

Disparities in Clinical Trial Participation

To fully ensure the safety and efficacy of anticancer therapeutics for everyone who will use them once approved, it is vital that the participants in the clinical trials represent the diversity of the patient population. Unfortunately, several segments of the population continue to be underrepresented in cancer clinical trials relative to their proportion in the overall U.S. population and/or the relevant disease population. Selected examples of these disparities are listed here:

<p>90% VS <25%</p>	<p>According to data from a biopharmaceutical company, 90 percent of their cancer clinical trials achieved representation of non-Hispanic White participants at or above U.S. census levels while only 24 percent, 16 percent, 8 percent, and 7 percent of trials achieved proportional representation of Asian, Black, Native Hawaiian or Other Pacific Islander, and Hispanic/Latino participants, respectively. None achieved census level representation of American Indian or Alaska Native participants.</p>
<p>HIGHEST incidence and mortality</p>	<p>Analysis of demographic data from 207 pancreatic cancer clinical trials reported between 2005 and 2020 indicated that White patients (85 percent) were overrepresented while Black (8 percent), Hispanic (6 percent), American Indian/Alaska Native (0.3 percent), and Asian or Pacific Islander patients (2 percent) were underrepresented compared to their disease incidence in the U.S. population. Research has shown that restrictive eligibility criteria contribute to low participation of Black patients in pancreatic cancer clinical trials. Notably, Black patients have the highest incidence and mortality from pancreatic cancer among all U.S. racial and ethnic population groups.</p>
<p>>70% VS <3%</p>	<p>Between 2009 and 2019, 81 oral chemotherapeutic agents were approved by the U.S. Food and Drug Administration based on data from 142 clinical trials. Only 52 percent of these trials reported on race/ethnicity. Among the participants, greater than 70 percent were White while only 2.5 percent and 2.3 percent were Black and Hispanic, respectively.</p>
<p>LOW enrollment</p>	<p>An evaluation of 53 cancer immunotherapy clinical trials indicated that enrollment of Black patients was 32-fold lower (for ovarian cancer trials), 19-fold lower (cervical), 15-fold lower (uterine), and 11-fold lower (breast) than expected if accrual rates were equal across all races. Enrollment of Asian patients was 3-fold lower (ovarian), 10-fold lower (cervical), 15-fold lower (uterine), and 2.5-fold lower (breast) than expected.</p>
<p>>65 YO low enrollment</p>	<p>Fifty-seven percent of people diagnosed with cancer in the U.S. are 65 years of age or older. Yet, according to a recent analysis of demographic data from a cancer registry in Wisconsin, patients older than 65 are 43 percent less likely to participate in clinical trials compared to those who are younger than 65.</p>
<p>AYA low enrollment</p>	<p>Cancer is a leading cause of death among adolescent and young adult (AYA) patients. While evidence suggests that AYA patients were better represented and more diverse than older participants in certain National Cancer Institute-sponsored clinical trials conducted over the past two decades, enrollment of Black participants continues to be low.</p>
<p>11% vs 24%</p>	<p>Among patients with blood cancer, those who reside in rural counties are less likely to enroll in clinical trials compared to those in urban counties (11 percent versus 24 percent).</p>

It should be noted that U.S. cancer incidence is from SEER data, which are often used as a comparator in studies evaluating racial and ethnic representation in clinical trials, and are collected from regions that overrepresent certain population groups and thus may not be an accurate estimate of the overall U.S. cancer incidence. Given the vital importance of these analyses in evaluating and ensuring racial and ethnic representativeness of past and ongoing clinical studies, researchers are working to identify better datasets for comparison, such as cancer incidence from the geographical areas from which the trial cohort was recruited or data from the North American Association for Central Cancer Registries (NAACR).