
# TACKLING BARRIERS TO CLINICAL TRIAL DIVERSITY

## FINDINGS FROM A COLLABORATION AMONG COMMUNITY-FOCUSED ORGANIZATIONS IN INDIANA

### Abstract

This is the final report for the Indiana Community-Focused Research Organization (CFRO) Board project. It contains an overview of and key learnings from an 18-month project in which Lilly and NEHI partnered to form a community-focused board comprising organizations in Indiana to develop and pursue a project to overcome barriers to clinical trial diversity.

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Submitted by NEHI-The Network for Excellence in Health Innovation
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# Contents

# Executive Summary

Clinical trials are a necessary part of the research required to evaluate the impact of interventions, such as drugs and devices, on health. However, most clinical trials fail to adequately enroll individuals from racially and ethnically diverse backgrounds. This report describes work that Eli Lilly and Company (Lilly) and The Network for Excellence in Health Innovation (NEHI) completed together to improve diverse participation in clinical trials and advance health equity. From 2022 through 2024, Lilly and NEHI (the Core Team) convened leaders from organizations in Indiana that shared this goal. This group identified barriers to clinical trial participation from a range of perspectives, identified ways to overcome those barriers, and implemented a solution to an issue they prioritized (the need to provide additional knowledge and awareness about clinical trials to diverse communities in Indiana through messengers that those communities trust).

## Project Overview

During this project the Core Team formed the Community-Focused Research Organization (CFRO) Board, comprising leaders from community-based organizations, research organizations, health care providers and insurers, and pharmaceutical companies in Indiana. The Board tested the hypothesis that a group of this design could, with facilitation from the Core Team, organize itself, align on a set of goals and priorities, test solutions, and uncover key learnings for future community-based initiatives. The project plan included the following key milestones:

**Form CFRO Board**
NEHI conducted 26 interviews with stakeholders in Indiana from many sectors. The Core Team invited these contacts to join the CFRO Board, which officially launched through its first meeting on August 29, 2022. We aligned on a Board Charter that would provide the governance and structure of the Board. We adopted the Board Charter on November 4, 2022.

**Discuss Barriers & Narrow Focus**
During the 1st CFRO Board meeting, the Board and Core Team discussed leading barriers to clinical trial diversity. In the following meeting, the Board narrowed its focus from an initial list of 13 barriers to 4 barriers.

**Organize Community Forums to Solicit Input**
After reaching consensus on 4 barriers to clinical trial diversity on which we may test solutions, the Board paused to solicit feedback from community constituents on the narrowed set of barriers and to get input on potential solutions to test. Board members organized 3 community forums to solicit this feedback.

**Discuss & Select Solutions**
Armed with feedback from 3 forums, the Board discussed potential solutions to the barriers it identified earlier in the process. After considering a list of potential solutions, the Board and Core Team aligned that it would test and measure the potential impact of a knowledge & awareness intervention delivered through trusted messengers.

**Launch & Carry Out Intervention**
The core activities conducted through the Knowledge and Awareness project were 1) creating a training focused on clinical trials and their impact on health equity; 2) recruiting and training trusted messengers (faith-based leaders in this instance) on those topics; and 3) facilitating the trusted messengers' transfer of this knowledge to their constituents.

**Document Process & Measure Impact**
At the conclusion of the project, the Core Team, supported by key Board members, documented the knowledge and awareness project process. In addition, the Core Team measured the impact and outcomes of the CFRO Board and the project.

Lilly's strong network and relationships with community organizations across Indiana and its financial support of the project were critical to this project's success. Its financial contributions funded the work of the Core Team as well as community organizations' activities in pursuit of the solution devised by the Board. The Core Team supplied the project with expertise in clinical trials, research, and project management. It also created the tools and materials necessary to complete each phase:

- Board charter and additional materials for facilitation of Board meetings and the Board's consensus- and decision-making processes.
- Agendas and presentations for community forums.
- Logic model and training materials for the Board's project.
- Survey tools and facilitation guides with participants and Board members to complete the evaluation of the Board and Board project.

## Outcomes:

During the project, we:

- Formed a board of 26 community leaders
- Aligned on key barriers to clinical trial participation and potential solutions
- Developed a project that tested one solution by working with faith-based leaders as trusted messengers to enhance clinical research awareness among diverse communities
- Completed the project, educating more than 100 community members on clinical trials and health equity, supported by training and resources from Lilly.

## Key Learnings:

We highlight the following key learnings, with further insights provided in our report:

- Addressing diversity in clinical trials necessitates the active involvement of various community leaders to identify and solve participation barriers. Success hinges on stakeholders' insights into regional health priorities and their commitment to the solutions.
- Trusted messengers, in this case faith-based leaders, effectively raised awareness about clinical trials within underrepresented communities, leveraging their experience and active role in project development.
- Engaging community members in conversations on clinical trial participation requires acknowledgement that, in many communities, basic health needs go unaddressed. The trusted messengers recognized that their communities desire information about a host of health and health care topics and that a program focused only on clinical trials may cause them to lose their audience.
- Projects of this nature require agility and sophisticated project management and facilitation throughout every phase. Taking direction from the Board and embracing changes in the project plan proved critical to the project's outcomes. Moreover, even a highly motivated and sophisticated group of community leaders requires significant support to pursue project work.
- A project plan should identify ways to mitigate lapses in engagement: Not all Board members remained equally involved in the work at the conclusion of the project. The Core Team concluded there were several reasons for this, including the seniority of the leaders involved, difficulty establishing a consistent meeting cadence, and our ability to define meaningful roles for participants given the focus of the project the Board selected to pursue.

## Conclusion

This project, while not a formal research project, adds to the evidence base around the need to strengthen community engagement in efforts to diversify clinical trials. Community leaders can identify priority challenges and create a forum for working together on an ongoing basis to test and evolve targeted and effective solutions.

## Introduction

In November 2022, Eli Lilly and Company (Lilly) and The Network for Excellence in Health Innovation (NEHI) pursued a project in Indiana to improve diverse representation in clinical trials. In this project, we formed a board comprising representatives from community-based organizations, research organizations, health care providers and insurers, and pharmaceutical companies. Together, this Board identified barriers to participation in clinical trials by underrepresented groups. We then identified ways to overcome those barriers and selected and tested a strategy for doing so. This report describes our project approach, key outcomes, and lessons learned.

## Background

Clinical trials are essential for assessing health interventions. The COVID-19 pandemic highlighted the need for diverse trial participants to ensure new treatments are effective across all groups. The Consolidated Appropriations Act of 2023 mandates that Phase 3 trial sponsors submit Diversity Action Plans to the FDA, detailing disease prevalence, subgroup distribution, enrollment targets, and strategies to achieve them[1].

There is ample documentation of disparities in clinical trial participation. Adult white individuals are typically over-represented compared to individuals who identify as Black, American Indian/Native Alaskan, Asian, Hispanic or Latino, and Hawaiian or Pacific Islander.[1] Women and older individuals are also often under-represented in research trials.[2,3] Fortunately, many stakeholders that influence clinical trial design are launching and strengthening efforts to address disparities in trial participation, including establishing research sites in non-traditional locations such as community health centers and pharmacies in diverse neighborhoods, developing greater diversity among investigators and associated staff, and establishing deeper relationships with community members and their trusted leaders.

In this project, we sought to build on these efforts. Our goal was to create a successful short-term strategy and, ultimately, sustainable relationships that may enable additional work to overcome barriers to diversify clinical trials. The outcomes and learnings from this project provide critical lessons in how to effectively engage and organize diverse community leaders and members to impact clinical trial participation.

# CFRO Board Process

The following sections describe the process the Core Team and CFRO Board used to achieve our goals and objectives. We describe this process at a high level and provide supplementary information in appendices at the end of the report.

## CFRO project launch

To provide structure to the collaboration we sought, the Core Team created what we called the Community-Focused Research Organization (CFRO) Board. Lilly's knowledge of and relationships with individuals and organizations in Indiana with an interest in and commitment to health equity was critical in helping to identify individuals representing multiple interests and populations who could populate the Board. NEHI also identified organizations through its network of stakeholders.

The Core Team considered individuals' ability to commit time to the project, their experience participating in advisory groups or other inter-agency collaborations, and their connections with others in the sector they represented (e.g., other health systems, academic institutions, and faith-based organizations). After identifying the initial target list, members of the Core Team sent formal invitations to approximately 30 community leaders, 26 of which agreed to participate. We clarified the scope of the project and Board members' responsibilities in a charter we developed and presented to the Board at its first meeting. (Board members formally approved the charter at their second meeting.) *Appendix 1. Recruitment and formation of CFRO Board* has additional details.

As part of the project launch, the NEHI team also conducted a literature scan of reported barriers to clinical trial participation. Barriers most often cited in the literature included lack of trust (both in the process and in the researcher) and access hurdles, comprising, among other things, physical access to trial sites, financial burdens, and restrictive eligibility criteria. NEHI team members also interviewed each Board member to get their initial thoughts on barriers, and in some cases, solutions to improving clinical trial diversity. Detailed findings from this literature scan can be found in *Appendix 2. Literature scan on barriers to diverse participation in clinical trials*.

## Orientation, discussion, and narrowing of barriers

To set the stage for the Board's project focus, the Core Team guided the Board through a multi-step process to 1) identify barriers to clinical trial diversity; 2) agree on the criteria they would use to prioritize those barriers; and 3) align on a narrowed set of barriers on which to focus. (See Figure 1.) The Core Team used the information it gathered in its literature search and through interviews as a basis for the Board's discussions.

Figure 1. Barrier identification, prioritization, and selection process


*Appendix 3. CFRO Board's process for identifying and narrowing focus on barriers* includes highlights from the Board's initial barriers discussion and the final criteria and voting exercise the Board used to narrow its focus to four key barriers.

## Four key barriers to participation in clinical trials

At the conclusion of the 2nd Board meeting, the Board agreed on four key barriers on which to focus:

- Need to address ongoing community concerns about being mistreated, experimented upon, or participating in research potentially harmful to them or without community benefit.
- Need for greater engagement and partnership between members of the community and researchers.
- Need to address patient financial burden, including time requirements, along with transparency in consent forms.
- Many individuals are not connected to health care, let alone clinical trials.

## Outreach to community constituents

Board members used their considerable experience to make judgments about where they should concentrate their energies in addressing barriers to clinical trial diversity. Nevertheless, they expressed discomfort in selecting a barrier on which their work should focus without first consulting with community members directly. Although this outreach was not part of the project plan, they asked the Core Team to support them in seeking direct feedback from community constituents.

The Board's desire to diverge from the original work plan at this stage was a key learning from this process. While the members of the CFRO Board represented a variety of perspectives and populations, their desire to return to their constituents has implications for future initiatives to address barriers.

Several Board members pursued opportunities to meet with and gather feedback from community members. With assistance from the Core Team, Board members held three community forums around the state of Indiana in early 2023.

*Appendix 4. Community forum summaries* documents findings from these sessions.

In all three forums, community members referenced knowledge and awareness of clinical trials as a key area requiring more attention. These forums were critical to the project, both in terms of engaging the Board and their constituents and in solidifying the barriers and solutions on which the Board would focus.

## Discussion of potential solutions

During its 3rd Board meeting, Board members noted that it is critical for people to gain more information about clinical research and to understand why participation in clinical trials is important, especially in the context of advancing health equity. Indirectly, this conclusion reflected the earlier discussion of barriers that focused on trust and the need to explain how clinical trials benefit community members.

The Board, informed by community forums and research, deliberated on strategies to diversify clinical trial participation (see ***Appendices 4: Community forum summaries and 5: Literature scan on potential solutions to improving diverse participation in clinical trials***), focusing on improved training for clinicians, community worker involvement, and enhanced diversity in visible research roles.

## Select solution and formulate project plan

The Core Team streamlined the decision on the Board's strategy by applying criteria of time, resources, reach, and impact. Given the time spent on community feedback, they prioritized adhering to the original timeline, opting to shape the solution pilot without further meetings while attending carefully to the Board's vision.

For the Board's final consideration, the Core Team proposed that the Board pursue an intervention that would aim to improve community members' knowledge and awareness of clinical research by relying on trustworthy messengers to deliver relevant content. This solution embraced feedback from the forums, which indicated that community members desire to learn about clinical trials and trial opportunities through trusted community messengers, role models, or messengers that share aspects like lived experience, race, and/or cultural beliefs.

In a 4th meeting, the Core Team structured its proposal to the Board as follows:

**Goal:** Improve knowledge of clinical trials in three (3) communities using three (3) different trusted community messengers.

**Project objectives:**

- Recruit and onboard three (3) trusted community messengers to reach approximately 100 participants each.
- Increase supportive knowledge, awareness, and resources of clinical trials of three (3) trusted community intermediaries.
- Increase basic knowledge and awareness about clinical trials in three (3) specific communities.

Short-term outcomes:

- Increased knowledge of clinical trials/ research (general) and benefits by community participants
- Improved attitudes toward clinical trials by racial and ethnic minority community group members

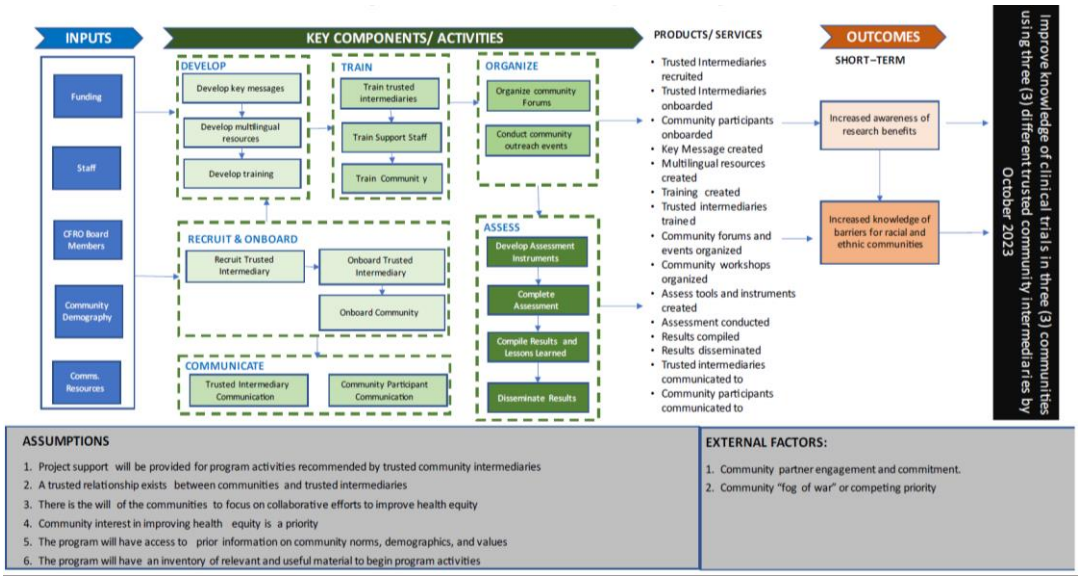
Knowledge and Awareness project phases:

To provide the Board with the full vision of how we would execute against our goal and objectives, the Core Team, over several meetings, iterated the project approach, which we organized into five project phases; we created a logic model to frame the project plan. (See Figure 2.) The five project phases were:

1. Recruit and onboard trusted messengers to the project.
2. Develop key messages and training materials.
3. Train trusted messengers and, if applicable, their support staff.
4. Organize community forums and conduct outreach and education events.
5. Assess the project outcomes against the established goals.

Finally, the Core Team developed a plan to engage Board members in each project phase, either by leveraging their direct contacts with community members or applying their expertise to key components of the project (e.g., developing training materials, assessing outcomes and impact). These opportunities are included in more detail in the 4th Board meeting materials.

Figure 2. Knowledge and Awareness project logic model




## Confirm solution and launch pilot

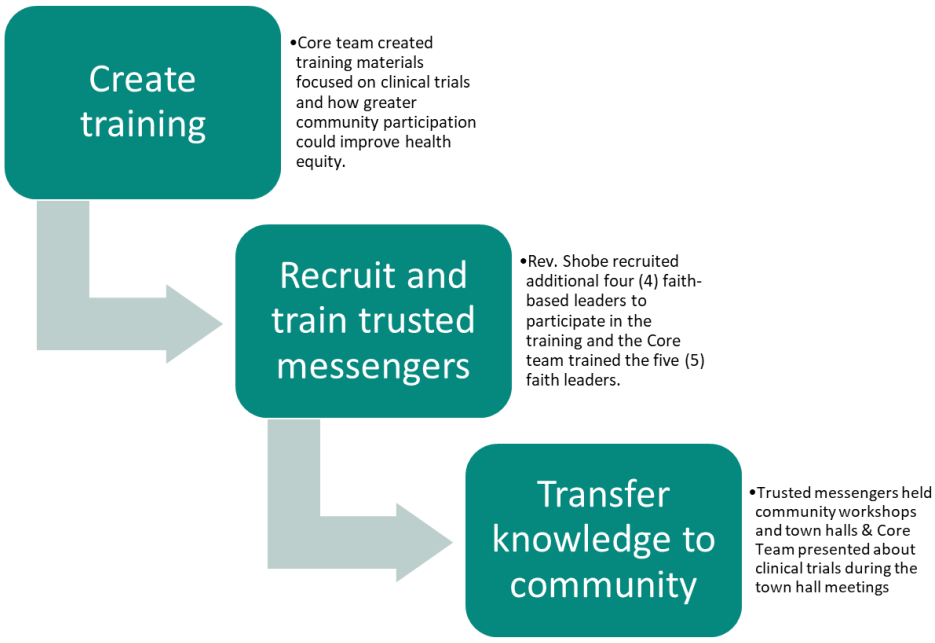
At the 4th Board meeting, the decision was made to focus the pilot project on faith-based leaders due to their foundation for training and community influence. Reverend Brian Shobe and Bishop Lambert Gates were chosen for their extensive networks and commitment to health initiatives. Bishop Gates presides over ministries that extend to geographies beyond Indianapolis. Rev. Shobe is a Board member of The Wellness Connection, Inc., a collaborative built to support pastors and ministries in emphasizing to their congregations the importance of health and wellness.

At the end of the 4th Board meeting, Rev. Shobe and Bishop Gates volunteered to serve as trusted messengers and help conduct the pilot project within their congregations. The Core Team also presented proposed volunteer opportunities to encourage Board member participation in the project, although it recognized that there were challenges integrating Board members into the project as structured.

## Project execution

After the 4th Board meeting, the Core Team worked closely with Rev. Shobe and Bishop Gates to formalize and execute the project plan. Before formally launching the project, the Core Team submitted the project protocol to an external Institutional Review Board (IRB) for review. Over the next four months, the Core Team pursued activities in three core phases. (See Figure 3.) Unfortunately, Bishop Gates had to step away from the project due to scheduling and time constraints. The Core Team continued planning and executing the project with Rev. Shobe.

**Figure 3. Knowledge and Awareness Project Core Phases**




The three-phase project involved the following key activities.

**Phase 1: Create training to deliver key messages on clinical trials and the importance of greater community participation in improving health equity.**

*Develop key messages:* The Core Team leveraged its collective knowledge, combined with additional research and resources, to iterate key messages about clinical trials and the importance of diverse participation in clinical trials. It attempted to formulate key messages that could be effectively used in training trusted messengers who volunteered for the pilot project.

*Create training materials:* Drawing from Lilly's expertise and additional external sources, the Core Team developed training materials for messengers who volunteered to work with their community constituents. The training materials included slides and video content produced by the Center for Information and Study on Clinical Research Participation (CISCRP).

### Phase 2: Recruit and train trusted messengers

*Recruit additional trusted messengers:* Rev. Shobe recruited four (4) additional faith leaders from the Indianapolis community to participate in a training session.

*Conduct trainings:* The Core Team conducted hybrid training for six participants, including Rev. Shobe and a faith leader's colleague, utilizing training materials. Two Lilly team members led the session, aligning with best practices for community engagement and the proven trust impact of representation within the Black community.

### Phase 3: Transfer knowledge to community members

*Work with Rev. Shobe and his colleagues to organize workshops and town halls:* Led by Rev. Shobe, the trusted messengers organized an action plan for 11 small-group workshops and two town hall meetings, which they planned to hold after the workshops. In total, the workshops and town halls reached 135 participants from the Indianapolis metropolitan area.

***Appendix 6. Additional CFRO Board Project Details*** includes more detail about the final key messages, key themes covered in the training materials, IRB submission, community workshops, and town hall meetings.

## Project evaluation

We leveraged qualitative and quantitative assessment tools to evaluate the project outcomes and impact. Through pre- and post-training surveys of the trusted messengers and an after-action review session with those participants, we learned more about what we achieved through this project phase:

- The trusted messengers felt more knowledgeable about clinical trials after the training than they did before they participated in the training.
- Trusted messengers ranked education on benefits and risks of clinical trials, general education about clinical trials, and impact on future generations as the top reasons they would consider participating in a clinical trial. The time commitment involved in participating in clinical trials was the leading barrier to their willingness to volunteer for a clinical trial.
- Informed consent ranked as the most challenging topic of the training, as most trainees said they would have a difficult time explaining this to their constituents.

Additionally, we used pre- and post-forum surveys and a discussion with a sample of participants to gather feedback on their experience and key learnings. These surveys indicated that the organizers were effective in delivering the key messages about clinical trials and clinical trial diversity.

The details of the project evaluation can be found in ***Appendix 7. Knowledge and Awareness Project Evaluation.*** In the 5$^{th}$ Board meeting, the Core Team presented the final outcomes from the Knowledge and Awareness project, as well as evaluation components that had been completed to date (the community participant feedback session was held after the 5$^{th}$ Board meeting).

## CFRO Board final evaluation and conclusion

The Core Team convened the CFRO Board for the 6$^{th}$ and final time, where the Core Team and Board members had a rich dialogue about the project learnings.

We also set aside time at the 6th Board meeting to gather input from the Board members. We encouraged Board members to submit their feedback on the following questions, which we adapted from the final Board evaluation interview guide:

- What did you learn—or take away—from this project?
- What recommendations do you have to improve the impact of this project?
- What did you learn from this project that might help you advance initiatives to improve clinical trials and other challenges in health and healthcare?
- How do you think you might use the project learnings and the relationships you developed through this project in your future efforts to improve health and healthcare?

Board members offered insightful feedback, reflecting their grasp of the barriers diverse communities face in clinical research. This input, enriching their knowledge and connections, equips them for future endeavors.

The Board members in attendance at the final meeting also shared feedback about the process. Their comments focused on their desire to have had more dedicated time to collaborate throughout the project, their ability to engage fully once the project focus was identified, and the importance of strong project management for projects of this nature.

The Core Team thanked all the attendees for their sustained commitment to the CFRO Board and for their considerable contributions to the success of the Board and the knowledge and awareness initiative. After the Board meeting, the Core Team sent all Board members an email containing the final meeting minutes, highlighting the four proposed follow-on opportunities discussed by the Board members. It also committed to share this final report.

## Key Learnings

A review of the process, outcomes, and impact that arose from this project revealed the following:

**Tackling barriers to diverse participation in clinical trials requires thoughtful engagement with diverse community leaders:** Engaging multiple organizations is crucial for addressing the barriers to diversity in clinical trial participation. Solutions to barriers that emerge from diverse community voices can produce effective strategies and advance ongoing collaboration.

Lilly's established connections with a broad array of stakeholders were key to forming an effective Board, while mindful facilitation by the Core Team ensured open discussions, despite potential reservations about pharmaceutical influences. The productive dialogue on participation barriers highlighted the Board's readiness to communicate candidly in Lilly's presence.

**Trusted messengers—in this case, faith-based leaders—can increase knowledge and awareness of the importance of clinical trials among underrepresented groups even without extensive involvement in clinical research.** The pilot's success hinged on the trust between the Black community and their faith leaders, who motivated participation in various project events. Experienced leaders, part of a health-focused congregational network, collaborated with the Core Team to tailor training and presentations, ensuring relevance and impact. Their informed strategies, including small workshops and town halls, maximized engagement and learning, bolstered by CISCRP's videos and Lilly's insights.

**Engaging community members in conversations on clinical trials requires acknowledgement that, in many communities, basic health needs go unaddressed.** The faith leaders recognized that their congregations desire information about many health and health care topics. They understood that a program, such as a community workshop or town hall meeting, that focused only on clinical trials may cause them to lose their audience. The trusted messengers were successful in promoting attendance and appreciation for the information they shared because they broadened the topics at the community meetings to include information directly related to common health issues and ways to address these. The faith leaders located the importance of participation in clinical research trials among other key health issues, which emphasized the role clinical research plays in promoting health.

**Projects of this nature require sophisticated project management and facilitation as well as agility.** Even a highly motivated and sophisticated group of community leaders requires significant support to pursue project work. The group progressed through various stages, first identifying the problem they wanted to tackle and then shaping the strategy that would enable them to address the problem. At each stage, the Core Team provided additional research and logistical support to define agendas and set milestones. The Core Team ultimately defined the Board's project, although Core Team members leaned heavily on the Board's discussions and findings to do so. The size of the Board and the time allotted to the project made support especially important.

Nevertheless, it is critical to balance traditional project management with the flexibility to take direction from the Board's participants and embrace changes in the project plan. Board members validated their own views of barriers by pausing the project timeline to meet with community members. They gained insights that helped them prioritize the project's focus. Building flexibility into the project timeline to allow for pivots by project participants is important. Additional pivots were required due to resource constraints, namely time commitments from Core Team members.

A project plan should identify ways to mitigate lapses in engagement. While a strong contingent of approximately 15 Board members remained actively engaged at the project's conclusion, not all Board members remained equally involved. In reflecting on this, the Core Team drew the following conclusions:

- Scheduling large group meetings was challenging, leading to gaps in member engagement. Regular meetings and consistent interaction could have improved cohesiveness and board member affinity.
- The project emphasized a subset of the Board's activities, despite broad participation in identifying diversity barriers in clinical trials. Board members, while invited, did not attend the trusted messenger training, finding it irrelevant to their roles. Clear role definitions could improve engagement and project ownership.

## Conclusion

Lilly and NEHI's two-year project united stakeholders to tackle clinical trial diversity barriers, proving community engagement's efficacy. Despite its informal nature, the project's methods and results offer a blueprint for future initiatives.

While this was not a formal research project (there were no controls and our project approach shifted considerably from the original plan), the project's process and outcomes can—and should—serve as a foundation upon which future projects may be based. Three points stand out. First, we relied on community leaders who were dedicated to the goal we set out to accomplish. Second, Board Members, the center of the project's activities, had experience engaging in collective work. Finally, we had significant resources with which to pursue our objectives. Using the lessons learned throughout the project will undoubtedly enable additional efforts to improve the diversity of clinical trials as well as address other pressing issues to advance health equity.

# Appendices

## Appendix 1. Recruitment and formation of CFRO Board

### Recruitment:

We crafted a detailed invitation outlining the 18-month project's scope, schedule, and expectations to ensure commitment clarity. Diverse Indiana stakeholders, including academia, healthcare, public health, pharma, CROs, community groups, and faith-based organizations were approached, with 26 confirming participation despite varying levels of clinical trial experience.

### Board member interviews on barriers to clinical trial participation:

From June to August 2022, the NEHI team conducted 26 interviews with representatives from the organizations described above. Interviews explored their background, current position, and organization focus and their prior involvement in clinical trials. We focused questions on interviewees' perceptions of barriers to participation in clinical trials by underrepresented groups and strategies to improve participation in clinical trials by underrepresented populations.

Barriers Board members identified during these interviews centered around three key themes:

- Lack of trust (or, as modified by the Board's discussion, lack of trustworthiness)
- Inadequate community engagement
- Insufficient access (to clinical research trials and health care)

These themes were covered in more detail in the report NEHI submitted to Lilly, *Clinical Trial Diversity: Barriers to Participation – Findings from Interviews with Stakeholders in Indiana.*

### Board Charter creation process:

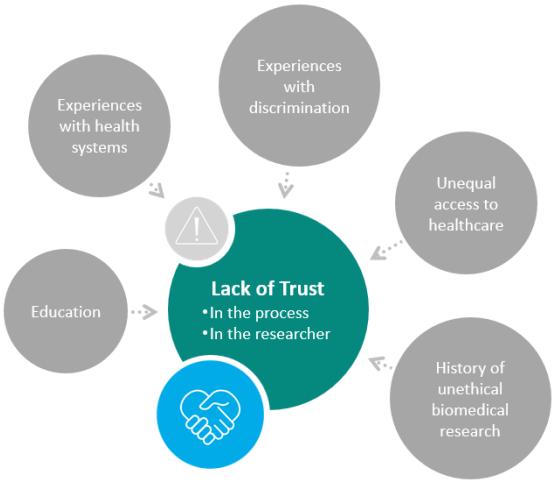
Finally, in preparation for the first meeting, the Core Team developed a charter that clarified the Board's shared purpose and mission, identified roles and responsibilities of Board members and staff, and outlined specific Board deliverables. The Charter also contained proposed procedural and participation guidelines.

## Appendix 2: Literature scan on barriers to diverse participation in clinical trials

Several factors contribute to the lack of trust among underrepresented populations and access to clinical trials by those populations. (See Figure 4.) Leading factors described in the literature on lack of trust include:

- Lack of diversity in research personnel[4,5]
- Lack of understanding of cultural norms[6]
- Little effort spent on understanding needs and preferences[7]

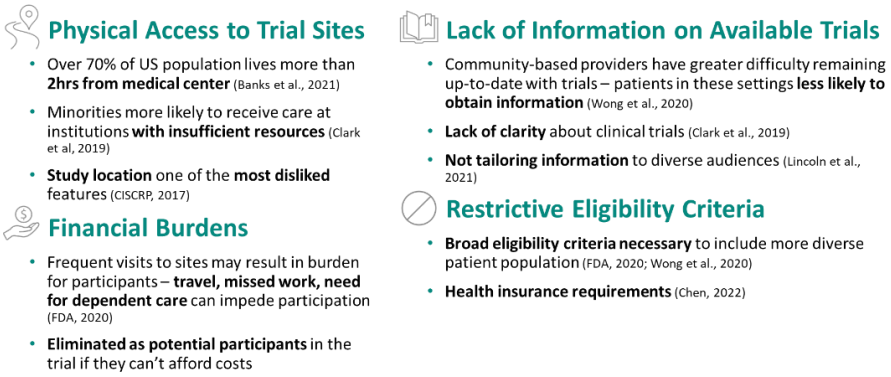
**Figure 4. Summary of literature on lack of trust in clinical trials**




Source: NEHI scan of peer-reviewed literature

Access barriers are the other leading barrier documented in the literature. Four key themes emerged from the relevant literature: physical access to trial sites, financial burdens, lack of information available on trials, and restrictive eligibility criteria. (See Figure 5.)

**Figure 5. Summary of literature on lack of access to clinical trials**

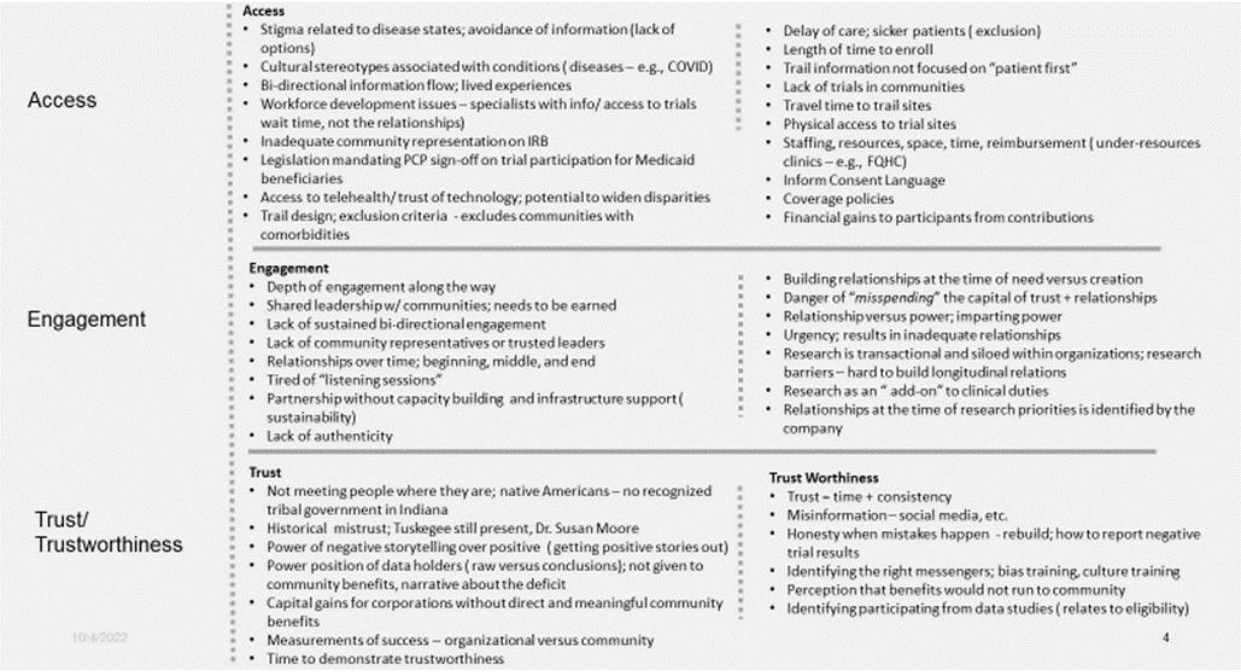



Source: NEHI scan of peer-reviewed literature

## Appendix 3. CFRO Board's process for identifying and narrowing focus on barriers

As we described earlier, the first step of the process in narrowing the Board's focus to a core set of barriers was to facilitate a discussion informed by the literature scan and their experience with and expertise on their respective communities. Figure 6 highlights key takeaways from Board members' initial discussion of key barriers to clinical trial participation.

**Figure 6. Key takeaways from initial barriers discussion**




After this discussion, Board members identified a prioritized list of 13 barriers:

1. Need for greater partnership between members of the community and researchers in defining research objectives, the data to be collected and the control of that data, including how it is presented.
2. Need to address ongoing community concerns about being mistreated, experimented upon, or participating in research potentially harmful to them or without community benefit.
3. Need for more people of color to be employed as research leaders, research staff, and outreach staff.
4. Need to address health literacy among community members and patients to understand information.
5. Need for greater engagement and partnership between members of the community and researchers.
6. Need to support community leaders to communicate about research / research opportunities, as well as combat misinformation.
7. Need for more accessible trial locations.
8. Need to address patient financial burden, including time requirements, along with transparency in consent forms.
9. Need for better coverage policies for the costs of treating any trial-related adverse events.
10. Need to present information without jargon + need to tailor material and link to community-based channels of distribution.
11. Need to connect providers with information about clinical trials / referral to clinical trials.

12. Need to limit broad exclusion criteria which disproportionately exclude underserved/underrepresented communities (preexisting conditions / co-morbidities)
13. Many individuals are not connected to health care let alone clinical trials.

During the 2nd Board meeting, the Board finalized the criteria it would use to prioritize barriers to tackle in the project. Criteria for assessing the barrier(s) upon which the CFRO Board would focus are defined below.

Figure 7. Final criteria for assessing the barriers


At the 2nd CFRO Board meeting, we posted the list of 13 barriers around the meeting room and asked each Board member to place their votes using the following process: Board members placed a red dot next to one of the 13 highlighted barriers that represented their highest priority and an additional three blue dots on other barriers of priority. We asked the Board to consider the criteria defined above while selecting their priorities, as well. This voting process resulted in the four prioritized barriers that we described earlier.

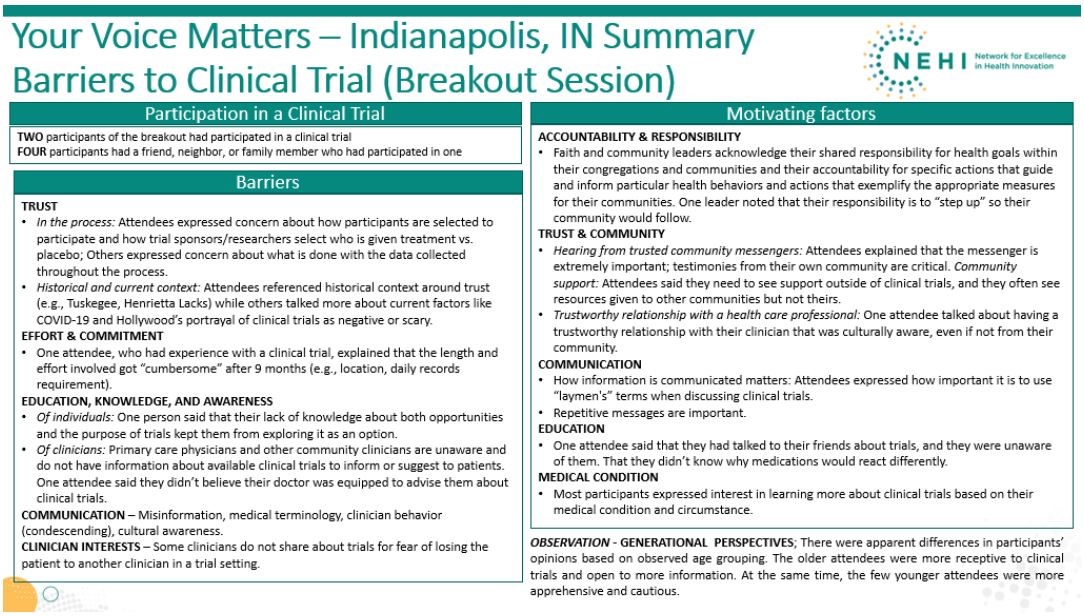
## Appendix 4. Community forum summaries

### Summary of *Your Voice Matters* community forum | February 23, 2023

Three CFRO Board members—Reverend Brian Shobe, Bishop Lambert Gates, and Misty Lewis—hosted a listening session in Indianapolis, IN. The forum included approximately 145 people, primarily representing constituents of various faith-based organizations in the city. The forum featured speakers on a broad set of topics related to health and wellness, including social determinants of health, preventive health services, and information about health care disparities in their community. A Lilly representative facilitated a breakout session on clinical trials during the event.

The session organizers also surveyed the participants on several themes, most notably asking what prevents them from participating in clinical trials. Respondents ranked education, knowledge, and awareness as the top barrier, followed by their need to have an existing medical condition. Highlights from this survey are included in the 3rd Board meeting presentation.

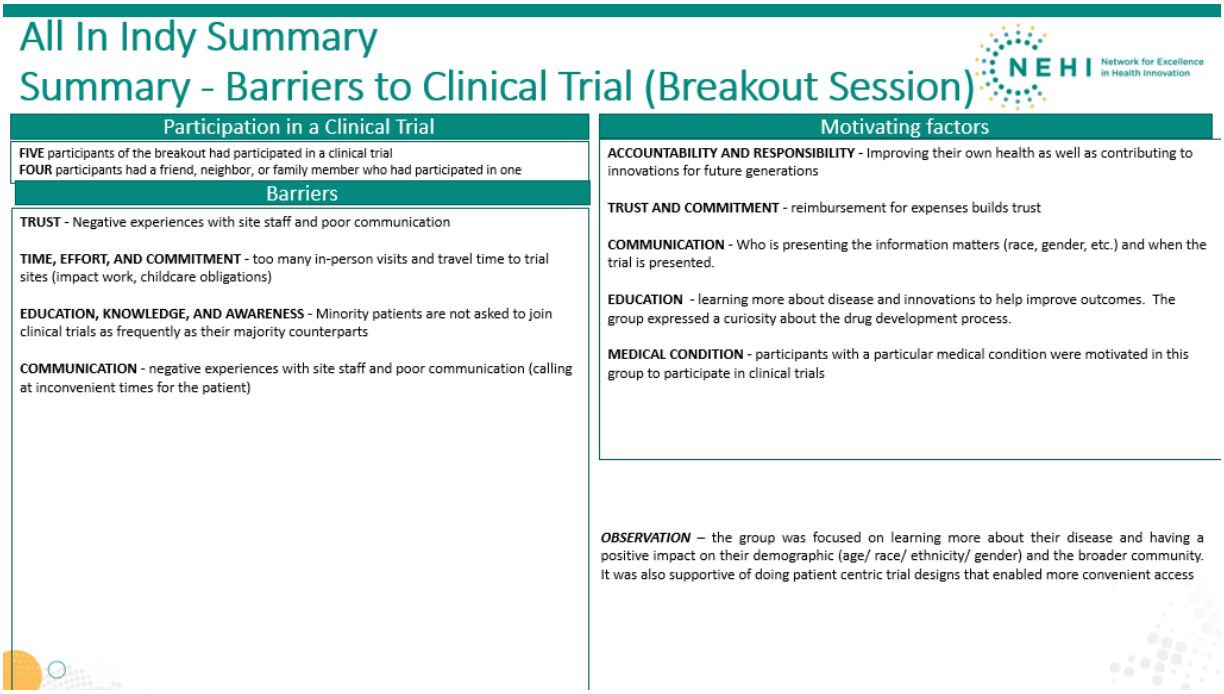
### Figure 8. Your Voice Matters key takeaways




### Summary of All In Indy meeting | April 12, 2023

Two Board members, Sarah Wiehe and Amy Knopf, who represented the Indiana Clinical and Translational Sciences Institute, a statewide partnership among Indiana's top research universities and the Regenstreif Institute, organized this event, which 17 people attended.

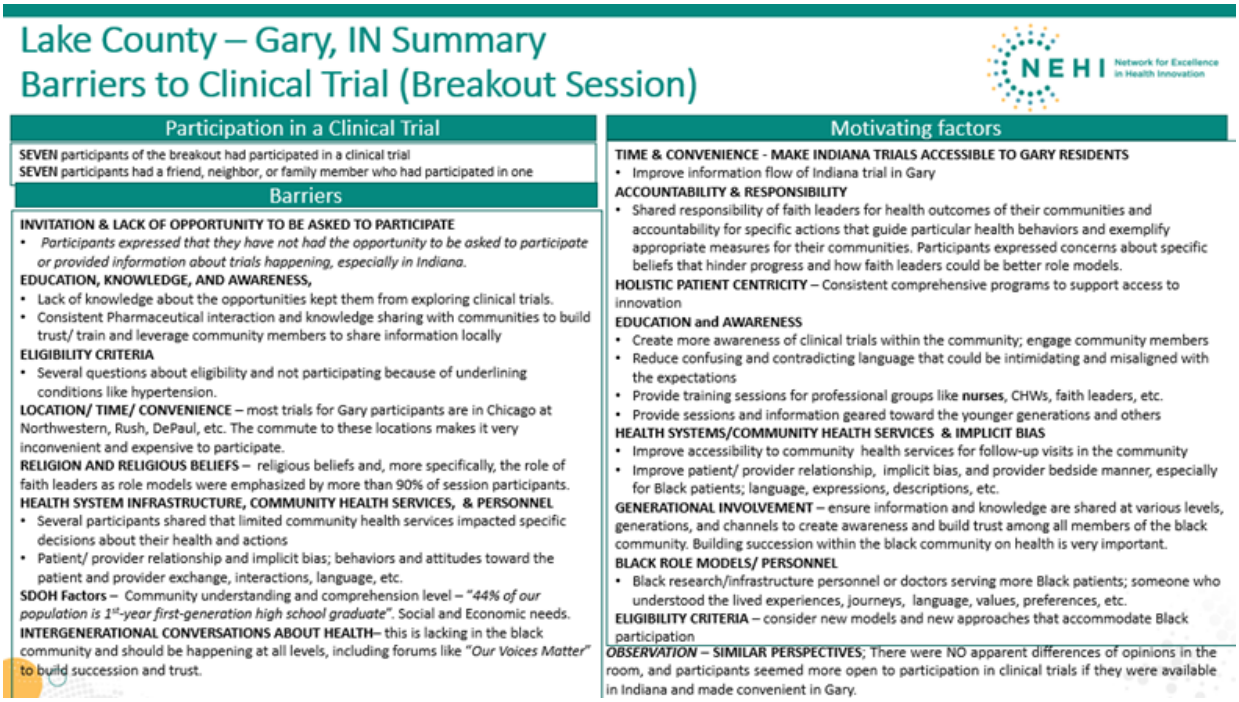
Figure 9. All In Indy key takeaways




Summary of Lake County meeting | April 26, 2023

Holly Wood, a Board member representing Purdue University, helped facilitate a third community forum, which was held in Gary, IN and brought together 68 community and faith-based organization representatives.

Figure 10. Lake County community forum key takeaways

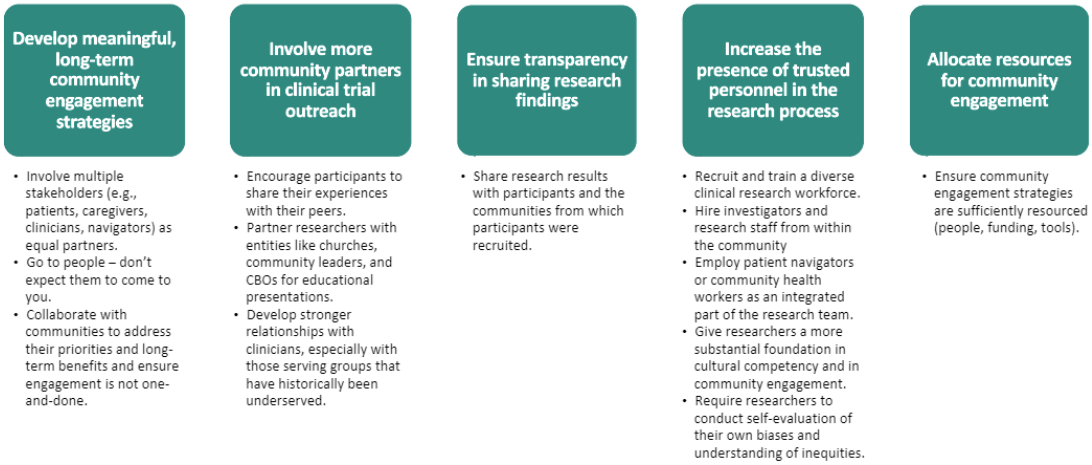


## Appendix 5: Literature scan on potential solutions to improving diverse participation in clinical trials

NEHI also reviewed literature that documents potential solutions to the known barriers to participation. This research discusses approaches aimed at several stakeholder groups: patients, potential participants, participants, community, providers, and researchers. Three key areas emerged from the literature scan, and NEHI combined these findings with additional information uncovered from Board member interviews.

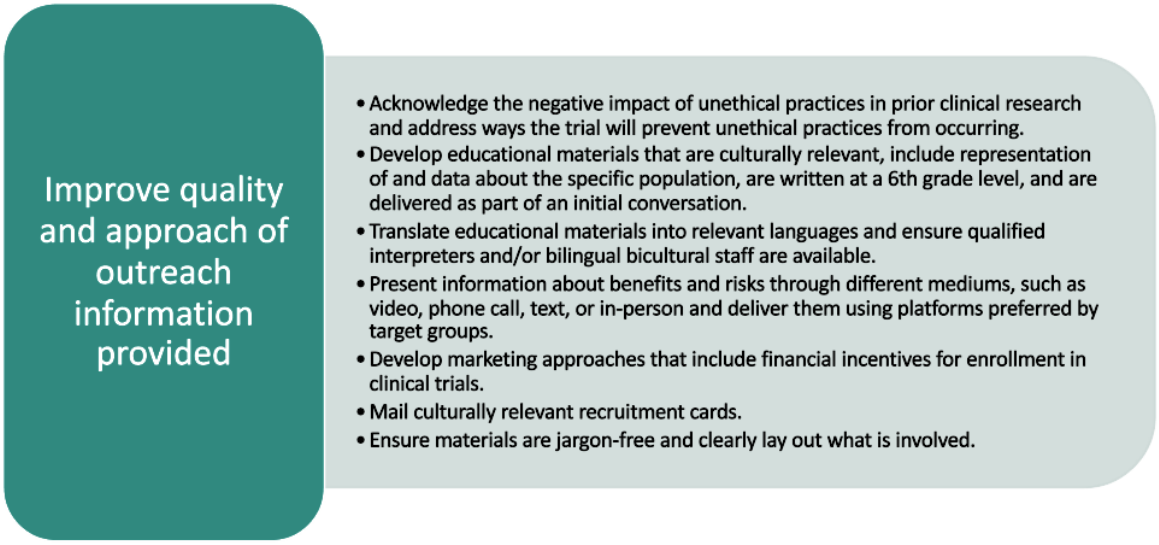
*Community relationships:* Numerous studies have found that strong community engagement approaches can improve participation of communities that have been historically underrepresented in clinical trials. As a threshold matter, they point to the need to involve multiple stakeholders—community members, patients, caregivers, and providers—with the explicit goal of addressing mistrust and alleviating fears. Figure 11 highlights the key solutions that emerged from the literature on community engagement.

Figure 11: Solutions aimed at strengthening community engagement in clinical trials



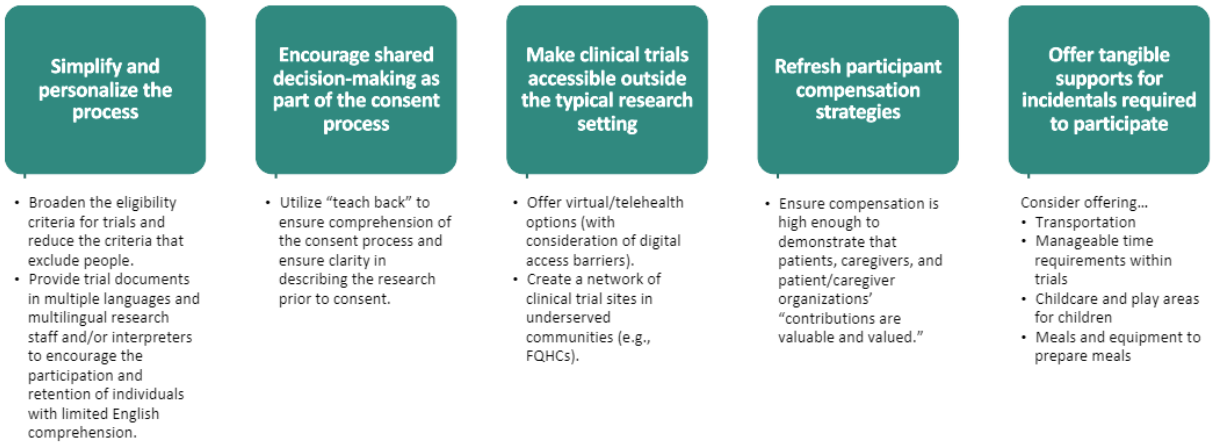

*Increasing knowledge about clinical trials:* Several studies highlighted the importance of how outreach materials are developed and presented—regardless of the source of information or who delivers it. The consensus among these studies is that educational approaches must be jargon-free, clearly lay out what is involved, use multiple modes of delivering the information, including graphics and interactive techniques, and deliver content via platforms preferred by the target groups. (See Figure 12.)

Figure 12: Solutions aimed at improving knowledge of clinical trials




*Clinical trial design:* Finally, a great deal of literature on solutions focuses on improving the feasibility of clinical trial participation for participants. The solutions in this space are multi-faceted and focus on improving the process for volunteers and refreshing approaches to compensation and support for other incidentals. (See Figure 13.)

Figure 13: Solutions aimed at improving clinical trial design



## Appendix 6. Additional CFRO Board Project Details

**Key messages on clinical trials:** As we described earlier, the Core Team leveraged its collective knowledge, combined with additional research and resources, to iterate key messages about clinical trials and the importance of diverse participation in clinical trials that it wished to transfer to the trusted messengers who volunteered for the pilot project. The final version focused on the following key messages:

*Message 1:* An explanation of clinical trials, including:

- Why medicines go through clinical trials before they can be used by the public.
- Who organizes and runs clinical trials.
- How individuals can get involved in clinical trials.
- Clinical trial phases.

*Message 2:* The role that clinical trials play in advancing health equity: Why clinical trials are important to individuals and communities, especially racially and ethnically diverse populations.

*Message 3A:* Key factors relevant to participating in a clinical trial.

- Time and resources
- Informed consent
- Out-of-pocket costs
- Medical / clinical support
- Compensation to participate in a clinical trial

*Message 3B:* Benefits and risks to participating in clinical trials

*Message 4:* Available resources supporting participation in clinical trials: primary care providers, ClinicalTrials.gov, and Indiana-specific organizations (Indiana Clinical and Translational Sciences Institute [CTSI] and All IN for Health).

**Training materials:** After finalizing the key messages, the Core Team developed training materials for messengers who volunteered to work with their community constituents. The training covered four key themes. (See Figure 14.)

**Figure 14. Four key sections of the trusted messenger training**

IRB Submission: The Core Team pursued an external IRB review for best practice assurance, detailing the pilot's protocol to Advarra. After providing further clarifications, Advarra, and independent IRB, exempted the project from oversight on September 22, 2023.

Community workshops: The faith leaders felt that small group workshops (no more than 10-15 people) would be most useful in facilitating dialogue about clinical trials and the impact diverse participation in clinical trials can have on health equity. They also felt the workshops would help prepare them for larger group meetings by providing them with an idea of questions and concerns that workshop participants had. Over the course of several months, Rev. Shobe worked with the other faith leaders to hold 11 workshops across six (6) separate congregations in Indianapolis:

- Shiloh Missionary Baptist Church (MPC) (3)
- Greater St Mark (1)
- Greater Mt Calvary (1)
- Living Word (1)
- Overcoming Church (2)
- Mt Pisgah MBC (2)
- New Vision MBC (1)

The faith leaders utilized the training materials provided during the trusted messenger training to organize the workshops, including the video-based materials from CISCRP. The workshops were organized and executed by the trusted messengers themselves, so the Core Team did not have visibility into the agendas for the workshops or into the workshops themselves. At the end of the project, the trusted messengers and a subset of the workshop participants shared with us their perceptions and feedback about these sessions. We explain this in the evaluation section.

Town hall meetings: The faith leaders designed the town halls to expand the number of participating constituents. They organized these sessions to focus on broader topics about community health and wellness, with key messages about clinical trials and diverse participation woven throughout. Panelists representing different health care stakeholders joined the town halls to share information about how individuals can proactively participate in their own health and health care, including by volunteering for clinical trials. Panelists represented trusted organizations from across the state. The town halls also gave participants and other community leaders an opportunity to connect with organizations and community leaders who could facilitate greater community engagement and increase diversity in clinical trials.

## Appendix 7. Knowledge and Awareness Project Evaluation

**Trusted messenger evaluation:** Our evaluation included quantitative surveys and an after-action review session with the trusted messengers:

*Pre- and Post-Training Surveys:* We assessed the impact of the trusted messenger training by asking trusted messengers to complete two surveys.[i] The surveys revealed key insights into what the trusted messengers learned through the training, which we explained above.

*After-Action Review Session:* To supplement the surveys, the Core Team also conducted an "after-action review session" with trusted messengers who participated in both the trusted messenger trainings and conducted workshops and town halls with their community constituents. Their feedback centered on their experience participating in the training session, their process and key learnings from outreach to and convening their constituents, and their vision for how they can continue to engage in this work.

**Community participant evaluation:** The project utilized surveys and discussions to collect community feedback at its end. Rev. Shobe facilitated pre- and post-workshop surveys for 135 participants, showing improved knowledge and attitudes towards clinical trials, detailed in the 5th Board meeting documents. Additionally, a focus group provided insights into the community's motivations, barriers, and views on the workshops and town halls, with findings recorded in the final Board meeting materials.

[i] Due to a technical error, the trusted messengers received surveys that had slightly different questions from pre-training to post-training. We also note that while six (6) participants completed pre- and post-training surveys, one of these participants was a colleague of Rev. Shobe's and was not part of the final cohort of trusted messengers that led forums with their constituents.

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