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One Way to Improve Racial and Ethnic Diversity in Clinical Trials

A study found that only 43% of clinical trials reported race and ethnicity. The FDA issued guidance to address these inequalities.

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Researchers conduct clinical trials to determine whether new drugs and medical procedures are safe and effective. However, because of biological differences, not all races and ethnicities respond to meds the same way. What's more, certain diseases such as COVID-19, HIV and Type 2 diabetes are more prevalent among minority populations, including African Americans, Latinos and Native Americans. To ensure that the data collected during clinical trials reflect the U.S. population and the people expected to use the drugs and procedures, the trials must include participants of those races and ethnicities.

To help boost diversity in clinical trials, the Food and Drug Administration (FDA) has issued "Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Subgroups in Clinical Trials." The guidance document recommends that the teams behind trials develop and submit to the FDA a Race and Ethnicity Diversity Plan early in clinical development. According to an FDA news release, the guidance also lays out a framework for creating such plans.

The guidance arrives as new study findings published in The Lancet Regional Health—Americas show that only 43% of clinical trials report race and ethnicity. For the study, researchers from Stanford University School of Medicine in California analyzed clinical trial records from March 2000 to March 2020, for a total of 20,6923 trials. When reported, the majority of enrollees in clinical trials were white, followed by Black, Latino, Asian and American Indian.

"Over the past two decades, the majority of U.S. trials in ClinicalTrials.gov do not report race/ethnicity enrollment data," concluded the researchers, adding that "minorities are underrepresented in trials with modest improvement over time."

Regarding the FDA's new guidance, the agency's commissioner, Robert M. Califf, MD, said, "Going forward, achieving greater diversity will be a key focus throughout the FDA to facilitate the development of better treatments and better ways to fight diseases that often disproportionately impact diverse communities. This guidance also further demonstrates how we support the administration's Cancer Moonshot goal of addressing inequities in cancer care, helping to ensure that every community in America has access to cutting-edge cancer diagnostics, therapeutics and

clinical trials."

According to the FDA news release, the drug guidance was developed by the Oncology Center of Excellence's Project Equity, which also seeks to ensure ethnic and racial diversity in research on cancer products.

The White House's Cancer Moonshot initiative aims to cut the cancer death rate in half in the next 25 years and "end cancer as we know it." To learn more, see "Biden Supercharges His 2016 Cancer Moonshot Program."

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