More than half of FDA trials recruit from lower middle income countries, but country enrollment is rarely reported

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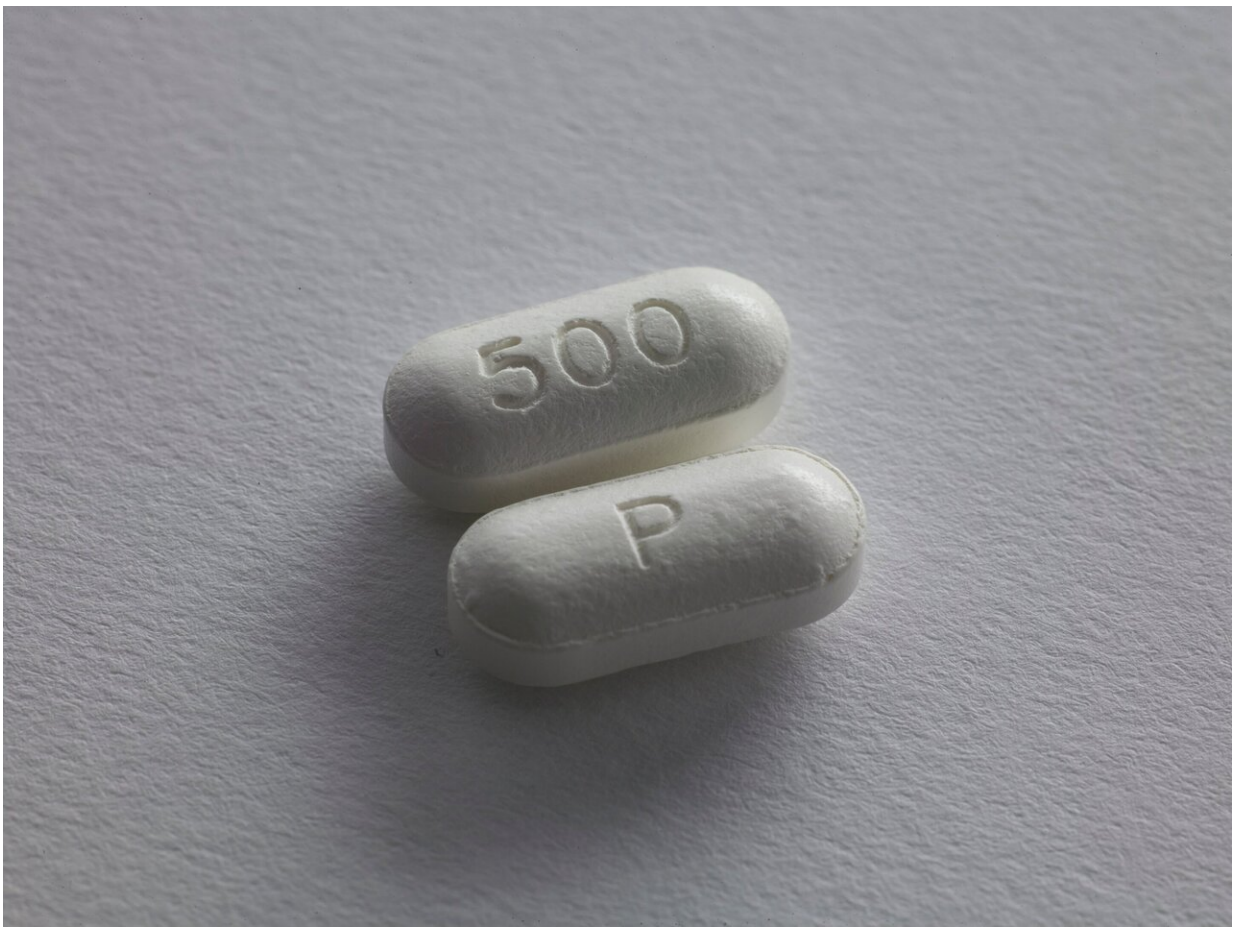

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An analysis of 144 pivotal trials for U.S. Food and Drug Administration (FDA)-approved medications in cancer, cardiovascular disease, and neurology has found that more than half of the studies recruit patients from low- and middle-income countries (LMIC). However, available country data for trials are sparse, contributing to problems with both study verification and participant recruitment ethics. The analysis is published in *Annals of Internal Medicine.*

Drugs sold in North America are often tested abroad, including LMICs. Recruitment from LMICs for trials intended to inform North American health care has scientific and ethical implications. Drug effects can vary because of geographic differences in patient baseline characteristics, diet, and comorbid conditions.

Recruitment in LMICs also raises ethical issues. Trials require extra clinic visits, procedures, and exposure to unproven treatments, including unknown risks. The FDA does not require sponsors to report or publicly disclose which countries participants are recruited from.

Researchers from the Department of Equity, Ethics and Policy, McGill University, conducted a cross-sectional analysis of 66 new drugs and 144 pivotal clinical trials. The authors evaluated 29 approved cardiovascular trials, 26 approved neurologic trials, and 61 approved cancer trials. They found that among all analyzed trials, 56 percent in cancer, 79 percent in cardiovascular disease, and 56 percent in neurology recruited from LMICs.

The authors also report that country-level enrollment figures were not available for 55 percent of multi-country trials. According to the authors, although recruitment is often reported by region or continent, such groupings can obscure important differences among host countries. They emphasize that sporadic availability of country enrollment can frustrate the valid interpretation of pivotal trial findings. It can also limit the

ability to monitor and hold research sponsors accountable for fair participant selection.

They urge journals, regulators, and ClinicalTrials.gov to establish policies that require public reporting of country-level information on recruitment.

More information: Fareed A. Awan et al, Participant Recruitment From Low- and Middle-Income Countries for Pivotal Trials of Drugs Approved by the U.S. Food and Drug Administration, *Annals of Internal Medicine* (2022). DOI: 10.7326/M22-1857