ACS CAN Supports the Clinical Trial Modernization Act (H.R. 3521)

Clinical trials are key to advancing new standards of care that can improve survival and quality of life for people with cancer. To be successful, trials must enroll an adequate number of participants. However, patient enrollment in cancer clinical trials is an ongoing challenge, and **some population groups are underrepresented, including certain racial and ethnic groups, older adults, rural residents and those with limited incomes.**

Trial participation costs are often barriers to enrollment.[1,2] For a patient, clinical trial costs involve both direct medical and non-medical costs. Most insurers are required to cover the direct medical or "routine costs" of treatment ordinarily administered absent a clinical trial (e.g., standard of care diagnostic testing), but patients often still have cost-sharing requirements associated with their coverage (e.g., deductible, copay, coinsurance).

Clinical trial sponsors cover the expenses for procedures or medications that are necessary only for the research study.

Non-medical costs associated with clinical trial participation can add to patient out-of-pocket costs, which can deter trial enrollment and decrease trial retention.

Non-medical costs can include transportation, lodging, and meals associated with trial enrollment. These non-medical costs can occur when no local trials are available and patients must travel to distant trial sites, or when there is a need for more frequent clinic visits for additional trial-related treatment or monitoring. The additional costs can lead to disparate participation rates between high- and low-income cancer patients and between patients in different geographies.

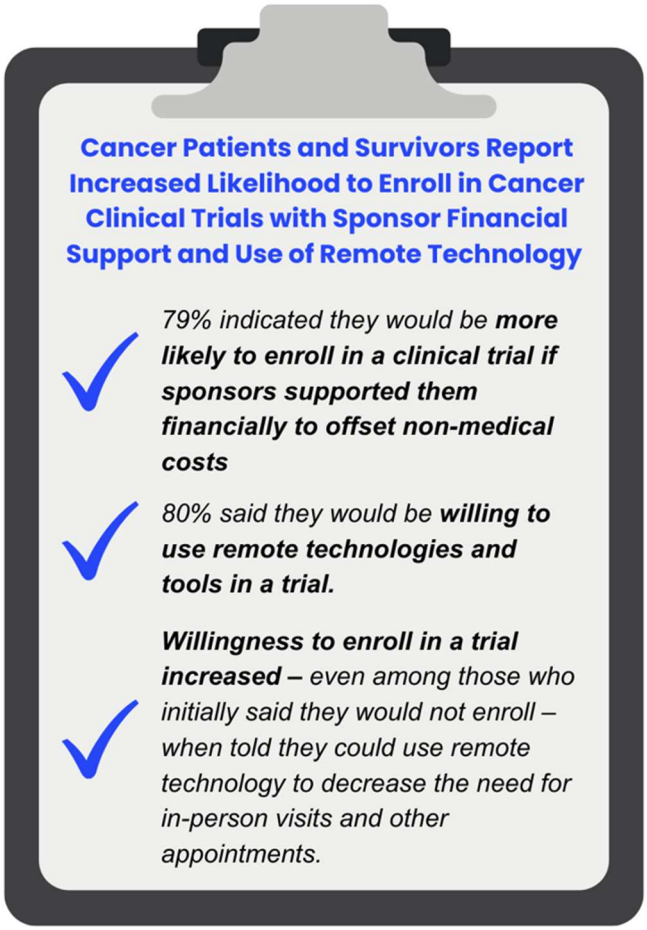
Offering to reimburse patients for non-medical costs associated with trials can increase overall enrollment and may also increase participation from underrepresented groups.[3]

Some trial sponsors provide financial support for non-medical costs. Those that do not often cite concerns about running afoul of federal anti-fraud restrictions on providing patients with what could be viewed as a "bribe."

Patients receiving care at community cancer centers – where most cancer care is provided – are less likely to have access to locally available clinical trials because trials require additional specialized personnel, training and resources that are more common at academic medical sites oriented toward clinical research.[4]

The bipartisan Clinical Trial Modernization Act (H.R. 3521) would make it easier for all people with cancer to participate in clinical trials, including those who are currently underrepresented, through:

- **Removing economic barriers** to increase clinical trial participation from all demographic, socioeconomic and geographic populations by allowing sponsors to financially support trial participants for both medical and non-medical costs associated with trial participation.
- **Facilitating remote participation in clinical trials** by allowing trial sponsors to provide patients with digital health technology necessary for participation at no cost to the patient.
- **Encouraging clinical trial enrollment by underrepresented groups** by allowing the Department of Health and Human Services (HHS) to issue grants to support community education, outreach and recruitment for trials.
- **Ensuring that the first $2,000 in non-reimbursable financial support from clinical trial sponsors provided to patients is not subject to taxation** or counted against income limitations for safety net programs. This matches the new 1099 payment reporting requirements effective beginning in 2026 as well as an existing $2,000 exemption for patients in rare-disease trials.



ACS CAN Position

ACS CAN supports the Clinical Trial Modernization Act (H.R. 3521) to ensure more patients – regardless of their economic means or their geographic location – have a chance to enroll in clinical trials.

[1] American Cancer Society Cancer Action Network. Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer, (2016). Available at www.fightcancer.org/clinicaltrialbarriers

[2] Unger, J. M., Gralow, J. R., Albain, K. S., Ramsey, S. D., & Hershman, D. L. (2016). Patient Income Level and Cancer Clinical Trial Participation: A Prospective Survey Study. JAMA oncology, 2(1), 137–139. https://doi.org/10.1001/jamaoncol.2015.3924

[3] Nipp, R. D., Lee, H., Powell, E., Birrer, N. E., Poles, E., Finkelstein, D., Winkfield, K., Percac-Lima, S., Chabner, B., & Moy, B. (2016). Financial Burden of Cancer Clinical Trial Participation and the Impact of a Cancer Care Equity Program. The oncologist, 21(4), 467–474. https://doi.org/10.1634/theoncologist.2015-0481

[4] Unger JM, Vaidya R, Hershman DL, et al: Systematic review and meta-analysis of the magnitude of structural, clinical, and physician and patient barriers to cancer clinical trial participation. J Natl Cancer Inst 111:245-255, 2019