

Research finds cancer clinical trials have become more diverse over past two decades

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Compared to the year 2000, a greater proportion of NCI-sponsored early-phase clinical trial participants in 2022 were older, from minority racial/ethnic groups, and lived in historically underrepresented regions of the U.S., according to a study presented at the [16th AACR Conference on the Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved](#), held September 29-October 2, 2023.

"Early-phase clinical trials, which primarily evaluate the safety of new therapies, have historically had insufficient representation of racial minorities, women, [elderly patients](#), and people from lower socioeconomic strata, among other groups," said Maria Farooq, MBBS, a clinical fellow at the National Cancer Institute (NCI). "This has limited the generalizability of trial results and increases the chance that important safety issues might be missed, which could further widen disparities in health care outcomes.

"The lack of diversity in early-phase clinical trial accrual also limits underrepresented patients' access to cutting-edge therapies only available in the clinical trial setting," she added.

To assess trends in early-phase clinical trial accrual, Farooq and colleagues compared demographic data of patients enrolled in NCI-sponsored phase I, I/II, and II clinical trials between 2000 and 2022. Data were obtained from the NCI Cancer Therapy Evaluation Program (CTEP)-sponsored early-phase oncology clinical trials database.

The comparison revealed significant changes in the age, race/ethnicity, and geographic location of patients enrolled in NCI-sponsored early-phase clinical trials over the time span. Representative results from two

time frames (2000-2003 and 2020-2022) are presented below.

From 2000-2003 to 2020-2022, the proportion of patients in older age groups increased.

- 75-84 years of age: 5.9% to 12.3%
- 65-74 years of age: 24.2% to 32.9%
- 40-64 years of age: 59.8% to 47.5%

From 2000-2003 to 2020-2022, the proportion of minority patients increased.

- Hispanic/Latino patients: 4.2% to 6.9%
- Asian/Pacific Islander: 2.5% to 5.4%
- Non-Hispanic Black: 6.3% to 7.1%
- Unknown or unspecified race/ethnicity: 3.3% to 7.6%
- Non-Hispanic white: 83.7% to 72.9%

The proportion of patients from the South and West regions of the U.S. increased from 2000-2003 to 2020-2022.

- South: 29.1% to 40.9%
- West: 7.9% to 18.2%
- Northeast: 23.9% to 20.8%
- Midwest: 24.4% to 19.4%

The proportion of patients who enrolled in trials close to home increased from 2000-2003 to 2020-2022.

- Patients enrolling in a trial within 50 miles of home: 46.5% to 64.5%
- Patients who had to travel over 200 miles to access a clinical trial: 16.1% to 8.3%

"Over the period evaluated, NCI-sponsored early-phase cancer clinical trials became more representative of the broader patient population," Farooq concluded. "These results are encouraging, but there is still substantial room for improvement in this area."

While the study did not examine the underlying factors influencing the observed trends, Farooq speculated that the greater number of available early-phase clinical trials, changes to [eligibility criteria](#), and an increase in the number of small sites offering [clinical trials](#) may have contributed to the increased diversity of clinical trial participants in recent years.

"Broadly, we believe that further increasing outreach and accessibility to marginalized communities, as well as strengthening trust between these communities and [research institutions](#), may continue to improve enrollment diversity now and in the future," she added.

Due to the observational nature of the study, researchers were unable to draw any conclusions about the causes of the observed trends. In addition, it is possible that the observed changes were influenced by changes in the cancer types and investigational therapies studied during each period.

The study was supported by the NCI, of which Farooq is an employee.

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