

# **Barriers** *to* *Patient Enrollment in Therapeutic Clinical Trials for Cancer*

## **Executive Summary**



# Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer - A Landscape Report

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# Executive Summary

The objective of cancer research is to generate new knowledge that can be used to improve survival and quality of life for patients with cancer. Clinical trials are the key step in advancing potential new cancer treatments from the research setting to the cancer care clinic, and patient participation in trials is crucial to this success. Most patients express a willingness to participate in clinical research, yet only a small fraction ultimately end up enrolling in a cancer clinical trial due to barriers that make participation difficult or even impossible. Consequently, approximately 20% of cancer clinical trials fail due to insufficient patient enrollment. Understanding and addressing these barriers is critical to accelerating progress in cancer research.

Enrollment in a cancer clinical trial involves a multi-step process and while participation is typically thought of in terms of a patient decision, it is notable that the patient is not presented with the option until the last step, which is only reached if previous barriers have not been encountered. Analyzing studies across a variety of settings suggests that:

- 56% of patients will not have a local trial available for their cancer
- 17% will be ineligible for a trial due to exclusion criteria
- Many eligible patients will not be asked by their provider to enroll
- Only 27% of cancer patients will have the option to enroll in a local clinical trial

Typically, greater than 50% of eligible patients asked to enroll will agree to do so, and those who decline to take part in a clinical trial cite fear of side effects, loss of control,

costs, and logistics involved with participating in trials as their primary reasons.

Healthcare providers and institutions have a significant impact on cancer clinical trial enrollment as a result of decisions regarding which and how many trials to open at a site, the quantity and type of research personnel employed, and whether and how they identify and enroll patients in trials. These decisions are heavily dependent upon adequate funding, often supplied from the National Cancer Institute or the pharmaceutical industry, to support necessary research personnel and infrastructure. Typically, high-performing sites manage their trial portfolios to match the patient population they serve, systematically pre-screen their patients for trial eligibility, and collaborate across networks.

As science propels cancer treatments forward, clinical trials are increasingly designed around very small genetically defined subsets of cancers, making finding eligible patients even more difficult. At the same time, eligibility criteria like age, HIV status and the presence of previous cancers are being reexamined to ensure that restrictions are not unnecessarily preventing willing patients from enrolling on trials. Involving patients in the design of clinical trials has also been found to improve their appeal to patients and accrual success.

This report is meant to serve as a resource to inform discussions and actions aimed at addressing the barriers preventing patient participation in clinical trials. Stakeholders ranging from cancer researchers, cancer patients, industry, as well as members of our society, will all play critical roles if these barriers are to be successfully overcome.



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This report is available at <https://www.acscan.org/policy-resources/clinical-trial-barriers>

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