Black patients still underrepresented in trials for new drug approvals

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Black patients are still underrepresented in most trials relating to

approval of new drugs, despite implementation of an action plan in 2015 to improve diversity, according to a report published in the March issue of *Health Affairs*.

Noting that in 2015, the U.S. Food and Drug Administration launched a five-year action plan, which aimed to improve diversity in and transparency of pivotal clinical trials for newly approved drugs, Angela K. Green, M.D., from the Memorial Sloan Kettering Cancer Center in New York City, and colleagues analyzed Snapshots data to examine whether the initiative had led to an improvement in the inclusion of Black patients in clinical trials.

The researchers found that based on data from the FDA Drug Trials Snapshots website, there was no evidence that representation of Black trial participants had improved. In clinical trials for drugs, Black patients remained inadequately represented, with a median of one-third of the enrollment that would be required; this finding was seen regardless of whether the trials were started before, during, or after implementation of the action plan. Data regarding treatment benefits or side effects were reported for Black patients for fewer than 20 percent of drugs, with no improvement in either measure during the action plan period.

"These findings suggest that the FDA should consider a new approach to improving clinical trial representativeness, reaching beyond reporting- and transparency-centered measures to implement representational requirements," the authors write.

More information: Angela K. Green et al, Despite The FDA's Five-Year Plan, Black Patients Remain Inadequately Represented In Clinical Trials For Drugs, *Health Affairs* (2022). DOI: 10.1377/hlthaff.2021.01432

Several authors disclosed financial ties to the biopharmaceutical

industry.