

Research shows structural barriers are the biggest reason for low participation in clinical trials

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A research team led by the Fred Hutchinson Cancer Research Center have determined the most significant barriers to clinical trial participation. The study published today in *Journal of the National Cancer Institute* (JNCI) upends the notion that patient factors are the driving forces behind why most clinical trials don't meet their enrollment targets.

The team from Fred Hutch, Columbia University Irving Medical Center, and the American Cancer Society Cancer Action Network (ACS CAN), combed through 13 studies spanning 15 years that involved over 8,800 patients. They found that 56 percent of patients didn't have a trial available to them at their institution and nearly 22 percent were deemed ineligible for an available trial. Combined, the authors concluded structural and clinical factors are the main reasons why most [cancer](#) patients don't participate in trials.

"These findings illustrate the need to reexamine the way we think about patient participation in [clinical trials](#)," said Dr. Joseph Unger, a health services researcher and biostatistician who led the study. "Most of the time it's not up to the patient. Instead, structural and clinical barriers are the reasons more than 3 out of 4 patients do not participate in trials."

Research about barriers to clinical trials often focuses on patient barriers, Unger noted, but when patients are offered the opportunity to

participate in a trial, they do so about half the time.

The overall trial participation rate for the studies analyzed by Unger and team was 8 percent, notably higher than the typically cited rates of 2 to 3 percent. Unger indicated that this is because about twice as many patients participate in pharmaceutical company sponsored trials than government sponsored trials, a factor which is often overlooked.

Even with the boost in pharma trials, the rate is still very low, which is a major problem for researchers. "Slow accrual to trials has many negative consequences," Unger said. "Many trials often fail to complete accrual, and those that do, may take such a long time to reach their goal, the research question may no longer be as relevant."

A number of key policy changes could help address the issue. "We believe expanding trial locations, updating eligibility criteria and encouraging physicians to proactively discuss clinical trial options with their patients will help give more [cancer patients](#) the opportunity to say 'yes' to clinical trial participation," said Dr. Mark Fleury, a policy principal and emerging science researcher at ACS CAN, who co-authored the study. Several organizations are already taking steps towards addressing the lack of access to trials. The NCI for example is expanding the NCI Community Oncology Program (NCORP) that serves smaller communities, and creating more permissive default [eligibility criteria](#).

"Ultimately, the goal is to provide patients with greater access to trials, more choices for treatment and complete [trials](#) faster," Unger said.

Provided by Fred Hutchinson Cancer Research Center

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