



MARCH 2022 REPORT

REIMAGINING CLINICAL TRIAL
RECRUITMENT THROUGH A
FAMILY-CENTERED LENS:

CAREGIVER RECOMMENDATIONS
FOR ENHANCING CLINICAL TRIAL
PARTICIPATION DIVERSITY



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Understanding the critical role that clinical trial enrollment diversity has on the health of communities and research alike, NAC became interested in the roles that family caregivers play in clinical trials recruitment.

ACKNOWLEDGMENTS

The National Alliance for Caregiving (NAC) is proud to present, *Reimagining Clinical Trial Recruitment Through a Family-Centered Lens: Caregiver Recommendations for Enhancing Clinical Trial Participation Diversity*. This report was made possible with support from Travele Therapeutics and builds on the 2019 report, [Paving the Path for Family-Centered Design: A National Report on Family Caregiver Roles in Medical Product Development](#).

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FOREWORD

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Family caregivers make critical contributions to our healthcare system – seeking and sharing information about care options, participating in shared healthcare decision making, ensuring medication and treatment adherence, and providing essential access to healthcare including transportation to and coordination of care.

In medical product development specifically, caregivers serve in these roles plus others – supplying valuable data and insights as observers and reporters. While the extent of engagement of caregivers in clinical development may vary by factors including the research sponsor, age of trial participants and therapeutic area, many important opportunities remain to further explore, expand, and support family caregiver roles.

As national discussions about medical product development increasingly take on patient and family-centered values, new opportunities have emerged to reimagine the clinical trial process through a family-centered lens. Understanding the critical role that clinical trial enrollment diversity has on the health of communities and research alike, NAC became interested in the roles that family caregivers play in clinical trials recruitment, as well as how researchers could better engage patients, caregivers and families most impacted by structural inequities in the research and development of products that touch their lives.

Engaging diverse caregivers and families in research is critical to engaging diverse patients. Diverse caregivers have answers to how researchers and innovators, sponsors, trial sites, providers and other stakeholders can develop synergistic relationships with communities and families that bring value to the medical product development process and the research, products, and people involved.

As research communities expand their approaches to increasingly recognize family roles, integrating caregivers into clinical trial processes is just one approach to promote better access to clinical trials by underserved and underrepresented patients. Better engaging caregivers offers an additional opportunity – the chance to explore and begin to leverage the full value of caregivers' own preferences, needs and knowledge related to clinical research.

At NAC, we envision a society that *values*, supports, and empowers family caregivers to thrive at home, work, and life. Recognizing the value – the contributions, the expertise, the health impact – of what caregivers do, as partners in innovation, is a key part of creating a more equitable, person and family-centered health care system.



Engaging diverse caregivers and families in research is critical to engaging diverse patients.



ROUNDTABLE SERIES PARTICIPANTS

This report was written following a series of three convenings held November 23, 2021, November 30, 2021 and December 15, 2021. The first convening included caregiver experts and was facilitated by the National Alliance for Caregiving and Health Leads. The second convening included clinical trial experts and was led by the National Alliance for Caregiving. The final convening was a design session featuring both caregiver experts and clinical trial experts and was facilitated by the National Alliance for Caregiving and Health Leads.

The National Alliance for Caregiving extends appreciation to all who participated in this series of convenings.

1 NOVEMBER 23, 2021 | CAREGIVER EXPERT ROUNDTABLE

Participants

Amy Aikins	Edna B. Williams	Kevin Carter	Parvathy Krishnan
Careen Williams	James Taylor	Mary Overfield	Sheila Collins
Cathy Salazar	Jon Strum	Meg Comeau	

2 NOVEMBER 30, 2021 | CLINICAL TRIAL EXPERT ROUNDTABLE

Moderator

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3 DECEMBER 15, 2021 | CLINICAL TRIAL AND CAREGIVER EXPERT ROUNDTABLE

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Careen Williams

Carmen White

Cathy Salazar

David Banda

Jon Strum

Leonore Okwara

Mary Overfield

Meg Comeau

Parvathy Krishnan

Sika Dunyoh

Susan Manoff

Tesheia H. Johnson



INTRODUCTION

In 2019, the National Alliance for Caregiving (NAC) released a first of its kind report in partnership with Leaders Engaged on Alzheimer's Disease (LEAD Coalition), [*Paving the Path for Family-Centered Design: A National Report on Family Caregiver Roles in Medical Product Development*](#).

In this report, the term “caregiver” and “care partner” refers to “a family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation,” as defined in the RAISE Family Caregivers Act.

In this report, the terms “care recipient” “patient” and “participant” refer to individuals receiving care and/or participating in a clinical trial.

Observing how shifts in cultural expectations, advances in technology and patient-driven policy changes had expanded opportunities for patients’ perspectives to shape biomedical research and development, NAC in partnership with the LEAD coalition hosted a multi-stakeholder summit to discuss opportunities for caregivers to participate in patient-focused medical product development.

This report affirmed that family caregivers should be included in emerging opportunities in patient-focused medical product development because of their key roles in medical decision-making and other health care tasks. It identified four key caregiver perspectives and roles as they relate to the care recipient:

- **Observer:** As an observer, the caregiver makes independent observations about signs, events, and/or behaviors related to the patient’s health condition. These observations do not require any medical judgement or interpretation.
- **Reporter:** When serving as a reporter, the caregiver captures information about symptoms, functional capacity, signs, events, and/or behaviors related to the patient’s health condition. In this role, reports may combine the patient’s own expressions and the caregiver’s observations. This role may be especially important in conditions where the patient’s self-perception, memory, and/or ability to communicate is impaired, compromised, and/or has not yet developed.
- **Surrogate:** As a surrogate, the caregiver substitutes for the patient, providing information about the patient’s condition or perspective based on what the caregiver has heard directly from the patient or understands to be the patient’s own experience or viewpoint.
- **Proxy:** The role of proxy involves more agency of the caregiver acting on behalf of the patient, which may be legal authority (such as authority conveyed through a medical power of attorney or being the legal parent/guardian of a minor child or other dependent) or simply the person who best knows the patient’s wishes or values. As a proxy, the caregiver may interpret circumstances through their prior interactions, such as, “This is what I believe he/she would want, based on decisions made in the past.”

The report also identified key opportunities where caregivers could inform medical product development at different points in the process:

- **Discovery & Pre-Clinical Phase**
 - Caregivers can provide meaningful observations to help build a holistic understanding of the natural history of a condition
 - Caregivers can be valuable partners in selecting trial endpoints, patient reported outcomes (PROs) and observer-reported outcomes (ObsROs)
 - Caregivers can provide guidance and recommendations on protocol design, informed consent content and processes, and recruitment and retention strategies

- **Phase 1-3**

- Caregivers can provide input on protocol design, informed consent content and processes, and recruitment and retention strategies
- Caregivers can contribute perspectives as an observer, reporter, surrogate, and/or proxy or may contribute their own independent preferences and perceptions of clinical benefit
- Caregivers can serve on data safety monitoring boards, and assess proposed communications with potential and enrolled clinical trial participants and caregivers

- **Regulatory Review**

- Caregivers can provide support to regulatory meetings by articulating unmet medical needs and desirability of benefits
- Caregivers may contribute valuable perspectives to packaging and patient-facing materials being developed

- **Post-Approval**

- Caregivers can contribute to evidence collection and other surveillance activities
- Caregivers may contribute to shared-decision-making tools related to initiating therapy and adherence

The opportunity for caregivers to provide input on recruitment and retention strategies, identified by summit participants as described above, is now a key focus of the current project described in this report.

Since 2020, the COVID-19 pandemic has highlighted and amplified structural weaknesses in America's healthcare system, including inequities in access to health services, information, technology, and resources. Subsequently, the imperative to better engage families and caregivers from populations most impacted by structural inequities in healthcare became clear. In November of the same year, the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), issued guidance, "[Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment, Practices, and Trial Designs Guidance for Industry](#)", to promote increased clinical trials enrollment of underrepresented populations. Emerging health equity commitments such as BIO's BIOEquality Agenda and PhRMA's Equity Initiative from medical product innovators, and research initiatives such as the *All of Us* Research Program and UNITE initiative from the National Institutes of Health, demonstrate a growing commitment to considering practices that promote health equity through greater diversity in the biomedical research enterprise and clinical trial enrollment. Drawing from these efforts and others, NAC's project took shape, aiming to mobilize NAC's network of researchers, policymakers, innovators, patients, families and caregivers to take the next steps to understand and develop caregiver-informed recommendations for including diverse patients, caregivers and families in clinical trial processes. In collaboration with Health Leads, NAC led a series of three meetings with stakeholders to discuss and develop strategies for improving how researchers engage caregivers from populations most impacted by structural inequities in order to better understand how to increase representation of diverse patients in clinical trials.

Convening in Fall and Winter of 2021, this series of three roundtables began by engaging a diverse group of caregivers to share their perspectives on the roles caregivers currently play in clinical trials, the value of caregivers bring to clinical trials, and obstacles experienced by patients and caregivers in clinical trials. Clinical trial experts met next, hearing first the key themes raised by caregivers, and going on to discuss current strategies for engaging diverse caregivers and families in clinical trials, defining current roles of family caregivers in clinical trials recruitment and identifying opportunities to include or expand the role of family caregivers in clinical trials recruitment. Finally, a subset of the caregiver expert roundtable and clinical trial expert roundtable met once more to review the shared values and themes that emerged from the previous convenings and co-generate recommendations for better-integrating caregivers into clinical trial processes. This report contains summaries of these individual roundtables as well as the recommendations co-developed by caregivers and clinical trials experts.

The opportunity for caregivers to provide input on recruitment and retention strategies is the key focus of the current project described in this report.

Learn more about these initiatives at:

bio.org/bioequality-agenda

phrma.org/Equity

allofus.nih.gov/

nih.gov/ending-structural-racism/unite



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CAREGIVER EXPERT ROUNDTABLE

A diverse group of 11 caregivers with a range of experience with clinical trials from no experience to the completion of multiple clinical trials were convened by Health Leads and NAC.

“When my late sister had Lupus, we were looking for information on clinical trials. My mom was afraid of the risks. Mom’s preference was to try alternative medicine.”

—Sheila Collins

“I had to travel over 2,000 miles with a sick child to a clinical trial testing site multiple times.”

—Cathy Salazar

“I want to know the commitment - how long is the trial. Is this something that we can even do?”

—Amy Aikins

“Most families aren’t searching for clinical trials, so the ability to have appropriate outreach and recruitment needs to happen for those groups. You can’t participate in what you don’t know about.”

—Jon Strum

“To get more information, I will say, sometimes you hear about a trial when it’s not even on clinical trials.gov. So, you go online and you look, and you know as a parent who’s waiting to try and enroll in something like this you’re excited I mean you might keep going back over and over again until finally it pops up and then you find... oh geez it’s in California and I live in Pennsylvania and then it’s like; what do I do here?”

—Amy Aikins

These caregivers served as experts, drawing on their lived experience and expertise and contributing their knowledge and insights. Caregiver experts were diverse in their age, gender, race, geographical location, and relationship to the person they provided care to. They had a range of experience with participating in patient and caregiver advocacy from no experience to significant volunteer and professional involvement. Key insights and potential direction provided by these caregiver experts are outlined below.

PURPOSE OF THE ROUNDTABLE

The purpose of the roundtable was to confirm the roles caregivers currently play in clinical trials, highlight the value of caregivers in clinical trials and unearth obstacles experienced by patients and caregivers in clinical trials. The roundtable discussion focused on:

- Defining caregiver roles in clinical trials;
- Understanding how caregivers access information about trials;
- Discussing factors caregivers consider in making decisions about clinical trial opportunities or other care choices;
- Understanding supports caregivers need to join and/or remain a part of trials;
- Discussing fears or concerns caregivers may have about clinical trials or other treatments.

THEMED RESPONSES AND KEY INSIGHTS

Information Seeking

Caregiver experts responded to questions about the kinds of information they sought in relation to clinical trial opportunities.

Responses included:

- Logistics of the trial: cost, location, length, inclusion and exclusion criteria
- An understanding of the screening process
- Will the treatment be harmful and what are the risks
- Number of required visits to the trial site
- The testing or trial site proximity to home (near, far)
- Alternative structures that are not necessarily pharmaceutical based (alternative medicine options)

“ Many trials are significantly delayed because it takes so long to recruit the desired number of participants...”

– James Taylor

“ We couldn't even find it on clinicaltrials.gov at least because we were so unaware of what to look for. The doctor told us about a black box warning so, then I went down that rabbit hole of like what does that mean, and then, I looked and then I was like oh my God.”

– Parvathy Krishnan

“ The tool comes back with the clinical trials that are in your geographic area, if you're willing to travel five miles, twenty miles. We ended up driving two hours each way for the trial that we eventually got in, but the problem is with this tool that it gives you a description of 10 or 15 or three clinical trials in your geographic area.”

– James Taylor

“ You may not be aware, but blacks develop Alzheimer's at twice the rate of Caucasians like myself and Hispanics at one and a half times the rate of whites and they're often the least served. They are diagnosed later in the development of the disease and therefore harder to get into clinical trials which are more often directed at early to mild stage as opposed to mild to moderate so those are some of the challenges, we have in recruiting individuals with Alzheimer's.”

– James Taylor

“ I heard frequently.... they're going to be hopeful; and so, they're going to participate, hoping that, even if it's a double-blind placebo-based study, they're going to be in the group getting the drug; and so maybe they're going to get better, and when there are no options, that's a good option.”

– Jon Strum

“ It was the only way to save her life, with the medical device, and so we literally had nowhere else to go...”

– Cathy Salazar

“ My husband just dropped out of the clinical study about a month ago, because he said at the time he didn't see the point anymore. Whereas when he entered it three years ago, he saw that he was contributing to scientific knowledge, and that he was going to help other people. There wouldn't be any direct benefit to him, but he could see sort of from an altruistic standpoint what the rationale was. His disease progression has meant that his capacity for empathy has changed significantly. It's just not there anymore, and so, for him all of those reasons for entering the trial, to begin with changed...”

– Meg Comeau

Obstacles to seeking or obtaining information about clinical trials were also discussed.

Responses included:

- Digital tools used to search for clinical trials are not comprehensive (e.g. clinicaltrials.gov)
- The clinicaltrials.gov site causes anxiety for some (hard to find certain rare disease trials)
- Clinical jargon and inaccessible reading levels make it difficult to understand terms of clinical trials
- Pre-existing conditions can be a barrier
- Access to care, screening, testing and diagnosis
- Individuals with disabilities and special needs may be unable to participate in a clinical trial due to a lack of accommodations
- Health care providers lack awareness of clinical trials
- People of color are not aware of or offered the opportunity to participate in clinical trials for diseases that impact communities of color at disproportionate rates

Decision Making and Participation

Caregivers responded to questions about the decision-making process around participating in clinical trials including motivation to enroll and other significant factors.

Responses included:

- To find a cure for themselves and family members who may be susceptible to a disease
- A desire to help others by contributing to research (driven by faith-based and/or agnostic personal belief systems)
- In hopes that other families do not have to face similar obstacles
- Caregivers' reasons may differ because their responsibilities and priorities vary depending on the age of the person being cared for and the disease
- A person's reason for initially joining a trial may change over time as their circumstances change or the disease progresses
- Reasons may range from cure to contributing to general research for the medical field

“ I really wanted to do the study, but I realized that there were no provisions made for my son, who has anxiety, and who would not do blood work every week, and so as a result, I had to withdraw from the study.”

– Careen Williams

“ The information is so complex that you're bound to think that you're going to die taking those medicines, even though you know that it's for saving us, I feel like there's definitely a disconnect between what it intends to do versus trying to cover everything it could possibly have side effects for that skew our perception of the trial itself.”

– Parvathy Krishnan

“ So I would say that the side effects are the biggest obstacle in any clinical trial that we've been involved in...it is the side effects and because every trial we've ever been in is a double blind, so we do not know if our daughter is getting a placebo or an actual medication that they're trialing.”

– Caregiver Expert

“ We were told that she was only going to need surgery probably twice a year and that didn't end up being the case, she ended up having surgery probably about four times a year for about six of those years and so the back and forth was extraordinarily hard, we were very fortunate to have access to a Medicaid waiver that helped pay for the travel...”

– Cathy Salazar



Obstacles and fears regarding clinical trial participation were also explored.

Responses included:

- Concern of being in a placebo group and not receiving treatment or receiving delayed treatment; when participating in double-blind clinical trial with placebo vs medication, patients are not made aware of whether they are receiving placebo or treatment
- Balancing quality of life for patients with the burden and risks of study participation
- Lack of children's hospitals near home (e.g. rural areas)
- Lengthy trial could discourage patients/caregivers from completing the trial as well as unanticipated barriers and cost associated with their participation
- Limited, loss of, or no access to financial resources (e.g. travel vouchers, paid care, Medicaid resources)
- Large packets that include medical terminology can intimidate patients and caregivers
- Not making clinical trials accessible by making accommodations for people with disabilities and special needs at each step of the clinical trial
- Lack of clinical trial resources for rare diseases that impact people of color as a majority
- Number of consent processes and forms to sign whenever a change of care is presented
- Concern about potential side effects
- Limited or no awareness of clinical trial opportunities

Throughout this initial discussion, caregiver experts identified solutions and generated initial recommendations for how sponsors, clinical trial sites, health systems and other stakeholders could begin addressing many of the challenges that were discussed. These initial caregiver recommendations are included below and center on three themes: communication, access and collaboration.

Communication:

- Information about trials should include lay terminology and be written at a reading level that is understandable by most people
- Establish an open-ended process on what the clinical trial procedure can look like, especially for medical devices (e.g. how many surgeries, side effects etc.)
- Present information on trials visually, using multimedia formats like videos that walk people through the entire process

- Give practical and tangible measures or examples to help families understand medical concepts (i.e. What does a vial of blood look like visually so patients can understand - do this in tandem with required consent documents)
- Participating in clinical trials can be a large endeavor and, in many cases, a very new experience for some families, therefore clinicians should develop better ways of communicating to families that clinical trials are based on science and research to reduce fear and participation hesitancy
- Provide support to caregivers of minors and other dependents to help them explore and determine assent when consent cannot be [given](#)



Access:

- Digital recruitment tools should be restructured to allow people to make appointments
- Digital recruitment tools should allow professionals and community members to provide recommendations for clinical trials
- Make accommodations for people with disabilities and special needs
- Increase primary care and physician awareness and confidence in trials to increase early referral - this could position physicians as trusted entities to educate and make patients and families aware of clinical trial opportunities
- Health disparities experienced by African Americans were noted multiple times and the need to explore solutions that increase African American involvement in clinical trial participation was highlighted
- Increase opportunities for decentralized clinical trials (trials where activities are partially or fully conducted in a home or setting convenient to the participant)
- Gene testing may increase clinical trial participation of individuals with an elevated risk of developing a disease
- Make provisions for dissemination of information outside of tech/digital spaces; digital only does not equal equity
- Utilize hospital social workers as a referral resource

Collaboration:

- Incorporating patients and caregivers as a part of the clinical trial design can better address communication and language barriers (*This has been a step successfully taken with one participant's clinical trial process as it relates to Alzheimer's disease*)
- Ensure caregivers are a part of the research design team from beginning to end, including design, recruitment, data collection, and dissemination of clinical outcomes
- Clinical trial investigators (physicians) should be a part of the design process

Participating in clinical trials can be a large endeavor and, in many cases, a very new experience for some families.



2

CLINICAL TRIAL EXPERT ROUNDTABLE

The National Alliance for Caregiving convened a roundtable of clinical experts that included NAC and Health Leads staff along with representatives from federal agencies including the National Institutes of Health (NIH) and Food and Drug Administration (FDA).

The purpose of the roundtable was to convene experts from the private and non-profit sectors as well as representatives from federal agencies to discuss strategies to promote the inclusion of family caregivers most impacted by structural inequities in the clinical trials process.

Non-profit and private sector representatives participated as well, including AARP Public Policy Institute, Amgen, Arcadia University, Association of Black Researchers, Avanir Pharmaceuticals, BIO, Black Women's Health Imperative, Children's National Hospital, Children's National Medical Center, Clara Health, Eastern Virginia Medical School, EMD Serono, EveryLife Foundation for Rare Diseases, Merck, National Health Council, National Minority Quality Forum, National Patient Advocate Foundation, Takeda, The Arc, The Children's Inn at NIH, THREAD, Pfizer, Travere Therapeutics, University of Alabama at Birmingham, University of Illinois at Urbana-Champaign, USAgainstAlzheimer's and Yale Center for Clinical Investigation. Key suggestions and potential direction provided by participants are outlined below.

PURPOSE OF THE ROUNDTABLE

The purpose of the roundtable was to convene experts from the private and non-profit sectors as well as representatives from federal agencies to discuss strategies to promote the inclusion of family caregivers most impacted by structural inequities in the clinical trials process. The roundtable discussion focused on:

- Responding to key themes and initial recommendations generated by caregiver experts in the previous roundtable;
- Sharing current strategies to engage diverse caregivers and families in clinical trials;
- Defining current role(s) of family caregivers in clinical trials recruitment; and
- Identifying opportunities to include or expand the role(s) of family caregivers in clinical trials.

THEMED RESPONSES

Value of Inclusion

Clinical trial experts discussed the importance of including diverse caregivers in research.

Responses included:

- Patients may require caregiving
- Caregivers are navigators and referral sources who help patients make decisions about care including clinical trial enrollment
- Family member inclusion in clinical trials processes such as the consent process may be culturally desired and valued

- Including family caregivers in research makes research more accessible to underrepresented communities
- Caregivers are advocates for their care recipients and care team members who help patients overcome barriers to remaining part of trials

Sponsor Roles

Clinical trial experts discussed potential roles sponsors could play to assist caregivers and researchers to connect patients and families with appropriate clinical trial opportunities.

Responses included:

- Ongoing engagement with communities and primary care providers
- Designing materials that help caregivers understand their specific roles and inputs in a clinical trial
- Including caregiver burden considerations in participant reimbursement/budget

Supporting Caregivers

Clinical trial experts discussed ideas for how various stakeholders could support caregivers before and during a clinical trial.

Responses included:

- Begin considering family caregiver roles in the design phase
- Consider family living situations in protocol design
- Developing communication materials that specifically target caregivers
- Integrate healthcare coverage support into the development of clinical trials
- Provide appropriate compensation for caregiver's time helping patients participate in trials and for acting as research advisors and stakeholders

Trust

Clinical trial experts discussed what was needed to build trust between families and caregivers and the research community.

Responses included:

- Taking a patient and family-centered approach
- Matching the language style and literacy level of caregivers in communications with caregivers and families
- Engaging caregivers early, when input they may share can be acted upon and make a difference

Opportunities to Integrate Caregivers

Clinical trial experts discussed potential opportunities to better integrate caregivers into clinical trials.

Responses included:

- Including caregivers in patient panels, listening sessions and/or other opportunities where they can provide their preferences and practical feedback
- Including caregivers in the informed consent process, where appropriate
- Exploring flexibilities in trial design that meet families where they are: digital engagement and telehealth, home visits, alternative meeting or care locations that are trusted (e.g. church)



KEY TAKEAWAYS

The following takeaways summarize the roundtable discussion by clinical trial experts:

- Caregivers make vital contributions to clinical trials in roles distinct from the patient;
- Caregivers need targeted information and support to care for someone in a trial; and
- Engaging caregivers and their input in trials is critical to trust-building and enabling access by diverse patients/participants.



3

CO-DESIGN SESSION WITH CAREGIVER EXPERTS AND CLINICAL TRIAL EXPERTS

With the shared themes and values from the previous two convenings in mind, a subset of caregivers from the first convening and clinical trial experts from the second convening met to co-develop solutions for better-integrating caregivers into clinical trials processes. Caregiver-informed recommendations are included below.

Shared Values

Diversity
Equity
Inclusivity
Patient and family-centered
Access and accommodation
Flexibility

Recommendations

Participants generated and prioritized recommendations that addressed the engagement of diverse caregivers during three stages of clinical trials: before a trial begins (the pre-trial stage), during trial implementation (the implementation stage), and after a trial is completed (the post-trial stage).

The three major themes that evolved around each stage were:



PRE-TRIAL STAGE RECOMMENDATIONS

To address the problem of recruiting more people from underrepresented communities, participants were asked to ideate around trust and relationship building with community.

Establish and Nurture Relationships.

- Build genuine relationships with partners that have established trust with the community (e.g. ministries and community health programs) and meet people where they are
- Developing relationships with community-based organizations that have the trust of populations that may be difficult to reach (e.g. people experiencing homelessness) can enhance access
- Intentional grassroots outreach efforts by health care professionals to directly serve the community (e.g. mobile units)
- Share resources with participants and caregivers, outside of the research process
- Engage with diverse caregivers when a product is being designed to understand their needs and their care recipient's needs, so the new product can help to meet those needs

Develop Infrastructure.

For clinical trials in general

- Create a peer referral program where caregivers can serve as advocates and navigators for other families like them to engage in trials, spread word about new trials, and share resources and information
- Educate primary care doctors and referral sources on implicit bias to improve referral of underrepresented patients to clinical trials
- Increase pipeline of healthcare providers and team members of color
- Focus on diverse professional recruitment in the industry so that the clinical team represents the diversity of clinical trial participants (diverse defined broadly and includes race, ethnicity, gender identity, sexual orientation, languages spoken)
- Support and educate medical students/residents so they are open to discuss clinical trials with families during their training and subsequent careers



For a specific clinical trial

- Establish a committee that would oversee designing the educational and campaign materials, include everyone from community members to those involved in lab specific work
- Researchers should host a community forum at the design stage, where they speak to the community about complex terms. Community can give insight on how best to word information when recruiting.

Focus on diverse professional recruitment in the industry so that the clinical team represents the diversity of clinical trial participants.

Design Inclusive Communication Tools.

- Use communication methods that explain the clinical trials process from beginning to end
- Materials should be in a format that is easily understood and should use less industry language with more infographics
- The average person should be able to walk away understanding each clinical trial step. This can be done by mapping out the entire process from pre to post trial. Materials should be co-designed with and for all audiences involved, including care partners, patients, families, and health care providers
- Communication efforts should provide language translation services, this helps to expand the inclusion of underrepresented populations
- Design separate information materials for patients, care partners, and families so that information about a trial addresses their unique roles and needs
- Be transparent and manage expectations during outreach/recruitment by including information on whether or not treatment could continue post-trial, and how much/what kind of information will be shared regarding the trial's outcome and/or next steps

Create appropriate ways to support trial participation that do not involve traveling to a physical site, explore telehealth for some visits.

Involve caregivers in communication channels so that there is an understanding of the needs and obstacles.



IMPLEMENTATION STAGE RECOMMENDATIONS

Participants were asked to focus on the supports and other resources caregivers needed during a clinical trial to cultivate and maintain an inclusive environment where all caregivers could participate and contribute their expertise.

Building Relationships.

- Remove the hierarchy from the process by creating contexts where everyone is an expert regardless of their educational level
- Lived experience is just as important in ensuring that a clinical trial is successful

Design Infrastructure.

- Clinical trial experts must consider the social determinants of health of families, for example, consider transportation costs to get to and from trial sites
- Consider caregiver needs to support their participation in clinical trials. Make resources available to relieve them of caregiving duties (e.g. for the trial participant or others they may provide care to including children) during times when they may be involved in trial-related meetings or activities
- Be flexible and address barriers as they arise; needs can change while in the trial
- Establish a peer-to-peer support group of people who have taken part in clinical trials where they provide info to interested caregivers who may have questions or hesitations
- Create appropriate ways to support trial participation that do not involve traveling to a physical site, explore telehealth for some visits

Effective Communication.

- Clinical trial experts must explain to patients what happens with their information
- Involve caregivers in communication channels so that there is an understanding of the needs and obstacles

- Provide caregivers with an estimated timeline of the trial and explain what their requirements will be
- When there are consent or assent changes, highlight what the changes are and explain to the caregiver and participant
- Include information on assent for when caregivers are going to be involved in trial participation
- Invite caregivers to be a part of the conversation when trial options are introduced to patients



POST-TRIAL STAGE RECOMMENDATIONS

Participants were asked to focus on integrating caregivers into post-clinical trial activities related to accountability, follow-up, clear communication methods, and culturally appropriate translation of information.

Continuing Established Relationships.

- It is important to emphasize the need to maintain those relationships with the community including community-based organizations (CBOs) and community centers well after the trial has been completed
- Conduct outreach to caregivers related to the condition - this could vary for parents/legal guardians vs partner/spouse, caregiver/loved one, adult/child
- Build a community of clinical trial participants to help inform of upcoming clinical trials

Reflect on the Design Process.

- A team should be established to follow up with participants for recommendations and referrals
- Share information about the clinical outcomes of the trial
- Collect and share information about what researchers learned from the patients and care partners in working with them, especially in terms of lived experience
- If a trial was stopped before completion, provide info to participants about why it was stopped

Keeping Communication Channels Open.

- The post clinical trial stage should contain a continuous feedback loop that allows the caregiver and patient to give feedback on their clinical trial journey to inform how future protocols and inclusion criteria considerations are developed and implemented
- Ongoing communication to participants and care partners regarding how their contributions impacted the research goals/objectives
- Depending on the results with each participant, strict follow-up should be enforced for a period of time to ensure that the participants are receiving the necessary resources or help needed after the trial has ended
- When there is consent for caregivers or as applicable, creation of a closeout document or plain language summary
- Send a thank you note or acknowledgement of caregiver engagement post-study

It is important to emphasize the need to maintain those relationships with the community well after the trial has been completed.



SUMMARY AND CONSIDERATIONS

The personal and professional experiences, insights and ideas shared by participants in all three roundtables highlighted the complexity of the clinical trial process for clinical trial teams and families alike.

Many caregiver-informed recommendations were developed, with an emphasis on the importance of:

- **genuine relationships**
- **clear and inclusive communication**
- **accessible design infrastructure**

Many caregiver-informed recommendations were developed, with an emphasis on the importance of **genuine relationships, clear and inclusive communication and accessible design infrastructure**. Recommendations included practical approaches and concepts that can be acted on by a range of stakeholders from individual, community and systems levels.

INDIVIDUAL-LEVEL FOCUS AREAS

Roundtable participants identified key focus areas for individual-level recommendations where **primary care and other providers, caregivers, patients** are positioned to take next steps:

- Outreach to provide resources and services to community members
- Caregiver peer support, referral and information sharing
- Provider referral and information sharing
- Adopting communication inclusive of caregiver and family health literacy level, literacy level, and language needs and preferences in communication style and method (e.g. spoken/written, fast paced/slow paced, virtual/in-person)

COMMUNITY-LEVEL FOCUS AREAS

Roundtable participants identified key focus areas for community-level recommendations where **sponsors, health systems, community-based organizations (CBOs)** are positioned to take next steps:

- Initiating, developing and maintaining relationships between sponsors, CBOs, other trusted community institutions, local and regional health systems
- Designing caregiver-targeted communications that address caregiver needs and roles

Roundtable participants identified key focus areas for individual-level, community-level and systems-level focus.

SYSTEMS-LEVEL FOCUS AREAS

Roundtable participants identified key focus areas for systems-level recommendations where **universities and medical schools, public health agencies, federal regulatory agencies, policymakers, public and private healthcare payers** are positioned to take next steps:

- Educate medical students and providers about implicit bias to improve referral of underrepresented patients to healthcare services including clinical trials
- Increase education and professional pipelines to promote broad workforce diversity in medicine and healthcare, clinical research and medical product development
- Promote the development of patient/family compensation policies and practices that consider family situations and enable appropriate compensation for caregiver time helping patients participate in trials and for acting as research advisors and stakeholders
- Remove healthcare coverage barriers that prevent beneficiaries from participating in clinical trials due to real or perceived limitation/loss of coverage or inadequate coverage and/or restricted access to screening and testing

Promote the development of patient/family compensation policies that consider family situations

A FINAL NOTE

Engaging caregivers more effectively in the clinical trials process is one strategy for advancing clinical trial enrollment diversity. But ensuring families, including caregivers from diverse backgrounds are engaged in clinical trials requires investment and collaboration from not only industry partners and sponsors but also from federal regulatory agencies, policymakers, healthcare leaders, community care providers and patients and caregivers themselves. Reimagining recruitment, through a patient and family-centered care lens, offers insights on the kinds of multistakeholder partnerships and coordinated efforts needed to align science-driven and health-equity goals in advancement of a more equitable, family-centered care system.



Multistakeholder partnerships and coordinated efforts are needed to align science-driven and health-equity goals in advancement of a more equitable, family-centered care system.



National Alliance for Caregiving

About the National Alliance for Caregiving

NAC's mission is to build partnerships in research, advocacy, and innovation to make life better for family caregivers. Our work aims to support a society which values, supports, and empowers family caregivers to thrive at home, work, and life. As a 501(c)(3) charitable non-profit organization based in Washington, D.C., we represent a coalition of more than 60 non-profit, corporate, and academic organizations; nearly 40 family support researchers with expertise in pediatric to adult care to geriatric care; and more than 50 advocates who work on national, state and local platforms to support caregivers across the United States. In addition to our national work, NAC leads and participates in a number of global meetings on caregiving and long-term care, working closely with peer organizations from more than a dozen nations. Learn more at www.caregiving.org.

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