



CARER Group
Catalyzing Access to Research and Equity in Representation

The Missing Piece in Clinical Trials: Why We Need to Include Black Participants

Between January 1, 2022, and December 31, 2024, **26 out of 139** (that's 19%) had no Black participants in the pivotal clinical trials. If Black individuals are left out of drug trials, it means these treatments might not be as effective—or even safe—for them compared to other groups. And this doesn't just impact a few people. It affects entire communities, leading to **health disparities** and unequal access to the benefits of modern medicine.

This is especially critical for diseases that disproportionately impact Black communities, like **hypertension, diabetes, and sickle cell disease**. Without Black participants in trials, we risk creating treatments that might not work as well—or even cause harm—for those who need them most.

Why does this happen? There's no simple answer. One of the biggest reasons is the **historical distrust** that Black communities have in medical institutions, built from years of mistreatment and unethical practices. There are practical barriers—like **economic, geographical, and logistical** challenges—that make it harder for Black people to access clinical trials. And there is a lack of **diverse research teams**. When researchers don't reflect the populations they're studying, unconscious biases can occur.

We need to be intentional and ensure **every** community gets the chance to benefit from the next generation of life-saving treatments.

The Numbers Behind the Data

- **Median Number of Black Participants Receiving Novel New Drugs: 5**
- **GRADE F for Black Representation reflects 1) enrollment % significantly below the US census data, 2) less than 30 participants receiving the novel new drug, and 3) a disease or condition that has increased incidence in the Black population**

A year-by-year breakdown shows the extent of the issue:

- **2022:** 3 out of 38 new drugs (8%)
- **2023:** 11 out of 55 drugs (20%)
- **2024** 6 out of 49 drugs (12%)

A Call for Action

If we want to see these numbers change, the **CARER Group, Catalyzing Access to Research and Equity Representation Group** (www.caregroup.org) calls for the following actions:

- 1. Increase Awareness and Simplify Enrollment**

Raise awareness about clinical trials and make the enrollment process more accessible by offering transportation and/or financial incentives to participants.

- 2. Build Trust with Black Communities**

Partner with trusted community leaders to bridge the gap between clinical research and the communities it serves. Ensure transparency in how clinical trial data is collected and used to gain the trust of participants.

- 3. Increase Diversity in Research Teams**

Ensure that more Black researchers, physicians, and community advocates are involved in the design and implementation of clinical trials. Diverse teams can improve cultural competence and address unconscious bias.

- 4. Collaborate with Regulatory Agencies**

Work with the FDA and other government agencies to establish requirements for clinical trials to include diverse populations in their research. Policy change is critical to see real changes.

- 5. Engage Directly with Communities**

Engage directly with Black communities to understand their concerns and needs. Design clinical trials that are culturally relevant and that address the real needs of the populations being studied.

- 6. Conduct More Clinical Trials in the United States**

The U.S. accounts for only about 29% of enrollment in clinical trials of new drugs approved by FDA which limits the representation of diverse populations and does not reflect the true demographic makeup of the country. Prioritizing more U.S.-based trials, especially with underrepresented communities, is key to improving clinical trial diversity.