

## Globalization of cancer clinical trials linked to lower enrollment of black patients

**08 MARCH 2021** - For the drug approval process in the United States, investigators have been expanding clinical trials to sites outside the country. However, a new study indicates that this trend may be widening racial disparities in patient enrollment in cancer clinical trials. The study is published by Wiley early online in *CANCER*, a peer-reviewed journal of the American Cancer Society.

Without adequate representation in clinical trials, it is difficult to assess whether a medication will be safe and effective for all populations. Unfortunately, Black individuals have historically been poorly represented in clinical trials of anticancer medications, and their inclusion has been decreasing in recent years. Globalization of cancer clinical trial enrollment may play a role in this trend: to reduce costs and expedite patient enrollment, trials have increasingly enlisted clinical sites outside the United States.

To investigate the issue, a team led by Matthew Galsky, MD and Serena Tharakan, BS, of the Icahn School of Medicine at Mount Sinai in New York City, analyzed demographic information from 21 cancer clinical trials leading to U.S. Food and Drug Administration approvals between 2015 and 2018.

The team found that clinical trials conducted primarily outside the United States were significantly less likely to enroll Black participants than U.S. clinical trials—on average, global trials enrolled less than half the proportion of Black patients than trials conducted primarily within the country. Of the 21 clinical trials supporting 18 FDA drug approvals where race and location data were available, 64 percent of patients were enrolled outside the United States, with Black patients accounting for only an average of 3.2 percent of enrollment.

“There have been a number of studies investigating factors such as access to healthcare, physician biases, and socioeconomic status that may lead to underrepresentation of Black patients,” said Tharakan. “However, to our knowledge, our findings are the first to quantitatively demonstrate that the globalization of cancer clinical trials may also be a key driver of racial disparities in the U.S. drug approval process.”

The study’s investigators hope that their results may help to inform policies focused on addressing racial disparities in cancer research and care.

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