Mitigating Financial Toxicity for Participants in Clinical Trials

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

EQUITABLE ACCESS TO CLINICAL TRIALS

Learn more at www.mrctcenter.org

Panelists

Dr. Barbara Bierer,
Faculty Director, MRCT Center

Wendy Selig,
Founder, WSCollaborative;
Project Lead, EACT initiative

Dr. David Gerber,
Associate Director of Clinical Research, UT Southwestern Medical Center

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About Us

MRCT Center is an applied policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials around the world.

Our Vision

Improve the integrity, safety, and rigor of clinical trials around the world.

Our Community

We engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

Mitigating Financial Toxicity for Participants in Clinical Trials

December 7, 2025

Almost 1 in 3 families facing pediatric ALL experience new catastrophic financial challenges

- Daniel Zheng, Children's Hospital of Philadelphia
- Survey of 422 participants: 1/3 families experienced new financial hardships within 2 years of diagnosis of pediatric ALL
  - 22% new housing insecurity
  - 15.9% food insecurity
  - 8.6% challenges paying for utilities

> *'What's so sad is that for some of our families, their child's cancer diagnosis is not the hardest thing they're facing."*
>
> *- Katie Oranges, NP*

Mitigating Financial Toxicity for Participants in Clinical Trials

RESEARCH NEWS

Drop in Credit Score After Cancer Diagnosis Linked to Increased Mortality, Study Shows

Massachusetts data shows a critical link between financial health and survival

Key Takeaways

- Among 42,451 patients, 8.5% developed financial toxicity (a credit score below 600) after their diagnosis; an additional 3% were already in that category.
- Patients whose credit score fell by two tiers within 12 months of diagnosis faced a 29% higher risk of death. Over any six-month period after diagnosis, a one-tier drop increased mortality risk by 12%, and a two-tier drop raised it by 63%, compared with patients whose scores stayed stable.
- An increase in credit score was not found to be a protective factor against mortality.

https://www.facs.org/media-center/press-releases/2025/drop-in-credit-score-after-cancer-diagnosis-linked-to-increased-mortality-study-shows/

Payment to research participants is ethical

SOUNDING BOARD

A Framework for Ethical Payment to Research Participants

Authors: Luke Gelinas, Ph.D., Emily A. Largent, J.D., Ph.D., R.N., I. Glenn Cohen, J.D., Susan Kornetsky, M.P.H., Barbara E. Bierer, M.D. , and Holly Fernandez Lynch, J.D. Author Info & Affiliations

The NEW ENGLAND JOURNAL of MEDICINE

https://www.nejm.org/doi/10.1056/NEJMsb1710591

- **Reimbursement** for out-of-pocket expenses
- **Compensation** for time and burdens
- **Incentives** for participation

Macklin R. On paying money to research subjects:'due'and'undue'inducements. IRB: Ethics & Human Research. 1981;3(5).

Dickert N, Grady C. What's the price of a research subject? Approaches to payment for research participation. New England journal of medicine. 1999 Jul 15;341(3):198-203.

Dickert N, Emanuel E, Grady C. Paying research subjects: an analysis of current policies. Annals of internal medicine. 2002 Mar 5;136(5):368-73.

Grady C, Dickert N, Jawetz T, Gensler G, Emanuel E. An analysis of US practices of paying research participants. Contemporary clinical trials. 2005 Jun 1;26(3):365-75.

Largent EA, Grady C, Miller FG, Wertheimer A. Money, coercion, and undue inducement: a survey of attitudes about payments to research participants. Irb. 2012 Jan;34(1):1.

Largent EA, Lynch HF. Paying research participants: regulatory uncertainty, conceptual confusion, and a path forward. Yale journal of health policy, law, and ethics. 2017;17(1):61.

Impact of clinical trial compensation on federally-funded means-tested programs


Assessing Federal Policies to Reduce Economic Barriers to Clinical Trial Enrollment

Daniel Albert-Rozenberg[1], David Peloquin[2], Joseph Liss[3], Erika Hanson[4] and Barbara E. Bierer[5,6]

Journal of Law, Medicine & Ethics (2025), 1–10
doi:10.1017/jme.2025.61

- Advance Premium Tax Credit (APTC)
- Children's Health Insurance Program (CHIP)
- Cost Sharing Reduction (CSR)
- Earned Income Tax Credit (EITC)
- Federal Low-Income Housing
- Modified Adjusted Gross Income (MAGI) Medicaid
- Supplemental Nutrition Assistance Program (SNAP)
- Supplemental Security Income (SSI)
- Temporary Assistance for Needy Families (TANF)
- Head Start
- Social Security Disability Insurance (SSDI)
- Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)

Panelists

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Project Lead, EACT initiative

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EACT Initiative: Presentation

Background on the EACT Initiative

- Launched in 2022 to understand landscape for lung cancer clinical trials
- Provide continuing forum for sharing best practices and collaborative action to advance financial neutrality for patients participating in all oncology clinical trials
- Issue are not specific/unique to oncology
- Initiative format, hosted by LUNGevity Foundation
  - Steering group & 3 or 4 “all hands” meetings per year on topics of shared interest
- Working groups
  - Identifying best practices & industry consensus standards for reimbursement programs (2023)
  - Defining and clarifying tax/legal issues with reimbursement programs (2023)
  - Expanding efforts to educate HCP’s about availability of reimbursement (2023)
  - Deeper dive for best practice and barriers for sponsors and sites (2024 & 2025)
  - Dissemination (2024 & 2025)
  - IRB Engagement (2025)

LUNGEVITY
Transforming Lung Cancer

EQUITABLE ACCESS TO CLINICAL TRIALS


Lazarex
CANCER FOUNDATION


LUNGEVITY
Transforming Lung Cancer


American
Cancer
Society
Cancer
Action
Network


LEUKEMIA &
LYMPHOMA
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Tigerlily
Foundation
Beauty. Strength. Transformation.


Yale CANCER CENTER
A Comprehensive Cancer Center Designated
by the National Cancer Institute


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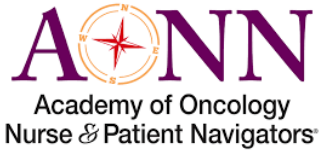
UT Southwestern
Harold C. Simmons
Comprehensive Cancer Center


AACI
Association of
American Cancer Institutes


ACCC
Association of Community Cancer Centers


AONN
Academy of Oncology
Nurse & Patient Navigators


ASCO
AMERICAN SOCIETY OF
CLINICAL ONCOLOGY


ONS
Oncology Nursing Society


AAHRPP
Association for the Accreditation
of Human Research Protection Programs, Inc.


ADVARRA


MONTANA
CANCER CONSORTIUM


SCRS
Society for Clinical Research Sites
Our Voice | Our Community | Your Success


ARCUS
BIOSCIENCES


Daiichi-Sankyo


JUVODA


Johnson&Johnson


Lilly


MERCK


muralhealth


parexel


Pfizer


SANOFI


Scout


EQUITABLE
ACCESS
TO CLINICAL
TRIALS

Website (eactproject.org)

EQUITABLE ACCESS TO CLINICAL TRIALS

Best Practice Considerations & Recommendations for Sponsors

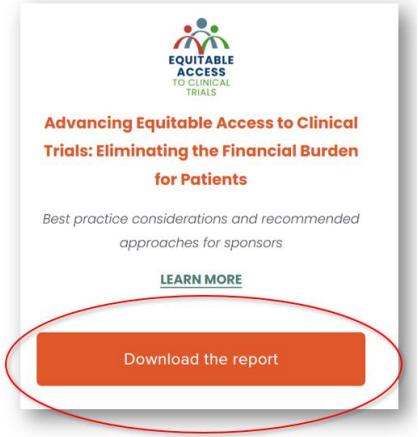
Best Practice Recommendations for Sponsors

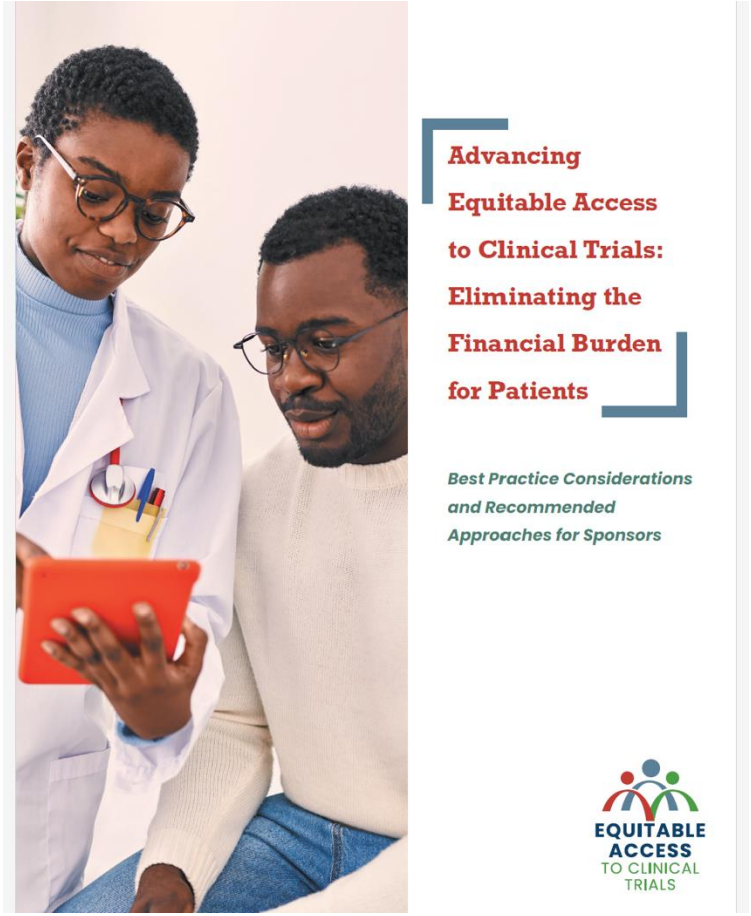
1. Visit the EACT Website at: https://www.eactproject.org/

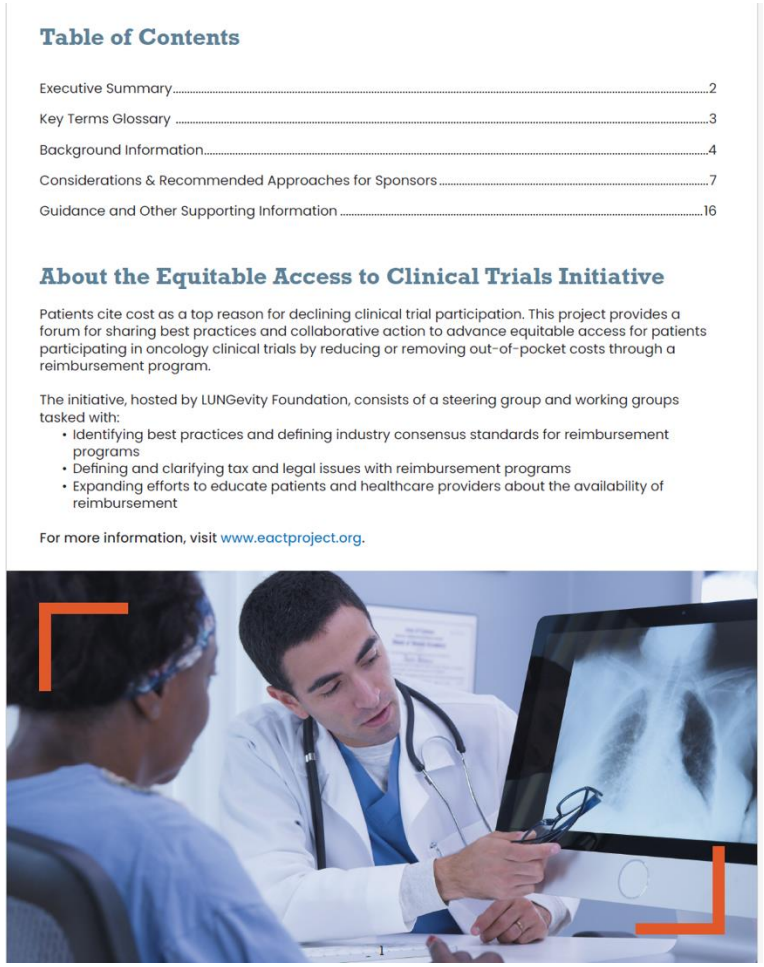
2. Scroll to bottom of home page to “Resources”

3. Click “Download the report” under “Advancing Equitable Access to Clinical Trials: Eliminating the Financial Burden for Patients”

Direct link to resource







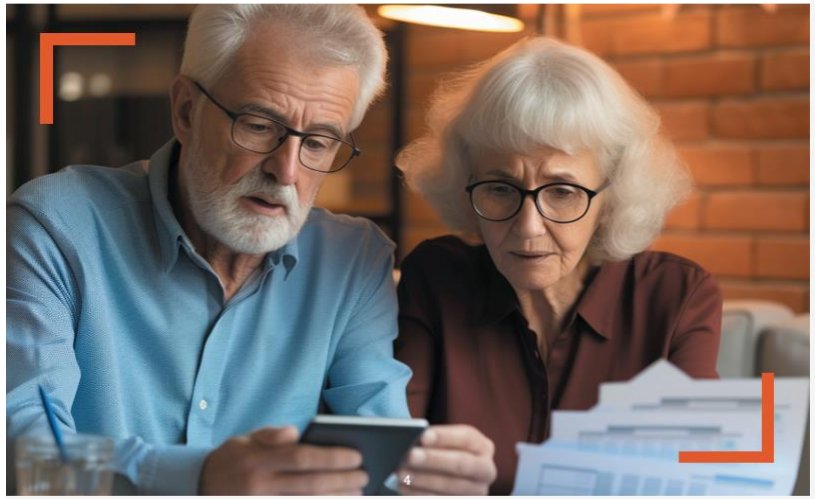
EQUITABLE ACCESS TO CLINICAL TRIALS

Best Practice Recommendations for Sponsors

Equitable Access to Clinical Trials: Why Advancing Financial Neutrality Matters

- Patients cite costs as one of the top reasons for declining clinical trial participation.
- Patients making less than $50,000 per year are nearly 30% less likely to enroll in cancer clinical trials. As income levels decreased, so did rates of participation.
- A Lazarex Cancer Foundation/MGH Cancer Care Equity Program found that, on average, patients enrolled with an annual income under $35,000 spent more than $600 per month to pay for the additional costs of travel and lodging.
- Clinical trial participation also creates financial burdens for caregivers (e.g., time off work, travel, etc.).

Sources:
American Cancer Society Cancer Action Network
IMPACT Program, Lazarex Cancer Foundation (lazarex.org/impact)
Association of American Cancer Institutes Survey, 2022
Emanual EJ. Cancer patients shouldn't be responsible for out-of-pocket costs. STAT News, 5/23/2023



Sources of Out-of-Pocket Costs in Clinical Trials

Out-of-pocket costs for clinical trials can be medical or non-medical. The considerations and recommendations in this document deal only with non-medical costs.

MEDICAL COSTS

- Insurance (copays, deductibles, premiums)
- Extra doctor visits
- Some medications, procedures
- Extra scans

NON-MEDICAL COSTS

- Travel and accommodations
- Meals
- Time lost (from work, family, etc.)
- Trial-related technology
- Responsibilities

EQUITABLE ACCESS TO CLINICAL TRIALS

Best Practice Recommendations for Sponsors

Executive Summary

THE CHALLENGE

Patients cite cost as a top reason for declining clinical trial participation. The role that financial considerations play in influencing someone's decision to join and/or stay in a study differs according to a range of factors: geography, personal support network, employment and/or government assistance status, and more.

Without comprehensive, explicit regulatory guidance on the acceptability of financial support for trial participants, sponsor and institutional review board (IRB) interpretations of what is fair, compliant, and achievable will continue to vary.

THE APPROACH

Hosted by LUNGevity Foundation, a multi-stakeholder group comprising patient and professional groups, IRBs, clinical trial sites, drug developers, contract research organizations (CROs), and more came together to understand gaps and barriers in the provision of support for clinical trial participants' non-medical out-of-pocket expenses.

The group homed in on three problem areas to address through working groups:

- Insufficient support programs provided by trial sponsors
- Lack of communication between trial sponsors and trial site staff, and between site staff and prospective participants, around the existence and scope of these programs
- Legal and tax implications for trial sponsors and participants, respectively, that may deter them from offering and utilizing financial support programs

DOCUMENT PURPOSE

This document is designed to outline key considerations for sponsors when designing financial support programs for trial participants by:

- Categorizing non-medical items most likely to have a financial impact on prospective and current study participants
- Illustrating unique considerations for patients and caregivers under various circumstances
- Highlighting pertinent regulatory guidance around coercion and undue influence of clinical trial participants
- Recommending sponsor approaches for relieving financial burden associated with non-medical, out-of-pocket costs incurred by trial participants

Glossary

FINANCIAL NEUTRALITY	For the purposes of this document, a state of financial equilibrium in which a patient experiences no negative financial impact from participating in a clinical trial.
MEDICAL COSTS	Expenses incurred by clinical trial participants when medical costs related to the trial (e.g., protocol-required procedure, labs, or medication) are considered standard of care and therefore are not covered by the study sponsor, and/or when protocol-required care goes beyond what insurance considers standard of care and thus is not covered. Insurance premiums, co-pays, and deductibles also fall in this category.
NON-MEDICAL COSTS	Expenses incurred by trial participants related to their participation that are not medical in nature (e.g., air, bus, or train fare, parking fees, meals, hotel stays).
OUT-OF-POCKET EXPENSE	An expense paid by the person incurring it with their own money at the time it happens.
PARTICIPANT EXPENSES	Costs incurred by a clinical trial participant that would not have occurred if they were not participating in that trial at that time. These can be medical or non-medical.
PREPAYMENTS	Money issued to trial participants by trial sponsors, sites, or third-party vendors before trial-associated costs are incurred, with the intent that the funds be used for those expenses.
REIMBURSEMENTS	Repayment for out-of-pocket expenses for clinical trial activities incurred by participants. Reimbursements must be substantiated with supporting documentation such as a receipt. Expenses eligible for reimbursement may include, but are not limited to, hotel stays, air and ground transportation, parking, meals, and childcare.
STIPENDS	Fixed payments offered to participants for completing study visits or other study activities (e.g., eDiary entries). Stipends are provided to compensate participants for their time, effort, burden, discomfort, and/or risk associated with participating in a clinical research study. For example, a study might offer a $120 stipend for every completed onsite visit, a $20 stipend for every completed phone visit, and a $5 per week eDiary stipend.
THIRD-PARTY VENDOR	In this context, a company that is not the trial sponsor that provides financial and/or logistical support for clinical trial participants, often by issuing prepaid debit cards.
TRAVEL SUPPORT SERVICES	Services provided by the sponsor, trial site, or a third-party vendor, such as scheduling and paying for travel accommodations, on behalf of participants. Depending on the needs of the study and participant, these travel services can range from simple (e.g., car service from the participant's home to the site) to complex (e.g., temporary housing, international flights).

EQUITABLE ACCESS TO CLINICAL TRIALS

Best Practice Recommendations for Sponsors

Recommended Approaches for Sponsors to Advance Financial Neutrality

Develop Corporate Policy/SOPs

- Develop and implement financial support policies and SOPs that anticipate stakeholder scenarios and questions and help relieve cost barriers for patients.
- Implement standardized programs across all trials.
- Ensure processes are streamlined and reflect patient centricity and sponsor values.
- Strike balance between flexibility and meeting baseline requirements.

Enable Effective Participant Communications

- Ensure that financial impact and available support are clearly detailed in consenting process (informed consent form).
- Adhere to digital health literacy principles.
- Test tools and materials with range of potential patients and advocacy groups to ensure ease of use.

Engage with IRBs

- Be prepared to educate relevant IRBs on your approach to providing financial support.
- Emphasize that the goal of providing compensation is financial neutrality, equity, and access.
- Proactively share with them relevant guidance (e.g., FDA, Multi-regional Clinical Trials, Council for International Organization of Medical Sciences, World Health Organization).

Support Site Readiness

- Ensure site personnel understand goal of financial neutrality and can help administer available financial support programs.
- Address variability across sites in their approach to implementing financial support programs.
- Present the option of third-party-provided compensation services to ease site burden.
- Test processes prior to recruitment and monitor throughout the trial.

Balance Abuse Mitigation with Meeting Participant Needs

- Create and communicate expectations for documentation without forcing participants to disclose their health status to employers.
- Seek to minimize risk by covering costs directly (or through a third party) when possible.

Advance Simplicity and Speed

- Reduce burden on sites and trial participants by simplifying processes and providing options.
- Utilize a third-party vendor that specializes in patient compensation and travel services and can provide flexible payment options, fast payments, and reduced out-of-pocket expenses.
- When out-of-pocket expenditures are required, reimburse or provide stipends quickly (e.g., immediately or within 24 hours).

Best Practice Recommendations for Sponsors

Category-Specific Considerations: TRAVEL

CONSIDERATIONS

- Where someone lives and the resources available to them (e.g., car, access to reliable, efficient public transportation) can impact their willingness and ability to participate in, and remain in, a study.
- Even when a study site may be considered local (< 1 hour from home), costs can add up, especially if a participant does not have a car or is unable to drive.
- Having to pay out of pocket – even when eventually reimbursed – can make study participation out of reach for many.
- When a caregiver accompanies the participant, some costs remain the same (i.e., shared taxi or driving together), whereas others will have per-person costs (e.g., rail or air fare).
- The FDA and other government bodies have stated that reimbursing travel costs does not constitute inducement or undue influence.

RECOMMENDED APPROACHES

- Seek to eliminate the need for participants to pay out-of-pocket when possible, taking into account potential tax impact of stipend or up-front payments.
- Reimburse for mileage and gas according to current US government rate.
- Request receipts for tolls, rental car, taxi, and other ground transportation.
- For commercial travel (i.e., air, train), consider using an experienced third-party vendor to arrange and purchase travel tickets.
- For lodging, benchmark against US government per-diem rates by geography or zip code. Note how local happenings may elevate prices (e.g., graduation weekend in Boston).

8

Category-Specific Considerations: MEALS

CONSIDERATIONS

- Cost of food is rising overall, especially out-of-home meals and healthy food options. If timely reimbursement or advance payment is not provided, patients' nutrition may suffer.
- Average meal costs vary by region.
- When a caregiver accompanies the participant, there are often additional (per-person) meal costs.
- Reimbursement for meals is not specifically called out in current guidance but could be inferred.

RECOMMENDED APPROACHES

- Establish and incorporate a per-diem stipend for participants; provide double when a caregiver attends.

9

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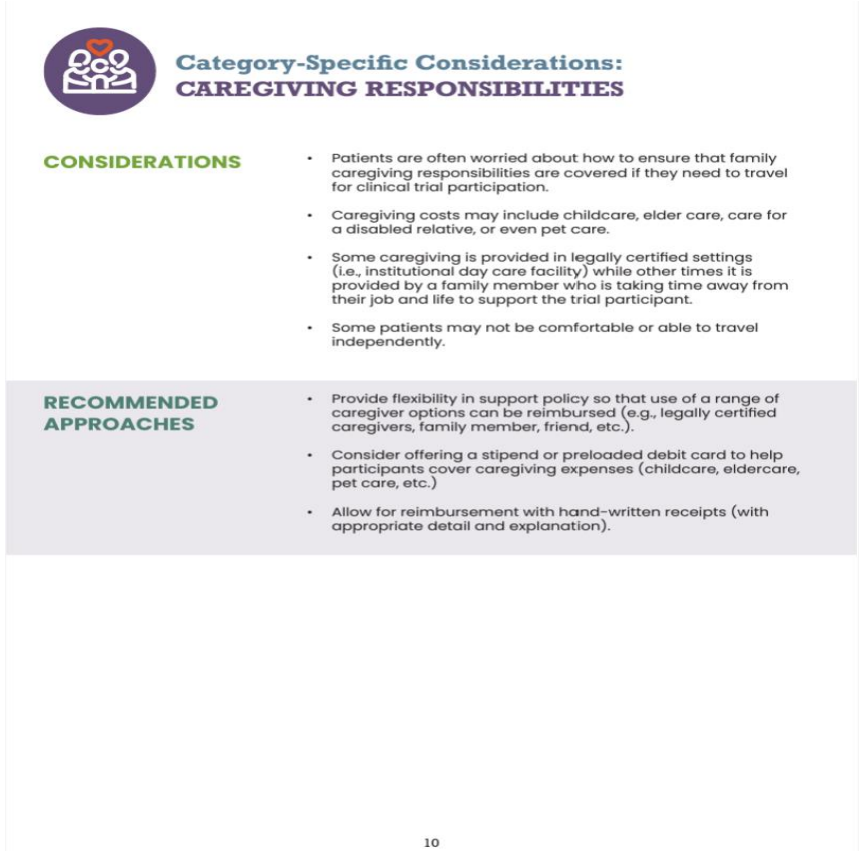
Best Practice Recommendations for Sponsors



Category-Specific Considerations: CAREGIVING RESPONSIBILITIES

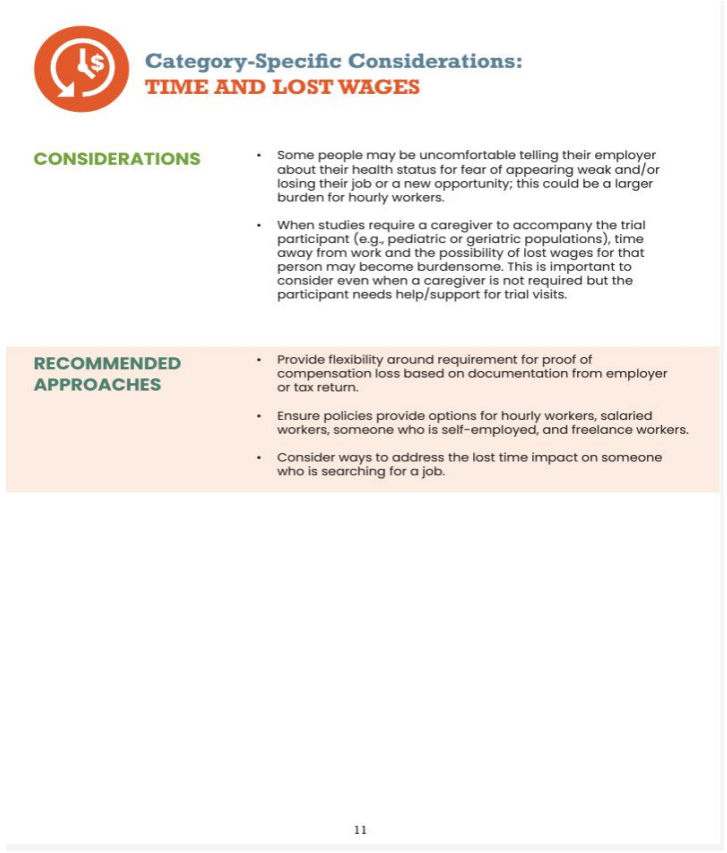
CONSIDERATIONS

- Patients are often worried about how to ensure that family caregiving responsibilities are covered if they need to travel for clinical trial participation.
- Caregiving costs may include childcare, elder care, care for a disabled relative, or even pet care.
- Some caregiving is provided in legally certified settings (i.e., institutional day care facility) while other times it is provided by a family member who is taking time away from their job and life to support the trial participant.
- Some patients may not be comfortable or able to travel independently.

RECOMMENDED APPROACHES

- Provide flexibility in support policy so that use of a range of caregiver options can be reimbursed (e.g., legally certified caregivers, family member, friend, etc.).
- Consider offering a stipend or preloaded debit card to help participants cover caregiving expenses (childcare, eldercare, pet care, etc.)
- Allow for reimbursement with hand-written receipts (with appropriate detail and explanation).

10



Category-Specific Considerations: TIME AND LOST WAGES

CONSIDERATIONS

- Some people may be uncomfortable telling their employer about their health status for fear of appearing weak and/or losing their job or a new opportunity; this could be a larger burden for hourly workers.
- When studies require a caregiver to accompany the trial participant (e.g., pediatric or geriatric populations), time away from work and the possibility of lost wages for that person may become burdensome. This is important to consider even when a caregiver is not required but the participant needs help/support for trial visits.

RECOMMENDED APPROACHES

- Provide flexibility around requirement for proof of compensation loss based on documentation from employer or tax return.
- Ensure policies provide options for hourly workers, salaried workers, someone who is self-employed, and freelance workers.
- Consider ways to address the lost time impact on someone who is searching for a job.

11

EQUITABLE ACCESS TO CLINICAL TRIALS

Best Practice Recommendations for Sponsors

Category-Specific Considerations: TECHNOLOGY

CONSIDERATIONS

- Even though broadband access has improved, access and affordability gaps are pervasive.
- Patients otherwise eligible to participate in a trial may not own or have access to a needed device (e.g., smartphone).
- For those who do own smartphones, limitations in device capabilities (e.g., storage), restrictive data plans, service disconnections, and/or spotty reception may pose barriers to participation.
- Some participants may require additional support to complete electronic patient-reported outcomes (ePRO) assessments (e.g., individuals with vision or dexterity limitations, those unfamiliar with the technology).

RECOMMENDED APPROACHES

- Eliminate device requirements in trial eligibility criteria. Consider a model that meets diverse needs by allowing patients to bring their own devices or have devices provided to them.
- Provide stipends to support tech acquisition or use and/or provide appropriate devices and training for their use.
- For internet service costs, consider reimbursing up to a fixed amount (e.g., $50 per month) and request a monthly bill, or provide a stipend per participant.
- Review **Mapping Broadband Health in America 2023** (US government resource for maps characterizing regions, patterns, and gaps to inform approach) to visualize key cross-currents in broadband and health data.
- Address tech support needs (e.g., training and support staff) and avoid placing extra burden on trial site personnel.

12

Additional Considerations for Specific Populations

Implementing best practice recommendations may require flexibility to address the needs of special populations.

PEDIATRIC

- Bank restrictions on reloadable debit cards issued to minors
- Parents with limited ability to leave work during regular office hours
- Childcare for siblings or travel costs for them to accompany patient and caregiver

DISABLED/SUPPLEMENTAL SECURITY INCOME (SSI)

- Limited travel options
- Technology compatibility
- Specific needs depending on disability
- Tax and safety net program considerations

UNDOCUMENTED

- Undocumented persons may not have or may be reluctant to share details required for standard reimbursement models: government-issued ID, wage declaration from employer, Social Security number, etc.
- Consider mechanism for verifying income if participant or caregiver does not feel safe disclosing their health status to their employer
- The same considerations apply to parents or guardians of undocumented children

RURAL

- Limited and/or expensive travel options
- Potentially limited access to technology and services

13

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Enduring Webinar Content

- 90-minutes
- Recorded 3.5.2025
- 100+ Registrants
- Content can be found at: https://www.eactproject.org/industry-sponsors-webinar

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Tax & Legal Issues with Compensation

Key Tax & Legal Issues

- Trial Participants
  - Tax implications
  - Safety net program eligibility implications
- Sponsors
  - Administrative burdens (e.g., receipts, bank accounts, etc.)
  - Legal issues--Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CMP) Statute

Tax & Legal Issue Brief

EQUITABLE ACCESS TO CLINICAL TRIALS

Tax and Legal Considerations for Compensation Programs for Clinical Trial Participants

Policy solutions for mitigating both perceived and actual risks

LEARN MORE

Download the report

Tax and Legal Considerations for Compensation Programs for Clinical Trial Participants

Policy Solutions for Mitigating Risks

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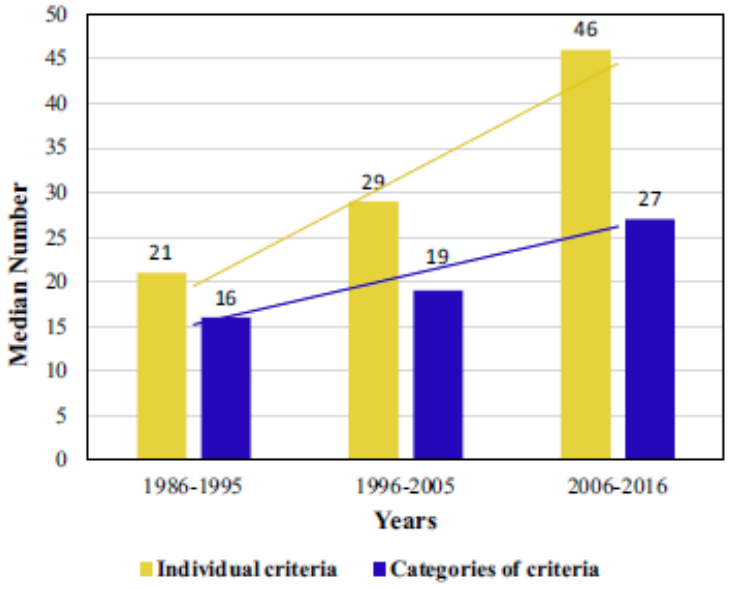
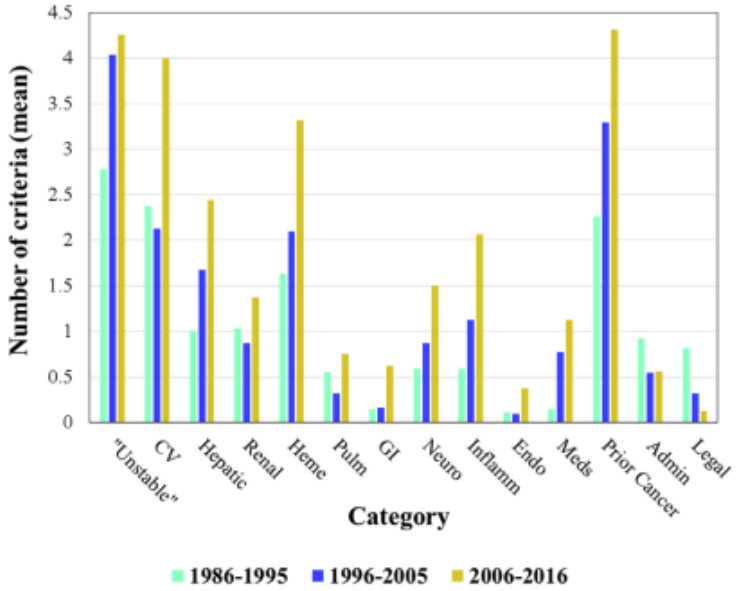
Resources for Clinical Trial Site Staff

Clinical trial enrollment and participation are becoming more complex





	1986-1995	1996-2005	2006-2016
Screening blood tests (n)	11	15	19
Timing—blood tests (d)	14	28	14
Screening imaging studies (n)	5	2	2
Timing—imaging studies (d)	42	28	28

Garcia S et al. *J Thorac Oncol* 2017;12:1489-1495.

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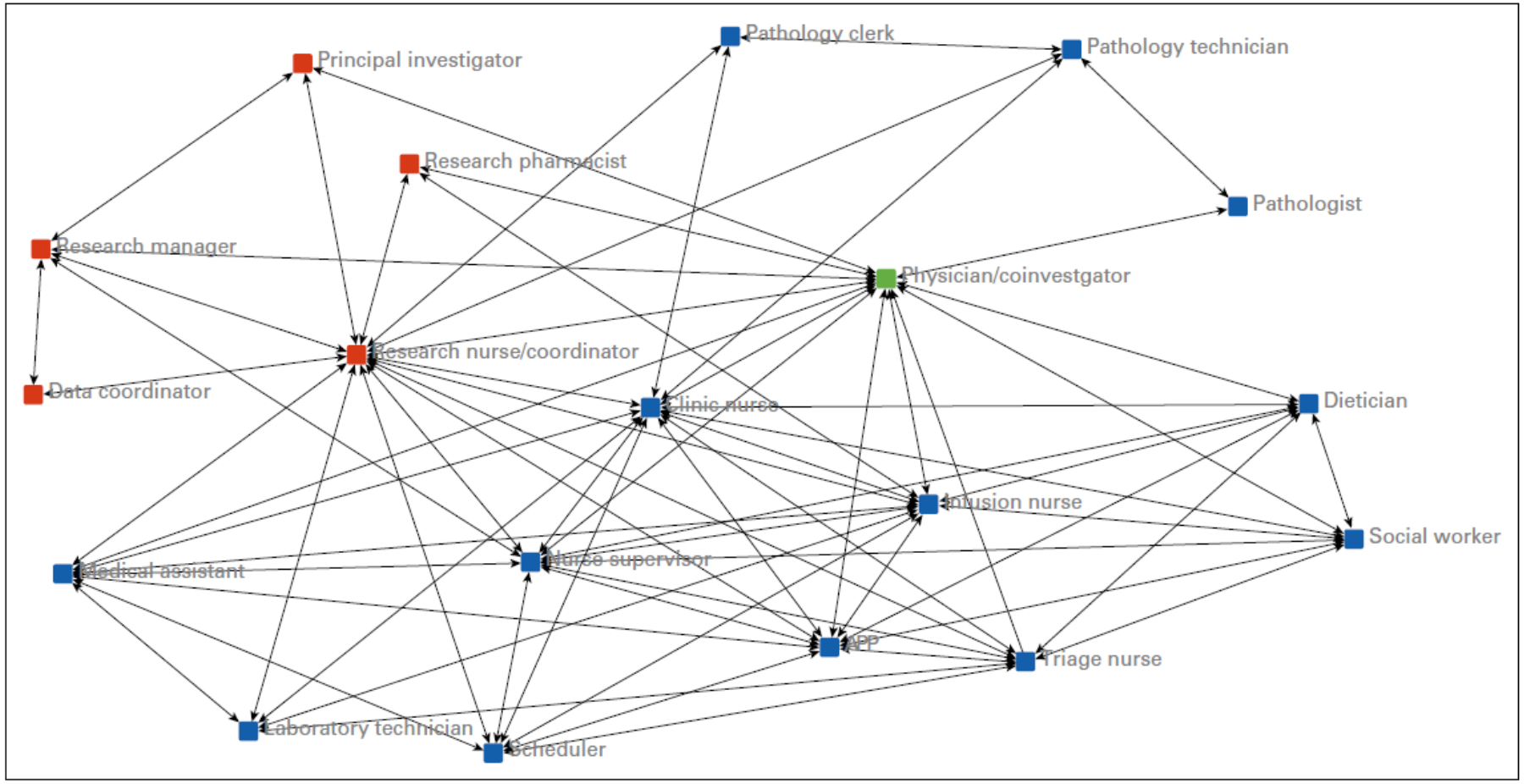
Numerous interactions required for these steps

RED = Research Team
BLUE = Clinic Team



Gerber DE et al. *J Oncol Pract* 2016;12:1020-28.

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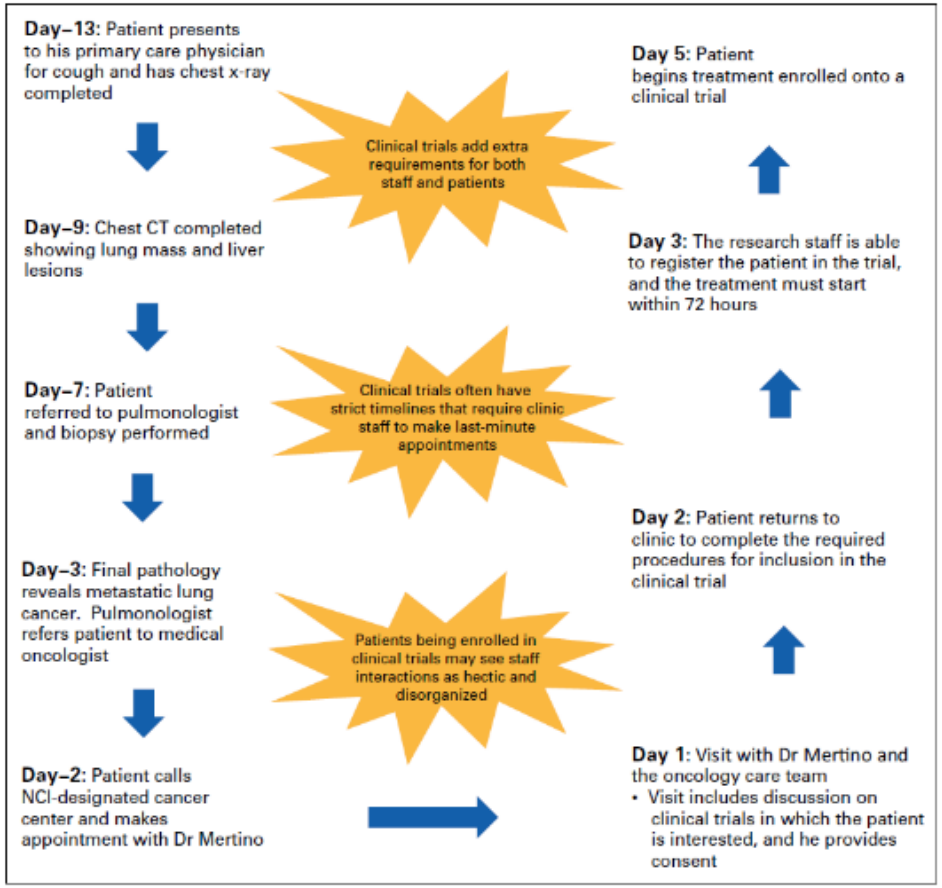
How do sites fit financial support into these processes?



Gerber DE et al. *J Oncol Pract* 2016;12:1020-28.

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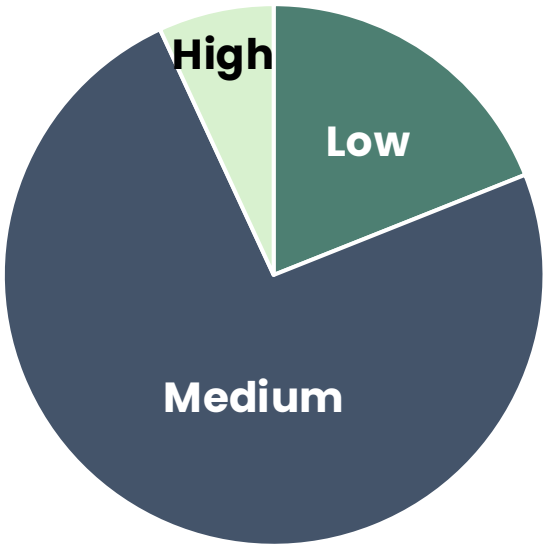
Awareness, understanding, and potential impact of financial support programs remains limited

EACT sponsored 6 optional questions at the end of the Annual AACI CTO Benchmarking Survey Conducted in November 2024. N=59 cancer center respondents

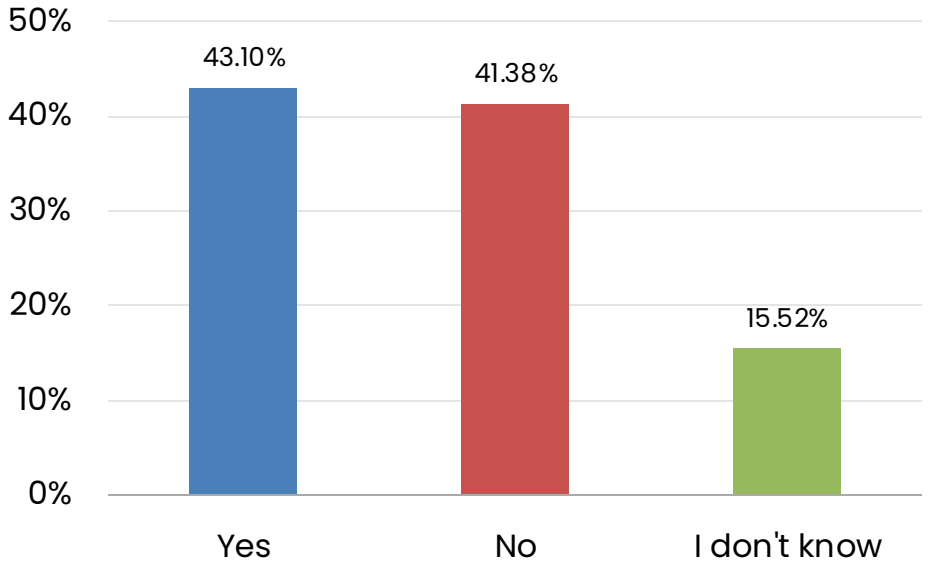
Level of awareness of financial support programs for clinical trial participants



70% of sites do not collect data on how often trial participants seek financial assistance for trial-related expenses

75% of sites do not collect data on how often potential trial candidates choose not to participate in clinical trials due to financial burden

Does your site have restrictions on the use industry-sponsored financial support programs for clinical trial participants?



AACI Association of American Cancer Institutes

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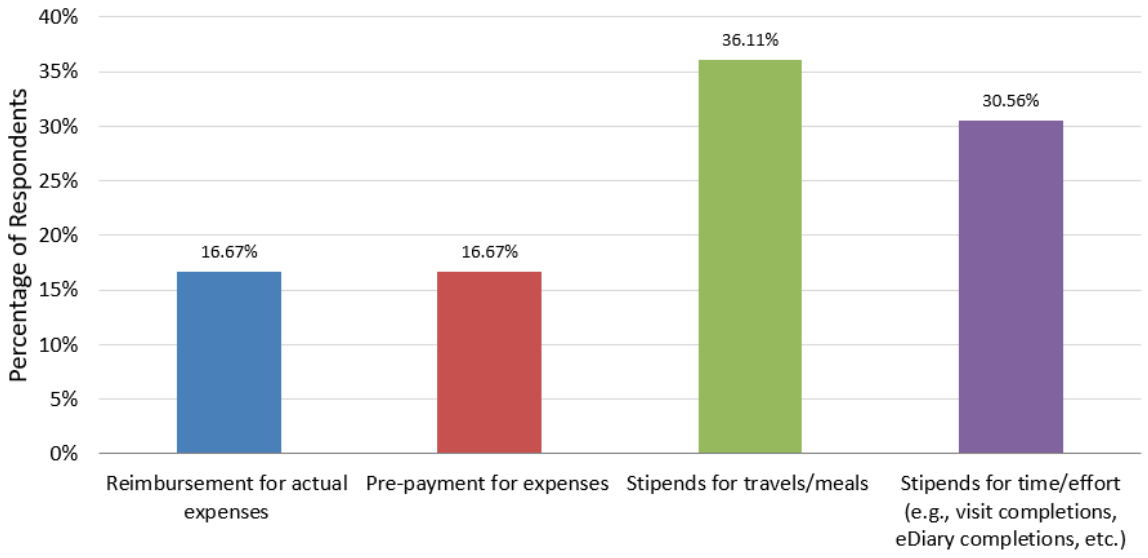
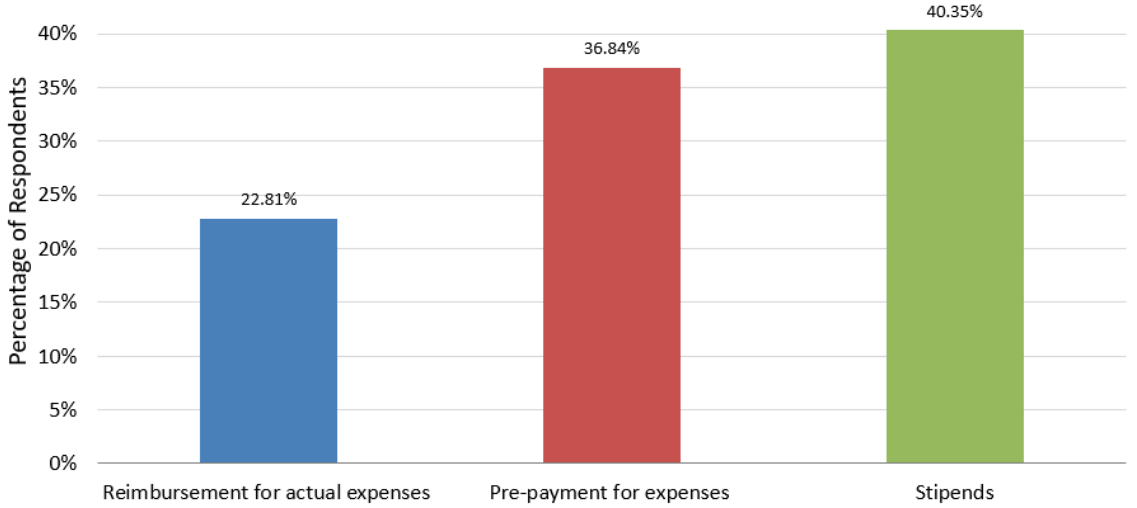
How such support is best provided remains unclear

EACT sponsored 6 optional questions at the end of the Annual AACI CTO Benchmarking Survey Conducted in November 2024. N=59 cancer center respondents

Financial Support Type Preferred by Site Staff



Financial Support Type Preferred by Trial Participants



AACI Association of American Cancer Institutes

EQUITABLE ACCESS TO CLINICAL TRIALS

A call to action for sponsors and site staff

Call to Action

EACT's goal is that every cancer clinical trial offers and provides financial support to make participation in studies cost neutral for participants. Achieving this goal requires some key things to be true, including:

All trial sponsors:

- Should include funding support for OOP non-medical costs (in addition to medical costs related to study requirements) for participants in every oncology study budget.[1]

All trial site staff:

- Should be educated and aware of the impact of OOP costs on trial participants and availability/rules for accessing support programs.
- Depending on the staff role (e.g., trial operations, nurse navigator, financial counselor etc.), individuals should become familiar with institutional policies, regulatory and legal requirements, and available resources from sponsors and third parties to provide financial support to trial participants.

Appropriate trial site staff:

- Should press trial sponsors upfront during budget negotiations to ensure that adequate funding is provided, and processes are streamlined, to minimize the administrative burden on staff and trial participants. [2]
- Should assess patients' individual circumstances and needs in managing OOP financial impact of trial participation upfront (prior to informed consent discussions) and again at various points throughout the trial. [3]
- Should have clear processes in place to support participants in accessing available financial support throughout the trial.

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Multiple opportunities to address financial support

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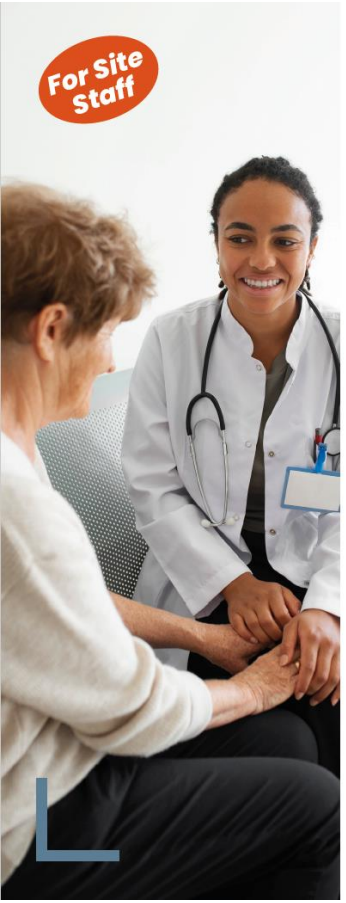
EACT resources can help sites assess needs and resources



EQUITABLE ACCESS TO CLINICAL TRIALS

Advancing Equitable Access to Clinical Trials: Eliminating the Financial Burden for Patients

Best Practice Considerations and Recommended Approaches for Clinical Trial Site Staff

Participant Needs Assessment and Discussion Guide

A tool to aid clinical trial site personnel in determining patients' assistance needs and directing them to resources

LEARN MORE

Get the guide

Engaging with Sponsors About Financial Support Programs for Participants

A checklist to help clinical trial staff ensure that study participants get the support they need

LEARN MORE

Get the checklist

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Sites Best Practices Guide

Table of Contents

Executive Summary

THE CHALLENGE

Patients cite cost as a top reason for declining clinical trial participation. The role that financial considerations play in influencing someone's decision to join and/or stay in a study differs according to a range of factors: geography, personal support network, employment and/or government assistance status, and more.

Without comprehensive, explicit regulatory guidance on the acceptability of financial support for trial participants, sponsor, site and institutional review board (IRB) interpretations of what is fair, compliant, and achievable will continue to vary.

THE APPROACH

Hosted by LUNGevity Foundation, a multi-stakeholder group comprising patient and professional groups, IRBs, clinical trial sites, drug developers, contract research organizations (CROs), and more came together to understand gaps and barriers in the provision of support for clinical trial participants' non-medical out-of-pocket expenses.

The group homed in on three problem areas to address through working groups:

- Inconsistent implementation of support programs among sponsors
- Lack of communication between trial sponsors and trial site staff, and between site staff and prospective participants, around the existence and scope of these programs
- Legal and tax implications for trial sponsors and participants, respectively, that may deter them from offering and utilizing financial support programs

DOCUMENT PURPOSE

This document is designed to provide information, support, and useful resources to site personnel as they ensure that trial participants can access financial support by:

- Understanding sources of out-of-pocket costs for clinical trial participants
- Defining financial neutrality and types of compensation for non-medical costs associated with trial participation
- Outlining key roles and responsibilities across site personnel
- Addressing tax and legal issues
- Providing examples of various approaches among cancer clinical trial sites

Glossary

FINANCIAL NEUTRALITY — For the purposes of this document, a state of financial equilibrium in which a patient experiences no negative financial impact from participating in a clinical trial.

MEDICAL COSTS — Expenses incurred by clinical trial participants when medical costs related to the trial (e.g., protocol-required procedure, labs, or medication) are considered standard of care and therefore are not covered by the study sponsor, and/or when protocol-required care goes beyond what insurance considers standard of care and thus is not covered. Insurance premiums, co-pays, and deductibles also fall in this category.

NON-MEDICAL COSTS — Expenses incurred by trial participants related to their participation that are not medical in nature (e.g., air, bus, or train fare, parking fees, meals, hotel stays).

OUT-OF-POCKET EXPENSE — An expense paid by the person incurring it with their own money at the time it happens.

PARTICIPANT EXPENSES — Costs incurred by a clinical trial participant that would not have occurred if they were not participating in that trial at that time. These can be medical or non-medical.

PREPAYMENTS — Money issued to trial participants by trial sponsors, sites, or third-party vendors before trial-associated costs are incurred, with the intent that the funds be used for those expenses.

REIMBURSEMENTS — Repayment for out-of-pocket expenses for clinical trial activities incurred by participants. Reimbursements must be substantiated with supporting documentation such as a receipt. Expenses eligible for reimbursement may include, but are not limited to, hotel stays, air and ground transportation, parking, meals, and childcare.

STIPENDS — Fixed payments offered to participants for completing study visits or other study activities (e.g., eDiary entries). Stipends are provided to compensate participants for their time, effort, burden, discomfort, and/or risk associated with participating in a clinical research study. For example, a study might offer a $120 stipend for every completed on-site visit, a $20 stipend for every completed phone visit, and a $5 per week eDiary stipend.

THIRD-PARTY VENDOR — In this context, a company that is not the trial sponsor that provides financial and/or logistical support for clinical trial participants, often by issuing prepaid debit cards.

TRAVEL SUPPORT SERVICES — Services provided by the sponsor, trial site, or a third-party vendor, such as scheduling and paying for travel accommodations, on behalf of participants. Depending on the needs of the study and participant, these travel services can range from simple (e.g., car service from the participant's home to

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Engaging with sponsors about financial support for participants

Engaging with Sponsors about Financial Support Programs for Participants: Checklist for Clinical Trial Site Staff

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During budget negotiations, staff should ask trial sponsors these questions regarding support for non-medical, out-of-pocket participant costs.

1. Does the sponsor offer financial support for trial participants' non-medical, out-of-pocket costs?

☐ Yes ☐ No

If "no," there is no need to proceed with questions. If "yes," ask for the following information.

2. Are there eligibility requirements for patients seeking to access this support?

☐ Yes ☐ No

If "yes," please list:

3. What type of support is offered?

☐ Prepayment ☐ Reimbursement

If "prepayment":

3a. provide details including how much support is provided, at what interval (e.g., weekly, monthly), and how funds are dispersed (e.g., preloaded debit card, direct deposit to bank account, other):

If "reimbursement," proceed with the remaining questions.

3b. What is the procedure for submitting and approving reimbursements?

3c. What are the participant's responsibilities (list below with any applicable time limits):

3d. What are the site's responsibilities (list below with any applicable time limits):

3e. What expenses are considered reimbursable? Check all that apply and provide any limits (i.e., maximum amount reimbursable) and restrictions:

☐ Personal auto travel (including tolls and mileage)

☐ Taxi, rideshare service, public transportation

☐ Airfare, train fare

☐ Parking

☐ Lodging

☐ Meals (is this per meal or per diem allowance?)

☐ Childcare, elder care, pet care

☐ Lost wages

☐ Equipment, IT needs

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Negotiating with Sponsors Checklist

https://www.eactproject.org/working-with-sponsors

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Participant needs assessment and discussion guide

For Clinical Trial Site Personnel: Participant Needs Assessment Tool

A clinical trial may have non-medical financial implications that could impact a patient's eligibility and adherence. This tool can be used to gather information from patients to provide a baseline assessment of non-medical financial needs before the patient is enrolled in a clinical trial as well as for reassessment after the patient is enrolled, as their needs may change during conduct of the trial.

Patient ID: _____ Trial: _____

This trial requires:

- ☐ Daily visits
- ☐ Weekly visits
- ☐ Monthly visits
- ☐ All care must be done at trial site
- ☐ Overnight hospital stay
- ☐ Multiple treatment days in a row or in the same week
- ☐ Patient must be accompanied by another adult for treatments
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____

Patient Needs Assessment Questions

These should be asked at baseline (pre-enrollment) and at periodic follow-ups (e.g., after the first and third treatment cycles).

1. Will needs like daycare, elder care, pet care, or child pickup interfere with your ability to make it to treatment appointments?

Baseline: ☐ Y ☐ N Date: _____
Follow-up 1: ☐ Y ☐ N Date: _____
Follow-up 2: ☐ Y ☐ N Date: _____

1a. If financial assistance were available, would it help?

Baseline: ☐ Y ☐ N Date: _____
Follow-up 1: ☐ Y ☐ N Date: _____
Follow-up 2: ☐ Y ☐ N Date: _____

2. Would financial assistance with costs related to travel to appointments (e.g., airfare, gas cards, parking assistance) help you adhere to your appointment schedule?

Baseline: ☐ Y ☐ N Date: _____
Follow-up 1: ☐ Y ☐ N Date: _____
Follow-up 2: ☐ Y ☐ N Date: _____

3. Will you need overnight lodging for yourself? For your family/caregiver?

Self:
Baseline: ☐ Y ☐ N Date: _____
Follow-up 1: ☐ Y ☐ N Date: _____
Follow-up 2: ☐ Y ☐ N Date: _____

Family/caregiver:
Baseline: ☐ Y ☐ N Date: _____
Follow-up 1: ☐ Y ☐ N Date: _____
Follow-up 2: ☐ Y ☐ N Date: _____

4. Do you know whether your insurance has coverage for clinical trials, including travel assistance?

Baseline: ☐ Y ☐ N Date: _____
Follow-up 1: ☐ Y ☐ N Date: _____
Follow-up 2: ☐ Y ☐ N Date: _____

4a. Would you like to meet with a financial counselor for help in reviewing your coverage?

Baseline: ☐ Y ☐ N Date: _____
Follow-up 1: ☐ Y ☐ N Date: _____
Follow-up 2: ☐ Y ☐ N Date: _____

5. Will you or a caregiver need to miss work to make it to study appointments?

Baseline: ☐ Y ☐ N Date: _____
Follow-up 1: ☐ Y ☐ N Date: _____
Follow-up 2: ☐ Y ☐ N Date: _____

For Patients: Potential Financial Resources

Patient ID: _____ Trial: _____

This guide gives you a list of resources that may help cover the non-medical costs of participating in a clinical trial. The resources may be provided by the trial itself, your hospital or clinic, or local or national organizations. ***If you have questions about how to access or qualify for these resources, please talk to your healthcare team.***

Your trial provides assistance with:

- ☐ Travel
- ☐ Meals
- ☐ Gas, parking
- ☐ Childcare, elder care, or pet care
- ☐ Missed work (patient and/or caregiver)
- ☐ Other _____
- ☐ Other _____

Resources provided by healthcare institution [site personnel to customize]

- ☐ _____
- ☐ _____
- ☐ _____
- ☐ _____
- ☐ _____

Local resources [site personnel to customize]

- ☐ _____
- ☐ _____
- ☐ _____

National resources [site personnel to customize]

- ☐ American Cancer Society www.cancer.org/support-programs-and-services
- ☐ Leukemia & Lymphoma Society www.lls.org/support-resources/financial-support
- ☐ National Cancer Institute supportorgs.cancer.gov
- ☐ _____

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Participant Needs Assessment Checklist

https://www.eactproject.org/assessing-needs

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Enduring Webinar Content

- Sites Personnel Webinar Recorded 12.11.2024
- 90-minutes
- ONS providing NCPD Credit
- 300+ Registrants; 200 Live Participants
- Content can be found at: https://www.eactproject.org/site-personnel-webinar
- NEXT WEBINAR:
  - Sites “201” Content Planned for February 2026

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Thank you!

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https://mrctcenter.org

https://eactproject.org

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