

Clinical trials on new cancer drugs still fall far short of including key data on several demographic groups

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Despite widespread agreement that clinical trials should enroll a representative sampling of individuals from different age, gender, and

racial and ethnic groups, a new Yale School of Medicine study shows that clinical trials on new cancer drugs still fall far short of including key data on several demographic groups. The findings were published in the journal *BMJ Medicine*.

For the study, the Yale team—led by Jennifer Miller, associate professor of medicine and senior author, and Tanvee Varma, a fourth-year [medical student](#) and lead author—developed a series of quality control metrics to assess how well [pharmaceutical companies](#) reported on and included demographic groups in cancer trials, conducted between 2012 and 2017, that led to U.S. Food and Drug Administration approval of new drugs.

Of the 24 companies submitting key trial results, all but one failed to publicly report at least some demographic data on participants, the researchers found. Although all of the companies reported participants' sex, more than 60% failed to report age and almost 80% did not report race and ethnicity data.

Half of the companies also failed to adequately represent women in at least one trial supporting their product approvals. About 75% of companies did not adequately represent older adults and more than 4 out of 5 did not adequately represent patients identifying as Black or Latinx.

"We created a baseline scorecard for companies to spur a race to the top in reporting and including under-represented groups in [clinical trials](#)," Miller said.

The importance of including diverse populations in drug and treatment trials has been known for decades; people can respond differently to [diagnostic tests](#) or treatments depending upon their sex, age, or racial background, which can affect the quality of treatment they receive.

"While a few companies have done well in meeting diversity standards,

most have substantial room for improving their fair inclusion of [older adults](#) and racial and ethnic minoritized patients, and to a lesser extent women, in cancer pivotal trials," Miller said. "We still need to move the needle."

More information: Tanvee Varma et al, Ranking pharmaceutical companies on clinical trial diversity, *BMJ* (2023). [DOI: 10.1136/bmj.p334](#)

Provided by Yale University

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