

Advancing Representation in U.S. Clinical Trials: An Analysis of Intent to Participate, Participation Dynamics, Barriers, and Motivations

If awareness, trust, and logistics all shape trial participation, which change would have the biggest impact right now: better provider outreach, stronger community engagement, or removing travel and cost barriers?

This dissertation by Maureen E. Shetty explores who takes part in U.S. breast and skin cancer clinical trials and why participation varies. The first study uses ClinicalTrials.gov data from 2017 to early 2024 to compare enrolled participants with national cancer incidence rates. Men are greatly underrepresented in breast cancer trials, with only 34 participants compared to an expected 73. Skin cancer trials tend to enroll more men, but both breast and skin cancer trials show very low participation from Black, Asian, Hispanic, and American Indian/Alaska Native groups. These disparities suggest trial results may not fully represent the broader patient population.

The second study surveys 306 adults to understand the factors that shape willingness to join a trial. People are more likely to participate if they already know about trials, trust their healthcare provider, or believe they could access better treatment. Common barriers include fears about safety, the burden of travel and time, and the potential costs involved. A modest but clear link is found between feeling connected to a provider and being willing to join.

The findings point toward practical steps to improve representation. Clearer and more inclusive outreach, materials that reflect diverse communities, transportation and financial help for participants, and stronger provider engagement can all make a difference. By addressing these issues, trials could better reflect the populations they aim to serve and make participation more accessible to all.

MAJOR TAKEAWAYS:

- Breast cancer trials enroll far fewer men than expected based on disease incidence rates.
- Minority groups participate in breast and skin cancer trials at much lower rates than expected.
- Awareness, trust, and patient-provider connection significantly improve willingness to participate in clinical trials.

WHO NEEDS TO KNOW:

- Healthcare Providers
- Academics
- Policymakers

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