

Based on the research from our white paper, <u>Achieving Representation in Clinical Research</u>, we've created a series of how-to guides all focused on the different factors that need to come together for successful diverse recruitment.

- ✓ 100+ interviews
- ✓ 14,000+ clinical trials
- ✓ 100+ literature reviews





How to optimize community engagement for diverse recruitment

Comprehensive engagement is crucial to dissolve barriers between communities and research, but there are no validated frameworks in wide use. When less diverse patient populations are easily available, there is a risk that the perceived investment to develop an engagement plan will outweigh the benefits. The solution is a comprehensive, validated framework for using engagement practices to achieve recruitment goals.

1. Develop relationships with organizations in diverse communities.

- · Contact organizations in diverse communities that have already established trust.
- Examples: non-profits, religious institutions, pharmacies, assisted living facilities, and other health care
 providers in the community.
- Find champions for your trials at these institutions.

2. Hire a patient board.

Meet monthly with diverse patient champions. Consult with them on the following:

Recruitment channels:

- Does your community use this medium?
- Would they engage with a clinical trial that they find via this medium?
- What channel would reach the most disengaged members of your community?

Recruitment materials:

- How would members of your community respond to this ad/phone call/email?
- What could we change about the outreach to improve engagement?
- · What elements would help reach the most disengaged members of your community?

Messaging:

- Does this phrasing make sense? Would it make you consider joining?
- · How could we rephrase to promote the positive elements of participating?
- · What element should we highlight to reach the most disengaged members of your community?

Trial ops

- Which of these trial schedules would be most interesting to your community?
- · Provide different scheduling options.

3. Hire diverse staff.

· Hire community engagement coordinators from the community you'd like to engage with.

4. Conduct and participate in outreach events.

- Research and attend outreach events in the community.
- Examples: educational seminars, health fairs, and lunch and learns.
- Host outreach events to embed your name in the community.

5. Track and leverage data.

- · Collect consistent data on what works and what doesn't.
- Over time, develop an engagement playbook stratified by patient group and therapeutic area.



2

How to budget for diverse recruitment

Most researchers care about recruiting a representative research population. But without explicitly designated funds, there is less motivation to act on these ideals. The solution is a comprehensive, validated framework on how to modify trial budgets to prioritize diverse recruitment.

1. Build diversity considerations into recruitment vendor selection.

- Collect data on the demographics of participants historically recruited by each channel in your suite.
- Reach out to channels that are known to recruit representative patient populations.
- Ask for data on recruitment demographics when meeting potential new vendors.
- Develop a checklist of channel characteristics to ensure baseline needs are met:
 - Default multilingual.
 - Include representative imagery.
 - · Adhere to the Web Content Accessibility Guidelines.
- Use this data in conjunction with other logistics when making decisions about channels for new trials.

2. Build diversity considerations into site selection.

- Choose sites in underserved areas and invest in comprehensive training.
- · Use sites in pharmacies wherever possible.
- Use sites with diverse staff, or who provide cultural competency training to their staff.

An investment in new sites upfront ensures that you are set up for recruitment success in the future.

3. Consider equitable reimbursement packages.

- Relativize travel reimbursement with respect to the distance traveled and time spent traveling.
 - If the participant does not have a car and public transit is slow, they should be reimbursed extra.
 - Provide taxi services to participants who live in transit-poor regions.
- · Allow additional travel reimbursement for participants with mobility impairments.
- · Support participants who require childcare through onsite services, or via a childcare stipend.
- · Provide additional support for participants who do not have adequate insurance coverage.

4. Hire a patient board.

- Paying community representatives to provide feedback on recruitment materials and strategies can be a quick solution to complement rigorous data collection.
- See the "How to optimize community engagement for diverse recruitment" one pager for examples.

5. Invest in community-based initiatives.

- These initiatives require minimal financial input and can improve long-term trust in minority groups.
- Initiatives include partnerships with disease advocacy groups for racial/ethnic minorities and trial champions in religious institutions, long-term care homes, and other locations in the community.



3

How to build diverse research teams

Patients are more likely to trust and participate in research when the research team reflects the diversity of the patient population. So one of the most efficient ways to improve minority recruitment is to hire diverse research and strategy teams. Here are the best methods for diverse hiring in clinical research.

1. Run campus recruitment events at HBCUs and Spanish-dominant colleges.

- Build relationships with HBCUs and colleges with substantial Spanish-speaking students.
- Participate in career fairs, sponsor career events, and post on campus job boards.
- Hire entry-level trial ops, research assistant, and trial outreach positions directly from these schools.

2. Update company-wide training for diverse recruitment.

- To recruit diverse employees: train managers and other hiring personnel in unconscious bias and effective interviewing techniques.
- To improve diverse participant recruitment: roll out unconscious bias and cultural competency training across existing trial sites.

Make diverse staff a consideration in vendor and site selection.

- If the companies you work with hire diverse staff, your outsourcing will be naturally more successful at hitting diversity goals.
- In particular, diverse PIs and patient-facing site staff are crucial to improving diverse recruitment.

4. Implement systems to track diversity metrics.

- Monitor racial and ethnic demographics in hiring across the company.
- Ensure that all teams have baseline representation, especially those whose decisions trickle down to patient relationships.
- Track diverse participant recruitment and identify company trends that improve or worsen participant representation.

5. Develop internal mentorship and career development programs.

- Promote diversity and inclusion within the company by supporting diverse employees.
- Improve employee retention, collaboration, and idea spreading via these programs.





How to create reimbursement packages for diverse participation

People from different backgrounds need different financial and logistical support to participate in research. Yet most trials treat every patient the same. Today, trials struggle to recruit diverse participants because of this disparity. **The solution is a validated**, **equitable reimbursement framework to meet every patient where they are**.

1. Relativize travel reimbursement.

- Set a maximum and minimum range for travel reimbursement.
- Calculate travel stipends based on time spent traveling to the site AND distance traveled.
 - Example: \$USD stipend per visit = (distance traveled in miles) + (1/4 x time spent traveling in minutes)
 - So, if a participant lives 8 miles from the site and it takes them 48 minutes to travel via public transit: $\$USD = (8 \text{ miles}) + (\frac{1}{4} \times 48 \text{ minutes})$
 - This participant would be eligible for a \$20 stipend per visit.

2. Partner with assisted transit providers.

- This strategy is ideal if an equitable travel reimbursement model is too complicated, or if participants require assisted transit.
- Taxi services ensure all participants can travel to the site, regardless of access to personal or public transportation.

3. Create systems for child and family care support.

- Partner with childcare providers near sites, or prioritize sites that make childcare considerations.
- Alternatively, provide a child or family care stipend for all participants with dependent family members.
- This initiative is especially important for trials with demographics who might have young children
 or older dependent family members.

4. Acknowledge the impact of insurance coverage.

- Sponsors may consider setting aside a budget to cover medical costs for a percentage of uninsured participants.
- In cases where participants' insurance is expected to cover fees associated with the trial, sponsors may consider paying those fees for a proportion of these uninsured participants.

5. Be transparent about reimbursement logistics.

- Include key features about your reimbursement program on patient-facing trial materials.
- Statements like "childcare support is provided" and "we will help you travel to the trial" can motivate instead of coerce people to sign up.



5 How to create systems for demographic reporting

Standardizing the reporting of key metrics such as patient demographics isn't widely adopted yet, which makes tracking diversity trends challenging. A validated system that provides demographic reporting at the site level is needed to normalize and standardize these trends.

1. Divide the recruitment funnel into steps.

- Choose a set of steps and ensure every site is familiar with them.
- Example steps:
 - Prescreening
 - Screening
 - Enrollment
 - Randomization

2. Use an online tool to track each participant's progress.

- The tool should let coordinators tag each participant as 'passed' or 'failed' at each stage.
- The tool should also record demographic data.

3. Use insights to focus diversity efforts.

- Use analytics to determine where you should focus efforts to increase diversity.
- If minority patients fall out of the funnel early: focus on better recruitment.
- If they fall out late: focus on equitable trial methodology and exclusion criteria.

4. Bring insights to a patient board.

 Compliment the data with insights from actual patients. Learn more about why their community may be disengaged at each step.

5. Track insights across trials and treatment areas.

- Build a database to understand how patients are impacted at each step of the funnel.
- Use this data to create proactive solutions for new trials so that they work immediately instead of after rescue attempts.

6. Create norms for sites to proactively track demographic data.

- If sponsors expect granular data on patient demographics per site, sites will naturally start to collect this information on their own.
- Lead with the expectation that sites should be collecting this data.
- Prioritize sites with transparent demographic data during site selection.
- Provide support to sites via tech packages and training.



6 How to build an implicit bias training program

People from minority groups are invited to participate in research at lower rates. Implicit biases in referring physicians and their teams impact these rates. To improve site-level representation, sponsors can build a validated implicit bias awareness program into their site start-up plan.

1. Identify sites that may need implicit bias training.

- Criteria for this selection can include:
 - Number of patient-facing minority staff.
 - Demographics of patients already receiving care at the site.
 - Demographic distribution in the site's catchment area.
 - Past performance of the site in recruiting representative participants.
- You may require implicit bias training at all sites or at a selection of sites that score the lowest on these indicators.
- During the first iteration, you could also provide training to a random sampling of sites to determine program effectiveness.

2. Create an implicit bias training program.

- Consult patients and the community on the most crucial points to highlight.
- Several free online resources can serve as starting points. Examples include:
 - · Five unbiasing guides from Google.
 - Implicit bias training from the AAFP.
 - NetCE implicit bias training.
 - Think Cultural Health training from the Department of Health and Human Services.
- Use these examples and tailor them to your treatment area and target patient population.

3. Roll out the training program.

- · Send the program to patient-facing staff at your chosen sites.
- Require proof of completion from all staff before site start-up.
- Incorporate a survey at the end of the training to receive suggestions and feedback from sites.

4. Monitor continuously.

- Track participant demographics at sites that received implicit bias training.
- Build alternative plans incorporating marketing and community engagement for sites that do not meet representation goals post-training.

5. Iterate new versions.

Incorporate survey results and effectiveness data in future iterations of the program.