

Do All Countries Benefit From Clinical Trials?

Five years after testing, only 24% of medicines had received market authorization in the countries where trials were conducted.

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A new study led by Yale's [Jennifer Miller, PhD](#), found that medicines are not physically accessible in many of the countries where they are tested for U.S. Food and Drug Administration (FDA) approval.

The findings [were published in JAMA Internal Medicine](#).

For the study, researchers analyzed 172 FDA-approved medicines tested between 2015 and 2018 in nearly 90 countries. They found that five years after testing, only 24% of the medicines had received market authorization, or approval for distribution and patient access, in the countries where the clinical trials were conducted. High-income countries had greater physical access to the medicines than upper-middle- and lower-middle-income countries.

"This gap raises concerns," says Miller, an associate professor of medicine (general medicine) and co-director of the Program for Biomedical Ethics at Yale School of Medicine (YSM). "According to ethical guidance, if you enroll a population in clinical research, they must stand to benefit from it."

The principle Miller references—distributive justice—is embedded in major ethical frameworks such as the World Medical Association Declaration of Helsinki, adopted in 1964, and the Council for International Organizations of Medical Sciences International Guidelines for Health-Related Research Involving Humans, published in 2016.

Yet, according to Miller, these guidelines are vague. "There's enough ambiguity that, if someone wanted to get around it, they could," she says.

Study co-author [Cary Gross, MD](#), professor of medicine (general medicine) at YSM, adds that people enroll in clinical trials for many reasons, including the opportunity to contribute to scientific progress. "But there is also a frequently unstated part of this 'bargain'—that if the new treatment works, then presumably people in your community—or country—will be able to access it," he says.

The study's findings confirm that many countries still host trials without ever gaining timely access

to the medicines they help test. To address this, Miller is expanding the Good Pharma Scorecard, an index she founded that rates and ranks companies on ethical performance—from data transparency to, soon, post-trial access.

“The scorecard sets clear goals for the sector,” she explains. “It defines what a good ethical company looks like, tracks progress, and makes the results public. When companies see their rankings, half of them improve within 30 days. We’re hoping to use that same incentive design to close the access gap.”

Miller’s team is also studying what she refers to as “bright spots”—countries like Ethiopia and Uganda that managed to secure full access to the medicines they helped test. With support from a [Yale and the World](#) grant, she plans to bring health ministers and clinical trial leaders from those countries to campus to share lessons with peer nations.

Ultimately, Miller says, fixing the “test it (but) don’t sell it” problem will require collective effort. “Pharma companies have to change, countries need to be empowered, and the media, NGOs, and patient organizations have to stay engaged,” she says. “We need all hands on deck.”

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