

# ACS CAN Supports the Diversifying Investigations Via Equitable Research Studies for Everyone (DIVERSE) Trials Act H.R. 5030/S. 2706



## Overview

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 groups are underrepresented**, including certain racial and ethnic groups, older adults, rural residents, and those with limited incomes.

**Cost to trial participants is often a barrier to their enrollment.**<sup>1,2</sup> For a patient, clinical trial costs involve both direct medical and ancillary (i.e., non-medical) costs. Most insurers are required to cover the direct medical or “routine costs” of treatment ordinarily administered absent a clinical trial, while trial sponsors cover the expenses for procedures or medications that are necessary only for the research study.

Patients are frequently responsible for non-medical costs such as transportation and lodging associated with trial enrollment. These ancillary costs can occur when no local trials are available and patients have to 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. **Offering to reimburse patients for ancillary costs associated with trials can increase overall enrollment and may also increase participation from underrepresented groups.**<sup>3</sup> Some trial sponsors provide financial support for ancillary costs. Those that do not often cite concerns about running afoul of federal research participant protections that could subject them to civil monetary penalties. This is despite clear guidance from the U.S. Food and Drug Administration and Institutional Review Boards that such support is acceptable.

**The bipartisan DIVERSE Trials Act (H.R. 5030/S. 2706) could increase diversity in clinical trials and make it easier for all people with cancer to participate in clinical trials by reducing their barriers to enrollment.**

## The DIVERSE Trials Act (H.R. 5030/S. 2706):

- Creates a statutory safe harbor so that patients may get financial support for the ancillary costs associated with their clinical trial participation,
- Allows trial sponsors to provide patients with technology necessary to facilitate remote participation in clinical trials, and
- Requires the Department of Health and Human Services to issue guidance on how to conduct decentralized clinical trials to improve demographic diversity.

## ACS CAN Position

ACS CAN supports the DIVERSE Trials Act (H.R. 5030/S. 2706) to ensure more patients—regardless of their economic means or their geographic location—have a chance to enroll in clinical trials.

**\$** Patients cite costs as one of the top reasons for declining clinical trial participation.<sup>1</sup>

Patients making less than \$50,000 per year are nearly 30% less likely to enroll in cancer clinical trials.<sup>2</sup>

**X** 1 out of 5 cancer clinical trials will fail due to inadequate enrollment.<sup>1</sup>

Ancillary costs associated with clinical trial participation can add to patient out-of-pocket costs and deter enrollment.

- Transportation
- Childcare
- Lodging
- Meals

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

<sup>2</sup> 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>

<sup>3</sup> 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>