# Clinical Trial Site Awareness and Experience with Participant Financial Support Programs

*Findings of an Association of American Cancer Institutes (AACI) and Equitable Access to Clinical Trials (EACT) Study*

LUNGEVITY
Transforming Lung Cancer

EQUITABLE ACCESS TO CLINICAL TRIALS

AACI
Association of American Cancer Institutes

## Background

Patients often cite cost as a top reason for declining to participate in a clinical trial. While trial sponsors largely cover medical costs associated with participation in the trial, many non-medical, out-of-pocket costs can be incurred by trial participants, including travel, lodging, meals, childcare, and other time-related expenses. The Equitable Access to Clinical Trials (EACT) initiative is comprised of patient and professional groups, IRBs, clinical trial sites, drug developers, contract research organizations (CROs) to make financial neutrality and financial support for trial participants the norm in all oncology clinical trials. To this end, EACT has developed best practice considerations and recommended approaches for trial sponsors when designing financial support programs for trial participants.

While these resources have supported awareness and increased communication regarding financial support programs, there continues to be varied implementation and acceptance of these programs across trial sites. To assess the current knowledge base and experience with financial support programs across trial sites, EACT partnered with the Association of American Cancer Institutes (AACI) to develop and perform a survey of cancer centers on their current practices, barriers, and needed resources for realizing financial support for trial participants. Learnings from these findings can support the need for continued education and awareness across trial sites, as well as the further development of site-specific resources to support trial site personnel in ensuring that trial participants can access financial support.

## Objectives

- Describe sites' knowledge and experience with accessing and providing financial support programs for clinical trial participants
- Understand familiarity of sites with EACT and its resources
- Gain insights into additional resources that would be valuable for sites to encourage financial support for trial participants

## Approach

AACI conducted their Clinical Trials Office (CTO) Benchmarking Survey for 2024, surveying AACI cancer center directors and CTO leadership, with instructions requesting a single submission per center to ensure comprehensive and representative data collection. The survey was sent between October and December of 2024 via email to AACI member institutions that are actively running interventional treatment clinical trials. Survey participation was voluntary and at the discretion of the invitee. Participants completing the survey were asked if they were interested in continuing to an optional survey "regarding

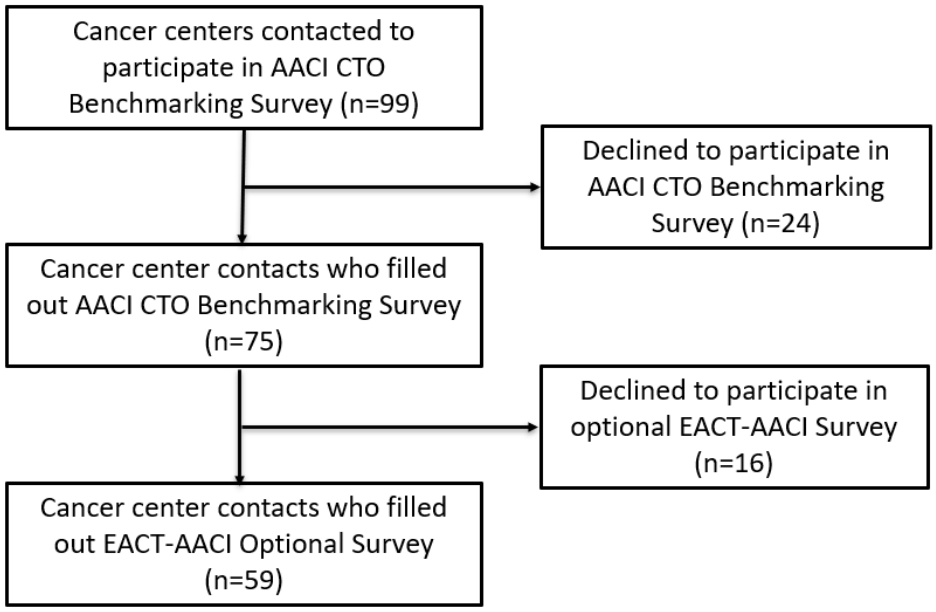
participant support programs for clinical trials", which included pertinent questions relevant to EACT's objectives. AACI reviewed the survey findings and presented aggregated, de-identified data from the optional survey to EACT.

## Survey Respondents

Seventy-five cancer centers participated in the 2024 AACI CTO benchmarking survey (**Figure 1**), of which the majority of respondents (93.75%) were from academic medical centers and 6.25% were from freestanding cancer centers. The majority of respondents were from NCI-designated comprehensive cancer centers (62.5%), with the remaining respondents being from an emerging cancer center that is not currently (at the time of survey) NCI-designated (28.75%) or NCI-designated center that is not comprehensive (8.75%).

The majority of respondents elected to participate in the optional survey (n= 59, 77.6%) focused on EACT-specific questions. Of those electing to participate, 55 respondents (93%) were from academic medical centers and 7% were from freestanding cancer centers. Thirty-seven respondents (62.7%) were from NCI-designated comprehensive cancer centers, 17 (28.8%) from an emerging cancer center that is not currently (at the time of survey) NCI-designated, and 5 (8.4%) from an NCI-designated center that is not comprehensive.

**Figure 1: Consort diagram of the approach for survey respondent inclusion in the analysis**



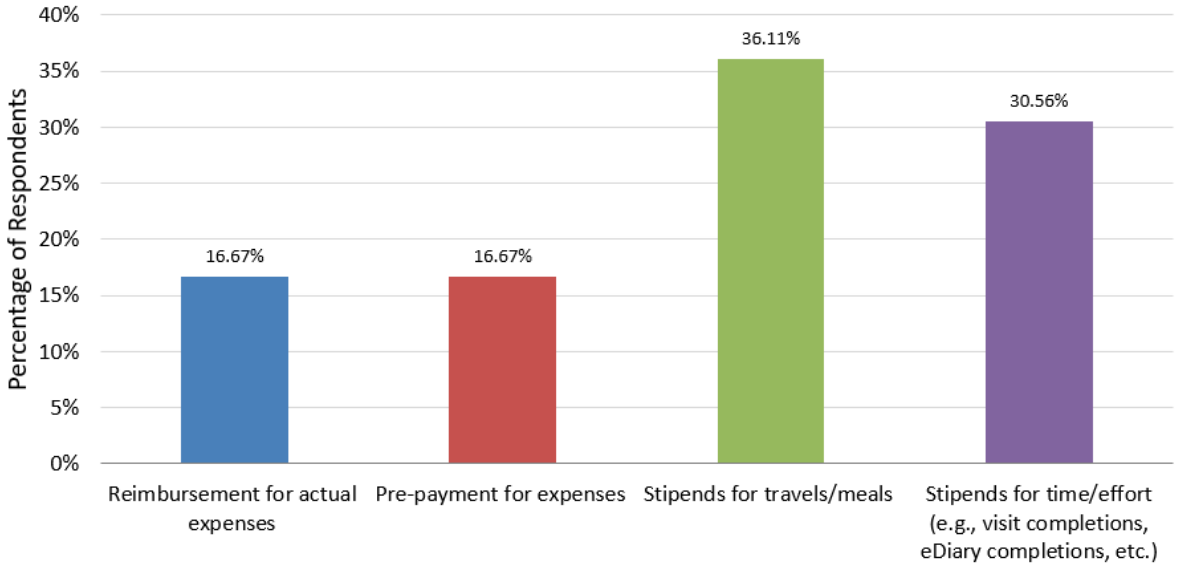

## Survey Results

Survey participants were asked if they collect data regarding how often trial participants seek financial assistance for trial-related expenses, with only 8.8% saying they knew the data

were collected, 70.1% saying it was not collected, and 17.5% responding they didn't know. Additionally, data were largely not collected (75% not collected, 3.6% NA, 8.9% I do not know) for how often clinical trial participants chose not to participate in clinical trials due to financial burden, highlighting the continued need for data to better understand how prevalent concerns around financial support are and its impact on trial participation.

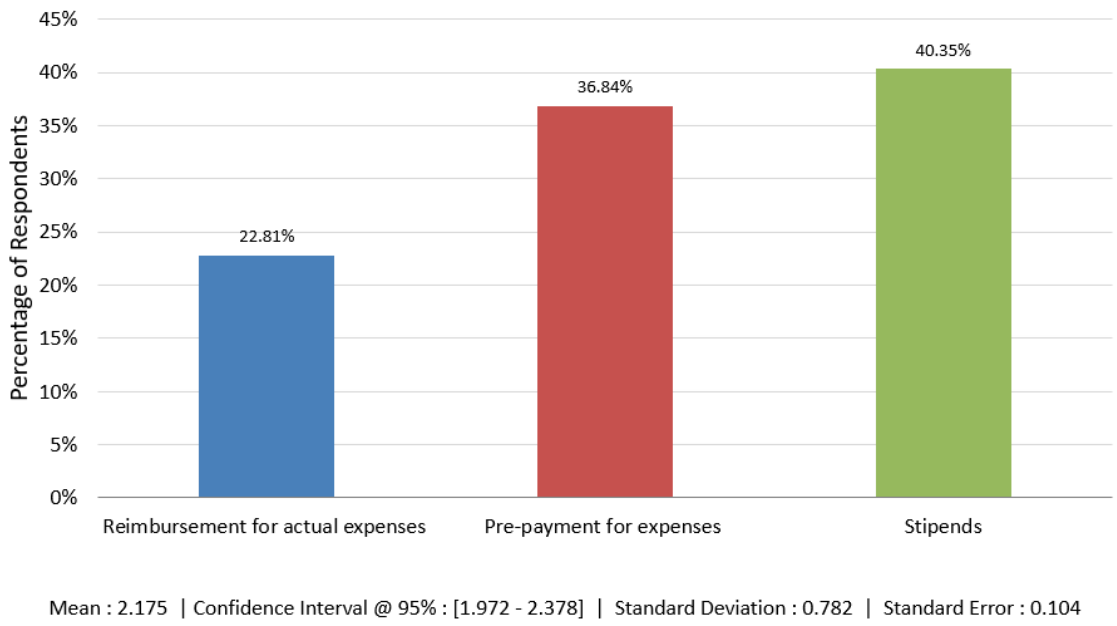
Survey participants were asked which type of financial support (reimbursement for actual expenses, pre-payment for expenses, stipends for travel/meals, or stipends for time/effort) were most preferred by site staff (**Figure 2**), as well as trial participants (**Figure 3**). Two thirds of respondents (66.67%) said stipends would be preferred by staff, and almost half (40.35%) said stipends would be preferred by trial participants.

**Figure 2: Participant Financial Support Preferred by Site Staff. Survey Question: Which type of participant financial support would be MOST preferred by your staff, whether or not your site has experience with the approach?**




Mean : 2.806 | Confidence Interval @ 95% : [2.458 - 3.153] | Standard Deviation : 1.064 | Standard Error : 0.177

**Figure 3: Participant Financial Support Preferred by Trial Participants. Survey Question: Which type of participant financial support would be MOST preferred for your participants, whether or not your site has experience with the approach?**




Mean : 2.175 | Confidence Interval @ 95% : [1.972 - 2.378] | Standard Deviation : 0.782 | Standard Error : 0.104

When asked to "describe your site's level of knowledge about the availability of and ways to access financial support programs for clinical trial participants", 74.14% said they had a "medium" level of knowledge, with 18.97% reporting "low" knowledge, and only 6.9% reporting a "high" level of knowledge. Respondents indicating a "low" level of knowledge were further asked what would be helpful to increase their awareness about financial support programs for clinical trial participants (**Table 1**). Responses highlighted a need for additional resources on available information for training and education as well as streamlined processes and communication on financial support programs.

**Table 1: Responses Detailing Helpful Resources to Increase Awareness**

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| *ADDITIONAL RESOURCES* |
| Provide a list of available tools |
| Provide survey results indicating what support programs other cancer centers are using |
| Education and a centralized website (2 responses) |
| Offer more training on what is available (2 responses) |
| Email notifications of discussions at AACI CRI conferences |
| We rely on clinical social workers and pharmacy support to help with costs and financial programs. We would love to know about options for our patients and how other sites have been successful. |
| |
| *TRANSPARENT/STREAMLINED PROCESS* |
| More transparent information from sponsors/CROs on the vendor/third party being used to manage patient reimbursements and stipends since it is not the same process or level of support from study to study |
| Easier if there was a process to follow and a central place to call or email. Each case is handled differently depending on the reimbursement and that causes delays with CRCs. |

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| With the high turnover of CRCs, they do not have the institutional knowledge and often have to escalate to a manager who needs to troubleshoot. |

Survey participants were asked if their site had "specific restrictions on whether or how to use industry-sponsored financial support programs for clinical trial participants", with 43.1% responding "yes", 41.38% responding "no", and 15.52% responding "I don't know". Those responding "yes" to restrictions, provided more details on the restrictions (**Table 2**). Multiple responses highlighted concerns around financial support being construed as coercing trial participation, as well as various institutional, state, and federal requirements or regulations impeding use of certain financial programs. Third-party vendors for processing payments for participants are noted as becoming more common and helpful to expedite the process, but challenges remain in their implementation.

**Table 2: Restrictions on Use of Industry-Sponsored Financial Support Programs**

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| *ETHICAL CONSIDERATIONS* |
| Stipends/reimbursement cannot be seen as coercing patients to participate in the trial. (3 responses) |
| |
| *LAWS/REGULATIONS* |
| We must follow all state guidelines, so pre-paid or stipend may not be options (2 responses) |
| Programs must be compliant (e.g., billing compliance, equitable treatment, etc.) |
| Industry sponsor financial support must meet IRS and Medicare billing requirements |
| Must be reviewed by IRB. (4 responses) |
| We are required to follow our institutional policies for non-employee reimbursements (e.g., caps on accommodations and meals/incidentals). (2 responses) |
| Amounts paid to patients cannot be above the institutional limit even if the sponsor agrees to pay more |
| |
| *EQUALITY/EQUITY* |
| Needs to be equitable for all participants on trial (3 responses) |
| Financial support must be distributed to all participants regardless of financial status. |
| |
| *THIRD PARTY VENDORS* |
| Using Greenphire or Clin Card because it allows more direct and faster payment to patients. Also, because the money does not filter through our state accounts (thus not subject to state procurement/reimbursement rules, the payments and expense documentation requirements are much more flexible for patients. (2 responses) |
| We only allow stipends for studies if the ClinCard will be managed by our center. Issuing of W9s and clear documentation of history of payments |
| When processing participant reimbursement or stipends, it is required to get personal info for tax purposes; 3rd party vendors (e.g., Scout, Greenphire) are becoming more |

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| common and in some cases require personal/bank information that patients do not want to share |
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| *SPONSOR RELATED CHALLENGES* |
| Specifically challenging is support for improving the diversity of trial participation. For such initiatives, we direct sponsors to fund central efforts to improve the diversity of cases at the center which we hope would have a correlative effect on trial diversity. Or we direct sponsors to support local community groups that we typically refer to all patients. |
| Our site tends to only use stipend-based financial support when we are able to utilize our own internal subject payments system and process to manage the stipends; the use of sponsor-required systems has proven too difficult to operationalize. |

When asked if respondents were aware of the resources available to sites on the EACT website, 82.14% of respondents said "No" and 17.85% said "Yes". Of the 10 respondents aware of the EACT resources, 80% (8/10) found the materials helpful, with 20% (2/10) not finding them helpful. Given the opportunity to share what materials would be most helpful for their site, respondents shared additional information on externally available resources would be most valuable (**Table 3**).

**Table 3: Materials that Would be Most Helpful for Sites**

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| Education or additional information regarding externally available resources for participants would be beneficial. (4 responses) |
| List of organizations that provide grants, funding, and support so that we can prospectively and proactively look for ways to pay for these important services. The guide and checklist are somewhat helpful, but for the most part, represent what most major centers already do. What we really need is a way to connect with entities that provide funding. |
| Workload benchmarking and assessment tools |
| Materials on financial aid applications, groups that can assist with financial aid, and translation services for aid. |
| Short loops of information for public (clinic and infusion) consumption. |
| Materials that support the justification for full-cost reimbursement to patients would be beneficial. Limiting reimbursements to parking/food is not equitable, as not all patients can afford to take time off of work, or pay for services to complete their family responsibilities in order to allow them to participate in research. There needs to be clarity to REB's and sponsors how this supports inclusivity in research, and that this is not an 'incentivization' of research. |

## Discussion and Next Steps

This survey in partnership with AACI and EACT of cancer centers on their current practices and barriers for financial support for trial participants highlights the need for additional education, resources, and awareness of financial support programs for clinical trial participants across clinical trial sites. This work does have limitations, as this survey was

voluntary and may not be representative of all cancer clinical trial sites. Further, the majority of respondents were from NCI-designated comprehensive cancer centers, which may have additional resources and/or staff to support such efforts that may not be available to non-designated institutions.

These data demonstrate a need for additional resources, specifically for trial sites, on available training and education programs that support communication and access on financial support programs. Further, additional barriers including ethical concerns and various requirements and regulations hinder the ability to provide adequate support. EACT will work to provide resources for sites and their personnel to raise awareness, encourage conversations, and support financial neutrality for clinical trial participants.