, unexpected bills,¹⁶ missing work, and childcare costs are among the concerns that restrict patients from trial participation. We should make every effort to ensure that all study patients have no out-of-pocket expenses while enrolled in a clinical trial.

SOLUTIONS: HOW TO MOVE FORWARD

Address Implicit Bias

As physician investigators, we need to examine our own biases. In addition, sponsors should have an “unmet

needs” dialogue with principal investigators to explain the importance of racial and ethnic diversity in trial participants. These dialogues should highlight disparities in disease prevalence, mortality data, and long-term disabilities within underrepresented groups. They should also emphasize that clinical trial recruitment must represent patients who will eventually, upon approval, be treated with the medication, and that efficacy and side effect data must reflect all races and ethnicities.

Increase Minority Enrollment in Medical Schools

Only a few years ago, I was the only African American retina specialist in the state of Ohio. In medical school, I was the only Black male in my class, and few of my fellow students and professors were people of color. To find my place, I quickly learned the value of mentors.

This is one of the reasons I strongly endorse initiatives such as the AAO's Minority Ophthalmology Mentoring program.¹⁷ We not only need to bring awareness of the field of ophthalmology to the next generation of students, but also to create an inclusive environment in which minorities can thrive. As a recipient of the Rabb-Venable Research Award from the National Medical Association,¹⁸ I know firsthand the difference these types of programs can make for a young medical professional.

Build Equity and Trust

Rebuilding trust within communities of color requires commitment from industry sponsors, policymakers, health care professionals, and patient advocates, among others. Outreach programs and support groups (eg, in churches and community centers) can help to increase the health literacy of minority patients and reinforce the importance of clinical trial participation.

Additionally, we must improve the informed consent process. Consent forms should be translated into the native languages of community patients and sent home with the patients for further review. A follow-up call afterward can address questions from the patient and family prior to the screening appointment.

Physicians have a responsibility to combat racial bias among staff members and colleagues. At my practice, our monthly meetings include a discussion of clinical trial recruitment strategies. It's important that we train our staff, make clinical study information accessible in exam rooms, and consider locating clinical trial sites near underserved areas.

Collaborate with Industry

In addition to making an impact in our local communities, we must also focus our attention on the regional and national landscape to reduce racial bias in clinical trials. Genentech's External Council on Advancing Inclusive Research, of which I've been a member for more than 2 years, seeks to ensure that trial

participants represent broader patient populations.

Our advisory council has helped Genentech shape its strategy and develop concrete recommendations to build more inclusive and equitable clinical trials.

The council has also provided guidance for sponsors working with principal investigators to make inclusion and exclusion criteria more inclusive (eg, by loosening strict HbA1C requirements). Moreover, because out-of-pocket costs can be a major factor preventing underrepresented minorities from participating in clinical trials, we have worked with Genentech to develop patient assistance programs and travel grants to reduce patients' cost burdens.

VISION FOR A MORE EQUITABLE FUTURE

I believe our health care future is bright and our drug pipeline is robust. We cannot afford to leave any patient behind and must be intentional about addressing the disparity gap in this country. Increasing the representation of minority patients in clinical trials is a step in the right direction, as it builds patients' trust in institutions, in their communities, and, most important, in you. ■

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