News and Perspectives

Keeping Clinical Trials on an Inclusive Track

Virginia Gewin, JMIR Correspondent

Key Takeaways

- Experts advocate a "participation-to-prevalence" ratio—the representation of a specific population relative to their representation in a disease population—of 0.8 to 1.2 to ensure adequate representation in clinical trials.
- Digital tools can help reach target trial participants, but they also pose privacy and ethical challenges.
- Working with patient advocacy groups from the outset can help shape research priorities, improve clinical trial design, and increase health impact.

In March 2025, Dinushika Mohottige, MD, MPH, a clinician at the Icahn School of Medicine at Mount Sinai in New York City, was notified that her US National Institutes of Health grant to study kidney disease in Black individuals [1] was terminated and $194,000 in funding was rescinded. The grant, she was told via email, was "no longer consistent with current policy priorities," as outlined in the "Ending radical and wasteful government DEI [diversity, equity, and inclusion] programs and preferencing" White House Executive Order issued on January 20, 2025 [2].

The grant aimed to study why Black individuals consistently have 2-4 times higher rates of end-stage kidney disease compared to White counterparts—and, importantly, to craft patient-centered clinical interventions to mitigate adverse health outcomes. "Genetic risk is not racial. However, we know that the prevalence of this particular high-risk allele...disproportionately burdens people who self-identify as having African ancestry," explains Mohottige.

While Mohottige's clinical trial funding was restored 5 months later, following a successful lawsuit, the delay postponed patient recruitment for the trial by roughly 10 months. Over that time, at least 5 potential participants became seriously ill, were hospitalized, or passed away.

Mohottige was hardly alone. In 2025, 383 clinical trials were disrupted. Funding terminations impacted roughly 1 in 30 clinical trials—totaling more than 74,000 clinical participants, according to a January 2026 study [3]. Trials that focused on infectious diseases, prevention, and behavioral interventions were disproportionately impacted.

The trial disruptions, many fear, threaten efforts to improve the lack of diversity in clinical trials. As it stands, fewer than 20% of drug trials conducted between 2014 and 2021 had data relevant to Black patients' benefits or side effects, according to a 2022 study [4].

Clinical trials can be funded by the pharmaceutical industry or the federal government. The goal, especially for pharmaceutical companies, is to get a clinical trial done as quickly as possible, says Sonia Anand, MD, PhD, FRCPC, director of the Chanchlani Research Center at McMaster University in Hamilton, Ontario, which is focused on health equity research. "As a result, many work with the same investigators at the same clinical sites with a proven track record. And by doing that, they have a relatively homogenous patient population," says Anand.

The bottom line is that it costs more money up front to make the effort to reach a diverse population. "We have to get over the short-term costs, and think of the long-term impacts," says Anand. In the wake of the Trump administration's targeted funding cuts, clinicians say efforts to achieve diverse, inclusive patient recruitment into US clinical trials has been dealt a blow, but two approaches are increasingly being adopted: digital tools and patient advocacy groups.

Structural Barriers

Underrepresentation in clinical trials spans many factors including race, age, language barriers, disability, socioeconomic status, geography, culture, and health literacy, describes Roxana Mehran, MD, a cardiology specialist at the Icahn School of Medicine at Mount Sinai. "The problem is not a lack of willingness to participate, but rather structural barriers that limit access to trials," says Mehran.

Underrepresentation of people from minority ethnic groups, for example, can lead to trial results that fail to characterize the efficacy and safety profile of the drug or intervention being tested, according to a study by Anand and colleagues [5]. Lack of representation comes with a hefty cost. Limited access to effective medical interventions or skewed trial results could cost hundreds of billions of dollars in reduced life expectancy and disabilities over the next 25 years.

Equitable clinical trials must "match the demographics of the disease burden under study. However, we remain far from achieving this goal," according to a 2022 National Academies report [6]. Anand and others advocate for a "participation-to-prevalence" ratio—the representation of a specific population relative to their representation in a disease population—of 0.8 to 1.2.

In December 2025, the US Food and Drug Administration released long-awaited guidance to enhance participation in clinical trials [7]. The document emphasized the use of digital

tools to lessen the burden on participants and increased public outreach, including through patient advocacy groups.

Digital Tools

Digital tools to enhance diverse recruitment of trial participants include electronic health records (EHRs), social media, research registries, and mobile apps using culturally tailored messaging to improve visibility and engagement [8]. Social media is also used to target recruitment advertising, while phone apps can make it easier to manage clinical trial consent and appointments.

"Social media and digital outreach are mainstream," says Rebecca Johnson, PhD, a clinical research trial recruitment strategist. "Recruitment providers feed lifestyle, behavior, consumer data, and other variables into models to precisely reach the right patients," she says. "What's often missing is the connectivity at the provider level."

Machine learning and artificial intelligence are increasingly being used to mine EHRs to search for the demographic and pre-existing health conditions of ideal participants [9]. It can also help identify individuals that are most likely to respond to treatment.

However, digital tools come with their own challenges including privacy concerns, digital literacy gaps, and ethical considerations.

"While we think AI digital apps will close the health equity gap, it actually has a great potential to widen it," says Anand. For example, some equity-deserving groups don't have access to cell phones. According to Anand, however, a greater concern is that surveys on the use of digital tools in clinical trial recruitment have revealed a lack of trust among women and non-White individuals. "They are worried about how the data might be used, so there's a lower uptake of these tools," says Anand.

Patient Advocacy Groups

Another strategy is to work with patient advocacy groups to build trust among communities that could benefit most from health interventions—and to identify potential trial participants. For example, Mohottige painstakingly assembled a patient board to guide her research effort, reflecting a growing trend to seek out community partnerships to inform research so that it has the best chance to make a positive real-world impact.

Patient engagement is essential, says Mehran. "Patients should be included in advisory roles or even as co-investigators, and trial materials need to be culturally appropriate and available in multiple languages," she says. Other efforts to reduce logistical barriers, such as offering flexible scheduling and transportation support and simplifying participation requirements, can also significantly improve enrollment. "Trials should go beyond large academic centers and include community-based and diverse settings to better reflect real-world populations," says Mehran.

"Working with patient advocacy groups raises credibility," says Johnson. It can also shape research priorities and improve trial design. That said, it doesn't consistently lead to higher enrollment, so it's important to set expectations up front and be clear on shared goals.

"I think patient advocates need to come in from the very beginning of the clinical trial design and be involved in conversations from step one," says Robert Sanchez, a patient advocate with kidney disease who works with Mohottige. "Numbers need to have a soul," he says.

Keywords: clinical trials; patient recruitment; health equity; health care disparities; ethics; patient advocacy; funding, government; digital health

Conflicts of Interest

None declared.

References

1. Structural racism as a "third hit" on kidney outcomes of Black individuals with APOL1 risk alleles. National Institutes of Health, RePORT. URL: https://reporter.nih.gov/project-details/10866289 [Accessed 2026-04-15]
2. Ending radical and wasteful government DEI programs and preferencing. The White House. 2025. URL: https://www.whitehouse.gov/presidential-actions/2025/01/ending-radical-and-wasteful-government-dei-programs-and-preferencing/ [Accessed 2026-04-27]
3. Patel VR, Liu M, Jena AB. Clinical trials affected by research grant terminations at the National Institutes of Health. JAMA Intern Med. Jan 1, 2026;186(1):126-128. [doi: 10.1001/jamainternmed.2025.6088] [Medline: 41247710]
4. Green AK, Trivedi N, Hsu JJ, Yu NL, Bach PB, Chimonas S. Despite the FDA's five-year plan, Black patients remain inadequately represented in clinical trials for drugs: study examines FDA's five-year action plan aimed at improving diversity in and transparency of pivotal clinical trials for newly-approved drugs. Health Aff. 2022;41(3):368-374. [doi: 10.1377/hlthaff.2021.01432] [Medline: 35254926]
5. Anand SS, Bosch J, Mehran R, Mehta SR, Patel MR. Designing inclusive clinical trials: how researchers can drive change to improve diversity. BMJ. Mar 11, 2025;388:e082485. [doi: 10.1136/bmj-2024-082485] [Medline: 40068858]

6. National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research. Bibbins-Domingo K, Helman A, editors. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. National Academies Press (US); 2022. [doi: 10.17226/26479] [Medline: 36137057]
7. Enhancing participation in clinical trials—eligibility criteria, enrollment practices, and trial designs: guidance for industry revision 1. US Department of Health and Human Services; Food and Drug Administration; Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER). 2025. URL: https://www.fda.gov/media/190162/download [Accessed 2026-04-29]
8. Tomiwa T, Wong E, Miller HN, et al. Leveraging digital tools to enhance diversity and inclusion in clinical trial recruitment. Front Public Health. 2024;12:1483367. [doi: 10.3389/fpubh.2024.1483367] [Medline: 39529717]
9. Kasahara A, Mitchell J, Yang J, Cuomo RE, McMann TJ, Mackey TK. Digital technologies used in clinical trial recruitment and enrollment including application to trial diversity and inclusion: a systematic review. Digit Health. 2024;10:20552076241242390. [doi: 10.1177/20552076241242390] [Medline: 38559578]

Please cite as:
Gewin V
Keeping Clinical Trials on an Inclusive Track
J Med Internet Res 2026;28:e99011
URL: https://www.jmir.org/2026/1/e99011
doi: 10.2196/99011