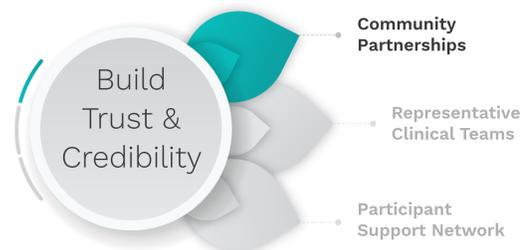


Develop Community Partnerships

What should I do?

Demonstrate a commitment to building trust and credibility by developing community partnerships. Sustained efforts to increase diversity and improve equity and inclusivity in clinical trials starts with building trust.



Why should I do it?

- Build trust and transparency between participants, sponsors and clinical trial teams for long term engagement with clinical trials and research.
- Increase and improve patient engagement and retention.
- Reduce burdens for participants and clinical trial teams by streamlining processes and including participants as partners.
- Increase compliance and participant adherence.
- Improve outcomes with more robust data collection.
- Increase access and awareness for participants to clinical trial participation.
- Increase awareness for participants on clinical trial participation value and process.

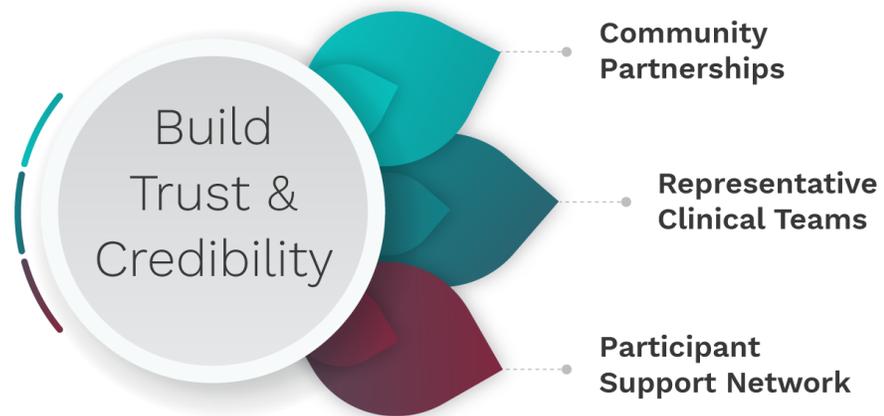
Ethical Considerations

Trust is hard to build and easy to destroy; therefore careful and respectful measures are needed. Community leaders and organizations are experts in building trusted relationships, and can serve as ambassadors for the clinical trial ecosystem. The recommendations provided here should be used as a starting point and then customized for diverse communities or geographic areas. Each community has specific experiences with the clinical trial or research industries. Deliberate and informed actions should be taken to ensure that past harms are not perpetuated.

Partnerships between clinical trial sponsors or clinical researchers and community organizations can be vital for **bridging the gaps created by mistrust and lack of knowledge** that have resulted in underrepresentation of diverse populations in clinical trials. Participants do not trust the clinical trials industry and do not usually have sufficient knowledge of clinical trials to fully benefit from them. Similarly, the clinical trials industry does not possess sufficient knowledge of participants and their lived experiences to adequately engage them in clinical trials.

Additional resources on **building trust and credibility**

1. [Diversify Clinical Teams to Build Trust](#)
2. [Develop a Virtual Participant Support Network to Build Trust](#)



Community partnerships can help those designing and implementing clinical trials by providing **deeper knowledge** on how to **continually engage** diverse participants. In collaboration with community partners, sponsors and clinical teams can begin to transform perceptions of the clinical trial system and develop sustainable strategies for long-term processes and future work.

Several digital tools can be utilized to develop community partnerships, including a RWD/RWE, Artificial Intelligence / Machine Learning (AI/ML), virtual visits, and additional digital solutions. See the “[Elements of a Diverse, Equitable, and Inclusive Digital Clinical Trial](#)” for details on using each of these tools.

Jump to:

- [Value of Community Partnerships](#)
- [Key Steps for Using Digital Tools to Identify Stakeholders and Develop Community Partnerships](#)
- [Principles of Partnerships](#)



Value of Community Partnerships

Community partnerships provide a **strong foundation** to create **person-centric strategies** that will lead to building credibility and gaining participant trust; ultimately leading to increased participation engagement and improved study outcomes.

1. Community groups:
 - a. Are **highly respected** and **trusted** within their communities
 - b. Provide **support, services, new ideas, solutions, and education**
2. Community partnerships should **focus** on:
 - a. Gaining **richer knowledge** on how clinical trial processes should evolve and be tailored to meet the needs of different populations
 - b. Developing and **nurturing** relationships
 - c. Providing additional, **relevant information** to communities
 - d. **Reducing inequalities**
3. **Collaborations** with community groups will:
 - a. **Inform** and **enhance** participant **engagement** and enrollment efforts
 - b. Inform and enhance efforts for participant **retention**
 - c. Extend the reach and **impact** of your work to underrepresented populations
 - d. Address issues like **health** and **technical literacy**, and **technical access**
 - e. **Address** existing **disparities** and inequities with clinical trial access.

Key Steps for Using Digital Tools to Identify Stakeholders and Develop Community Partnerships

1. Draft your **goals** for diverse and inclusive enrollment.
 - a. Include the **purpose** of your clinical trial.
 - b. Include **anticipated outcomes**.
 - c. Include **answers** to the following questions:
 - i. Which populations would you like to include?
 - ii. What are your enrollment goals?
 - iii. How do you anticipate this clinical trial will affect these populations (potential benefits and/or risks)? What is your evidence?
 - iv. What digital tools will be used in the clinical trial?
 - v. What digital measures will be collected?
 - vi. How will the collected digital measures/data be used?
 - vii. What are the long term goals with this clinical trial? How will the results advance the field?



2. Determine which **stakeholders** can help **refine** your enrollment **goals**, by identifying additional **benefits** and/or specific **challenges** or barriers for communities who should be included in your trial. These stakeholders should be your **partners**.
 - a. Use AI/ML to interrogate RWD/RWE to identify populations that could benefit from your clinical trial.
 - i. Social determinants of health databases can be especially informative on lived experiences for different communities.
 - b. Start with recommendations from the “[Use Real-World Data/Real-World Evidence](#)” resource to optimize your queries, and identify the best data sources.
 - c. Use these outputs to identify community groups with whom you should establish a partnership.
 - d. Reach out to faith-based or cultural organizations, schools, advocacy groups, and community health centers.
 - e. Consult with patient advocacy and patient engagement groups for additional recommendations.
 - f. Check local government websites for local public health departments, and social and civic groups.
 - g. Community health workers, often associated with Federally Qualified Health Centers (FQHCs), are a great resource for connecting with communities on specific health issues.
3. Approach potential partners with the **intention of collaborating** to refine your enrollment plan and overall person-centric strategies. Demonstrate **respect and appreciation** for community partners’ input.
 - a. Based on the questions above, draft the enrollment plan and leave room for input from your community partner(s).
 - b. Do your due diligence. Complete basic research to ensure appropriate language and customs are used to communicate with potential partners. Customize your approach to be culturally respectful of your potential community partners.
 - c. Design curiosity questions to bring to your potential partner. Start with questions that allow partners to share their vision for providing benefit and value to their community members, while helping you achieve your outcomes.
4. **Meet** with your **community** partner and enter into a partnership.
 - a. Share your project purpose, goal, and possible/intended outcomes.
 - b. Describe your specific needs from a community partner:
 - i. What do you want to learn about the community or potential participants?



- ii. How will your work help the community or participants?
 - iii. What benefits will the community partners receive for their participation? This does not have to be monetary; think about the value your work will bring.
 - c. Listen to the community partner, learn what they would like to gain from this partnership, and allow their feedback to guide the strategy for getting to your outcomes.
 - d. Identify specific contacts for continued work and set guidelines and expectations for your work together, including frequency of updates from you for the duration of your work together.
 - e. Identify additional opportunities to connect with the community directly.
 - f. Explore opportunities for sustained presence and interactions with the community.
 - g. Identify opportunities to provide information or share knowledge with the community.
5. Develop or **refine** your overall **engagement plan** with the community partner.
- a. Determine the best mechanisms for participant input (focus groups, interviews, surveys).
 - b. Identify barriers to participating in your trial and solutions for overcoming them or strategies to mitigate without compromising on inclusivity.
 - c. Discuss options for data analysis and dissemination.
6. [Design an inclusive engagement plan](#) as a core component of your deployment plan, based on your work with the community partner, to **ensure equitable participation** for diverse groups.
- a. Review the “[Plan for Diverse, Equitable, and Inclusive Engagement](#)” for additional recommendations and resources.
 - b. Apply strategies from the engagement plan throughout the clinical trial process and offer various opportunities for feedback.
 - c. Develop a system for a long-term partnership and open communications for continuous collaborations.

Principles of Partnerships

The American Hospital Association published principles of partnerships based on **lessons learned for community health-related partnerships**. These principles have been adopted and modified for diverse, equitable and inclusive digital clinical trials.

- **Culturally respectful:** To fully appreciate an individual’s unique lived experiences you need to understand the community from which they came. And you cannot effectively help them without understanding their social



determinants of health.

- **Community-driven:** Engage a diverse group in your community that strives to address a problem common to all.
- **Achieve more together:** Leverage each partner's complementary talents and resources to create synergy among partners that accomplishes more.
- **Meaningful engagement:** Include representation by all community stakeholders in determining, planning, and executing priorities.
- **Clear and open communications:** Ensure that all communications are transparent and culturally respectful.
- **Partner equity:** All stakeholders are considered equal, regardless of size or financial or in-kind contributions to the partnership.
- **Shared purpose:** As stewards of the community's resources, partners are committed to working collaboratively for the benefit of the community.
- **Establish long-term relationships:** Partnerships should become part of your clinical trial infrastructure. Make investments in educating and supporting communities for future research participation.
- **Best practices and innovation:** Community health is complex, involving multiple social needs. Best practices and innovative approaches are required.
- **Systems approach:** A systems approach can better create a foundation for integrated community delivery systems. Create a community needs assessment to gain deeper insights on how to support the community.
- **Goals and progress reports:** Change requires focusing on results. Measures or indicators of progress and communication to the community offer direction, inspiration, and motivation. Monitoring demonstrates partner accountability, earns community trust and builds hope.
- **Governance structure:** Sustainable governance structure is dependent on a clear purpose, partner commitment, a plan of action, adequate funding, effective implementation and demonstrated progress.

Adapted from "[Learnings on Governance from Partnerships that Improve Community Health](#)" as shared in [Building Hospital-Community Partnerships](#).





References & Resources

1. [Addressing Social Determinants Of Health To Improve Clinical Trial Diversity](#). An overview on the role of SDOH in health equity and clinical trials.
2. [Advancing health equity through community-based ecosystems](#). Stronger partnerships can help health systems address drivers of health and create a world in which everyone thrives.
3. [Assessing Meaningful Community Engagement: A Conceptual Model to Advance Health Equity through Transformed Systems for Health](#). True, meaningful community engagement requires working collaboratively with and through those who share similar situations, concerns, or challenges.
4. [Building Hospital-Community Partnerships](#). Leveraging strengths to improve community health, for hospitals and health systems.
5. [Developing a Process to Help Community Stakeholder Organizations Set Research Agendas](#). This comprehensive guide was developed by a Patient-Centered Outcomes Research (PCORI) awardee to assist with community outreach and engagement.
6. [Diversity in clinical trials: an opportunity and imperative for community engagement](#). Leveraging partnerships between academia, community, government, and industry presents a tremendous opportunity to cultivate and sustain clinical trial diversity.
7. [Engaging Your Community, A Toolkit for Partnership, Collaboration, and Action](#). This toolkit provides strategies for building and maintaining community partnerships, including strategies for effective outreach and communication.
8. [How can biopharma companies challenge systemic racism?](#) Developing partnerships with people of color to remove barriers to high-quality care and inclusive research.
9. [How NIH Uses Community Health Partnership for Participant Engagement](#). Through the *All of Us* Research Program, NIH turned to community partnerships to establish trust with underserved communities to drive diversity and patient engagement.
10. [Increasing Diversity In Clinical Trials: The Critical Role Of Community Partnerships & Collaborations](#). Patient and community engagement can be thought of in two separate but related contexts: medical care and research.
11. [Learnings on Governance from Partnerships that Improve Community Health](#). Models on multi-sector collaborative partnerships involving hospitals, health systems, public health and other community organizations developed to address community health.
12. [Our Healthy Community \(OHC\)](#). A network of community-based organizations



committed to improving health equity and reducing health disparities in underserved communities.

13. [Takeda's global quest for health equity](#). Takeda's U.S. Health Equity division is also built on establishing community-based partnerships, sharing knowledge and creating sustainable organizational structures.
14. [To Recruit Diverse Research Participants, Get Out of the Clinic and into Your Community](#). Emerging community-based research in underrepresented populations shows that we can successfully enroll and retain 70% of participants.
15. [Toolkit for Developing Community Partnerships](#). This toolkit provides information for researchers, clinicians, and others interested in learning about the community and conducting community-based research.
16. [Understanding Health Disparities Series](#). NIMHD's online resource to provide educational information and resources on topics and concepts originated by and/or impacting minority health and health disparities research.
17. [Utilizing Social Determinants of Health \(SDoH\) to Provide Context for Your Clinical Research](#). Overview on how SDOH can affect clinical trial diversity and a digital solution to learn about and use SDOH data.
18. [Who are Community Health Workers, How Do They Treat Patients?](#) Community health workers serve as liaisons between health/social services and the community.

