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Researchers Look for Ways to Make Drug Trials More Diverse

Technology platforms let researchers draw on participants of various races, ages and locations

By Brian Gormley

Pharmaceutical researchers are turning to technology to broaden access to experimental treatments, and make clinical trials more equitable in terms of their inclusion of minorities

Minorities are often underrepresented as participants in studies of new drugs—leaving them with less access to new, potentially lifesaving drugs, and making scientists less aware of how medicines affect people of various races differently. One reason is minority groups, because of abuses in the past, sometimes distrust the medical system. Minorities also can lack the resources needed to travel or fulfill other requirements to be able to participate in drug trials.

Now new technology platforms are making it possible for researchers to draw on more diverse pools of participants in terms of race, age and geography. Tools such as wearable devices and telemedicine enable patients to participate in studies from their homes. In addition, researchers are able to mine electronic health records to discover patients who qualify for clinical trials but who might not have been offered the opportunity in the past.

"If there was one easy answer, we would have fixed it by now," says Dr. Ankit Kansagra, assistant professor of Medicine and Eugene P. Frenkel M.D. scholar of clinical medicine at UT Southwestern Medical Center. "A holistic approach is needed. Technology is an extremely important piece."

Racial and other disparities currently exist across various types of clinical trials. A February study of U.S.-based infectious-disease vaccine trials in JAMA Network Open found underrepresentation of minorities, including Black and Hispanic people, and older adults. A paper in the Journal of the American Heart Association last year concluded that women and minorities, especially African-Americans, are underrepresented in clinical trials of novel cardiometabolic drugs. A study published in JAMA Oncology in 2019, meanwhile, said that race wasn't reported in more than one-third of 230 cancer-drug trials studied, and that among trials that did report race, Black and Hispanic representation was low relative to their proportion among U.S. cancer patients compared with whites.

Knowing the race of test participants and encouraging trial diversity can be critically important to experimental drug research. Cancer patients of different races might respond differently to a drug because of genetic differences in their tumors or variations in the way they metabolize their medication, says Dr. Jonathan Loree, a medical oncologist at BC Cancer and assistant professor at the University of British Columbia, who was an author on the JAMA Oncology study.

Trials that under represent racial groups also make it difficult to generalize results to our diverse population and accurately portray a drug's risks and benefits for all patients, says Dr. Kanwal Raghav, associate professor, gastrointestinal medical oncology, at the University of Texas MD Anderson Cancer Center, and a fellow author of the study.

For many, mistrust of clinical trials stems from infamous research that began in the 1930s to study the effects of untreated syphilis in Black men in Tuskegee, Ala. In the study, which lasted 40 years, infected men were left to die from the disease decades after treatment existed.

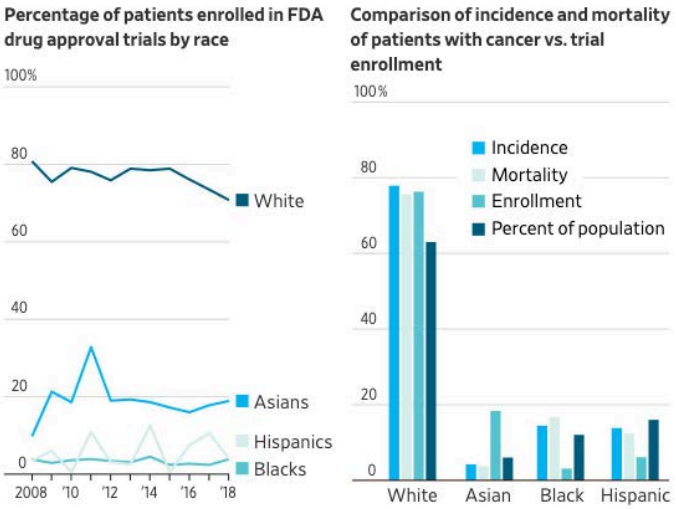
In November, Pharmaceutical Research and Manufacturers of America, an industry group, disclosed new principles on trial diversity that include building trust and making studies more accessible. That same month, the Food and Drug Administration issued recommendations for making drug trials more diverse along several lines, including sex, race, age and ethnicity. Both bodies called for researchers to consider, where appropriate, using technologies such as devices that capture and transmit study data and reduce the need for participants to visit trial sites.

In recent years, drug companies have sought to increase the racial inclusiveness of their clinical studies. The pandemic, and its disproportionate effect on minorities, have added urgency to that effort. When Moderna Inc. was running Covid-19 vaccine trials, it slowed the pace of enrollment to ensure the study was representative of the multiracial U.S. population, according to a spokeswoman.

Biotechnology company Genentech joined with doctors from hospitals with diverse patient populations to design a Phase 3 trial of the drug Actemra in people hospitalized with Covid-19 pneumonia. The company sought to conduct the research in medical centers that weren't often included as clinical-trial sites, including community hospitals serving diverse communities

Trial Populations

Race reporting and race-related subgroup analyses in trials for FDA approval of hematology/oncology drugs



Source: JAMA Oncology (trials, incidence, mortality and enrollment); CDC (population)

where Covid-19 was prevalent, according to a spokeswoman. U.S. trial sites included hospitals in New York, Detroit, Miami and Oakland, Calif., and about 84% of the study's 389 patients were from minority racial and ethnic groups.

"It goes to show we can reach more patient populations if we're mindful and proactive about it," says Dr. Nicole Richie, global head of health equity and population science for Genentech, a member of Roche Group.

Drug companies are using a mix of outreach and technology as they widen their search for study participants. For Belgian drugmaker UCB SA, that means meeting patients in the communities where they live and joining with companies, such as Los Angeles-based Science 37 Inc., that bring clinical trials into patients' homes, says Kim Doggett, UCB's head of site engagement.

Science 37 uses telemedicine, nurses who visit patients in person, and a technology platform it developed to help UCB and others run "decentralized" trials in patients' homes. Trial participants initially have a telemedicine visit with a physician and sign an e-consent form that Science 37's system records. Depending on the trial, participants may also receive a wearable device that records and transmits data. Science 37's platform enables coordination among patients, investigators and others involved in the trial, according to Chief Product Officer Chris Ceppi.

"We're going to try to bridge the gap between the community and the science," Ms. Doggett says.

Industrywide, some 10% to 15% of clinical trials are decentralized, says Maria Fotiu, executive vice president of decentralized solutions for Syneos Health Inc., a Morrisville, N.C.-based provider of clinical research and commercial services to drugmakers. "But we see an upward trajectory" in that figure, she says, largely because of efforts to make trials more diverse.

Fear prevents some patients from participating in experimental treatments that are part of some clinical trials. Medable Inc., a Palo Alto, Calif.-based startup that helps enable decentralized trials, works with primary-care doctors to educate prospective test participants about the research involved and how the studies work, says co-founder and CEO Michelle Longmire. Because of the relationships people have with their primary-care doctors, this approach helps establish trust, says Dr. Longmire, adding, "It's one strategy we have found resonates with patients."

Elligo Health Research Inc., of Austin, Texas, provides technology and personnel to enable physician practices in smaller cities and rural areas to serve as clinical-trial sites, another approach that lets patients participate in studies under their own doctors' supervision. A partnership formed in December with electronic health records provider Cerner Corp. will extend Elligo's reach to additional rural and midsize health systems, which often have more-diverse populations than the larger, urban medical centers that typically run trials, Elligo CEO Dr. John Potthoff says.

Mining large datasets is also helping expand trials to new areas and participants. TriNetX LLC, a health-research technology company, aggregates electronic-medical-record information from a network of 170 healthcare organizations spanning 30 countries. Drugmakers use it to identify sites with patients who meet specific trial criteria. In some cases companies can loosen the criteria without compromising the study, which may enable them to expand the eligible patient population to allow studies to enroll more diverse subjects, says Jennifer Stacey, senior vice president of clinical sciences and operations for the Cambridge, Mass.-based company.

Another approach proposed by a healthcare-data-mining company represents a big twist on a common testing model traditionally used in trial design—a twist that could make it easier for trials to meet diversity goals by requiring fewer participants. Typically, companies testing a new drug must recruit large numbers of patients to fill two different sets—one group that gets the drug, and one that doesn't, the so-called control group. Boston-based COTA Inc. proposes that some cancer trials enroll only one group: patients who get the new drug. The control group would consist of patients, discovered in electronic health records, who are already receiving only standard, existing treatments.

COTA has agreements with medical centers and physician practices that give it access to electronic-health-record systems where it can find such patients, using software technology. Humans extract the relevant data, which COTA forwards—minus the patients' identities—to the drug companies, says CEO Michael Doyle, who adds that some drugmakers are experimenting with this approach already.

Mining medical data and other technological advances will help trials recruit more patients in currently underserved communities, says Christopher Boone, vice president and global head, health economics and outcomes research for pharmaceutical company AbbVie Inc.

But the industry also must build trust, he says, through measures such as increasing the number of minority clinical-trial investigators and making study designs clearer to the lay public.

"Trust is rooted in transparency," Dr. Boone says.