More than half of clinical trials do not report race/ethnicity data

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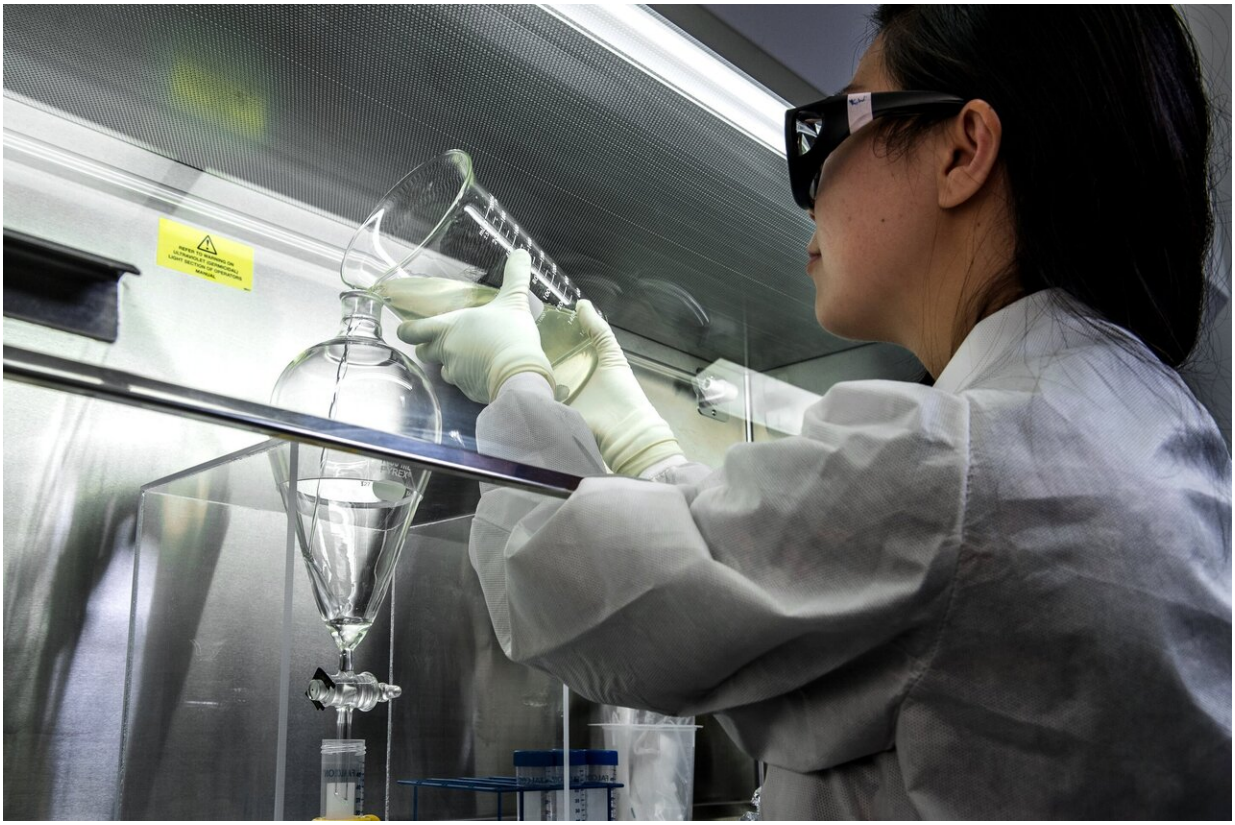

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Clinical trials represent one the largest investments of collective resources in science. These studies, which recruit participants and rigorously evaluate new interventions and therapeutics, aim to advance

scientific knowledge and improve patient treatment. Including diverse and representative patient populations in clinical trials is essential to accurately predict how well therapies will work in the real world. For several decades, the United States has taken steps to try to increase enrollment of minority populations in clinical trials, but it's remained unclear if these initiatives have improved representation. A new study led by investigators from Brigham and Women's Hospital examined two decades worth of data from over 20,000 clinical trials and looked for changes over time. The team found that less than half of trials reported race/ethnicity data. Among those that did, minorities remained underrepresented, but there were improvements among certain groups over time. Results are published in *Lancet Regional Health —The Americas*.

"While we found some improvement in trial diversity, minorities overall remained underrepresented relative to their U.S. populations," said corresponding author Brandon Turner, MD, of the Department of Radiation Oncology. "Our data show that, with investments and initiatives, we can address underrepresentation in clinical trials, but these improvements have been unequal, and we need to think more broadly about why that is and what best practices should look like."

Turner and colleagues analyzed detailed trial records from ClinicalTrials.gov, a database of privately and publicly funded clinical studies, from March 2000 to March 2020. They aggregated data from trials representing over 4.7 million people and compared race/ethnicity data to U.S. Census population demographics.

According to the authors, the new study represents the largest analysis of race/ethnicity enrollment in clinical trials, allowing them to tease apart relationships for specific minority populations and explore possible mediators like trial funding and design. The team found that fewer than 44 percent of trials report any race/ethnicity data, but that this

percentage had improved rapidly over the past few years. Among the 8,871 trials that did report race/ethnicity details, minorities were underrepresented. White enrollment exceeded the U.S. census of white people in the U.S. population (79.7 percent versus 72.4 percent). About 10 percent of trials reported 100 percent white enrollment.

When the team analyzed the five most commonly reported race/ethnicity groups (White, Hispanic/Latino, Black, Asian [including Pacific Islander and Native Hawaiian], and American Indian [including Alaskan Native]), the biggest gaps were seen in Hispanic/Latino and Asian participants. Overall, Black enrollment was not statistically below U.S. population representation, but about 21 percent of trials reported 0 Black enrollees.

Industry-funded studies appeared to have the greatest gaps in enrolling minority participants.

"This is troubling because industry-funded trials often feature drugs and devices with great promise for translation to patients in the clinic," said Turner.

The authors note that while ClinicalTrials.gov represents the largest repository for clinical trial data, it is incomplete—many trials are not registered and many more never report results.

"From the data we do see, reporting and enrollment is poor, but it's improving, and, from a policy perspective, this should be encouraging," said Turner. "It's important to examine these data and learn from the patterns that emerge; we can't improve what we don't measure."

More information: Turner BE et al. "Race/ethnicity reporting and representation in US clinical trials: A cohort study", *The Lancet Regional Health—Americas* (2022). DOI: 10.1016/j.lana.2022.100252

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