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Advancing Equity in Cancer Clinical Trials: Barriers, Evidence-Based Solutions, and an Integrated Multilevel Model for Underrepresented Populations

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Abstract

Diversity among clinical trial participants is essential to assessing the efficacy and toxicity of targeted cancer therapies, yet racial and ethnic minorities remain persistently underrepresented, limiting the generalizability of findings and perpetuating disparities in cancer outcomes. This review examines the multilevel barriers to equitable participation – lack of awareness, mistrust, insurance issues, immigration status, language, transportation, and limited access to culturally competent care. The review will also synthesize evidence-based solutions, including community-engaged research, patient navigation, culturally tailored education, workforce diversity, language access, financial reimbursement, decentralized trials, and improving community trial infrastructure. Using clonal hematopoiesis of indeterminate potential (CHIP) as a case study in inequitable access to precision prevention, we argue that no single intervention suffices and propose an integrated, sustained, multilevel model to advance equitable oncology research and care.

Take Home Messages

1. Racial and ethnic minorities remain significantly underrepresented in cancer clinical trials, limiting generalizability of findings and contributing to persistent disparities in cancer outcomes.
2. Barriers to equitable participation operate simultaneously at the patient, provider, institutional, and policy levels. This includes mistrust, financial burden, language exclusion, immigration-related fears, transportation challenges, and the absence of culturally competent research environments.
3. Evidence-based interventions including community-based participatory research, patient navigation, financial reimbursement, decentralized trial design, and culturally and linguistically tailored education have demonstrated measurable improvements in minority trial accrual and must be implemented in combination, not isolation.
4. CHIP exemplifies a precision prevention area where underrepresented populations like Asian American and Pacific Islander (AAPI) face compounded inequities in research access; community-engaged, multilevel models offer a viable path to closing this gap.
5. Achieving equitable clinical trial participation requires coordinated, sustained action from sponsors, health systems, policymakers, and communities with mandatory diversity reporting, expanded cost coverage, language access mandates, and policies addressing protected pathways for immigrant participants.

Introduction

The importance of diversity among clinical trial participants is a well-recognized principle. Diversity is essential to assessing the efficacy and toxicities of new targeted therapies, particularly for cancers that disproportionately affect certain racial or ethnic groups.[1] However, persistent underrepresentation of minorities in cancer trials remains a critical problem despite a growing body of advocacy and regulatory attention.[2] This leads to inequities in access to research, limits the generalizability of study findings, and contributes to persistent gaps in cancer outcomes.[1]

There is a wealth of evidence that highlights racial disparities in clinical trial participation. An analysis of more than 200,000 participants in NCI-sponsored breast, colorectal, lung, and prostate cancer trials between 2000 and 2019 found that proportions of Black African American (BAA), Hispanic, and Asian American and Pacific Islander (AAPI) patients fell well below each group's share of cancer incidence.[3] A study comparing enrollment data to cancer prevalence across trials from 2003 to 2016 found significant underrepresentation of BAA and Hispanic populations relative to non-Hispanic White patients.[4] This pattern extends to specific therapeutics: although Black patients represent approximately 20% of new multiple myeloma cases, only 5% were enrolled in the pivotal trial leading to FDA approval of Teclistamab in 2022.[1]

The 2024 AACR Cancer Disparities Report documents racial inequities across all major cancer treatment modalities including surgery, radiotherapy, chemotherapy, immunotherapy, and targeted therapy. Although innovative surgical techniques have decreased overall mortality rates after surgery, the mortality gap between Black and White patients has not narrowed. For example, BAA women with breast cancer are less likely to receive curative surgery and more likely to experience treatment delays compared to non-Hispanic White women.[1] One of the major barriers to receiving radiation therapy is geographic location and poor access to radiation oncologists and facilities. A study by Tappara et al. showed that Black women with cervical cancer and Native Hawaiian and other Pacific Islander women with endometrial cancer are significantly less likely to receive brachytherapy compared to non-Hispanic White women.[5] Rates of early onset colon cancer are increasing with evidence showing BAA patients have worse outcomes compared to White patients. BAA colon cancer patients are 22% less likely to receive chemotherapy, and those with rectal cancer are 68% less likely to receive chemotherapy compared to White patients.[6,7] Similar disparities are observed in the use of immunotherapy and targeted therapies. One study noted that BAA individuals with late-stage non-small cell lung cancer have a 40% lower likelihood of receiving immune checkpoint inhibitor therapy.[8] Another study investigated CDK4/6-targeted therapies which improve survival in breast cancer and found that its use is lower among patients of lower socioeconomic status

and among BAA patients.[9–11] These disparities are not incidental; they reflect structural and systemic inequities that limit access to the full spectrum of cancer innovation.

The lack of representative racial diversity in clinical trials limits generalizability of data and contributes to inequities in cancer outcomes. More specifically, these gaps restrict the scope of precision oncology, which is dependent upon the diversity across populations to make holistic and applicable discoveries in cancer prevention. In this review, we discuss how racial disparities in trials can worsen without early identification and engagement of underrepresented communities. We also examine real-world barriers to building representative participant pools and propose actionable strategies and models that clinicians, researchers, health systems, and policymakers can implement to improve trial diversity and equity.

Major Barriers to Equitable Screening and Clinical Trial Participation

Barriers to clinical trial participation among underrepresented populations are multilevel. These include lack of awareness, cultural perceptions of cancer, mistrust of the medical system, financial constraints, insurance gaps, immigration status, language barriers, transportation, and limited access to culturally competent care (Figure 1).

For example, Dr. Glavin and colleagues conducted a study to better understand barriers to clinical trial participation among AAPI communities in Greater Cleveland. Through surveys and focus groups with Chinese, Pakistani, Afghan and other participants, the study explored cultural and socioeconomic challenges in the healthcare system. The goal was to inform strategies that promote community engagement and support more patient-centered care. In this not-yet-published work, one preliminary finding showed that while 58% of participants had heard of clinical trials, only 15% had participated or knew someone who had.[18]

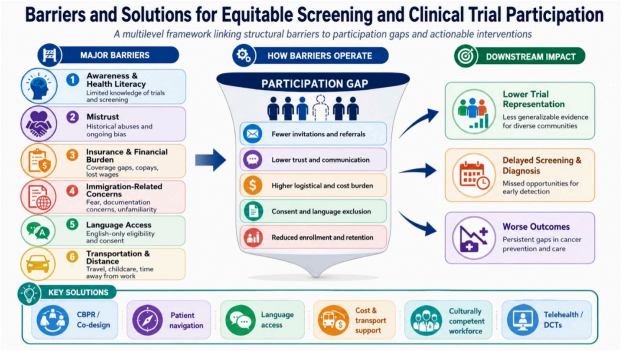


Figure 1. Barriers and Solutions for Equitable Screening and Clinical Trial Participation.

Lack of Awareness

Low awareness of clinical trials remains one of the most significant and modifiable barriers to minority enrollment. Using data from the Health Information National Trends Survey (2008 and 2012), higher education (OR 3.52; 95% CI 2.16–5.74), higher yearly income (OR 1.84; CI 1.17–2.89), and internet use (OR 2.13; CI 1.52–3.0) were each significantly associated with trial awareness.[19] A 2021 national survey published in *JAMA Network Open* found that only 1 in 10 Americans reported being invited to participate in a clinical trial, and of those, only half enrolled. Healthcare professionals were identified as both the primary and most trusted source of trial information, underscoring the centrality of the patient–provider relationship in driving awareness and trial enrollment.[20] Since health literacy varies among patients, physicians have the responsibility to communicate these complex protocols effectively. A temporal analysis of head and neck cancer trial data spanning 20 years found that minority patients were invited to participate less frequently than White patients; yet when offered the opportunity, Hispanic patients demonstrated significantly higher consent rates (55.9% vs. 41.8%), and BAA patients showed slightly higher rates as well (45.3% vs. 41.8%).[21] These findings reframe the issue as one of access and invitation, linking both implicit and explicit biases among clinicians and trial coordinators as drivers of enrollment disparities.[20]

Mistrust of the Medical System

Mistrust among minority patients operates at both interpersonal and systemic levels, shaped by previous healthcare experiences and by this country's history of research abuses targeting minority com-

munities, most notably the U.S. Public Health Service Tuskegee Syphilis Study.[22,23] This mistrust is deepened by ongoing experiences of racial discrimination within healthcare today.[24] A systematic review of barriers to clinical trial participation among BAA women identified the fractured relationship between this group and the medical research establishment as the most consistently cited obstacle. Mistrust manifested in multiple ways: apprehension about being subjected to experimentation, uncertainty about what consent truly entailed, and concern about the safety of investigational treatments. Taken together, these findings reflect a community whose historical and ongoing experiences within the healthcare system have produced a well-founded wariness of research participation that cannot be addressed through information alone.[25] Despite this mistrust, evidence consistently demonstrates that minority patients are willing to participate in trials when opportunities are equitably presented, suggesting that structural and access barriers may play a greater role than patients' reservations alone.[21,26]

Financial Toxicity

Financial burden remains one of the most frequently reported obstacles to clinical trial participation. A prospective survey among lymphoma patients at MD Anderson Cancer Center found that 71% identified insurance coverage and financial support as the most helpful interventions to improve trial enrollment decision-making.[29] A large cross-sectional study of American adults identified inadequate insurance coverage for standard-of-care costs as a key deterrent, and found that Medicaid-enrolled patients were more often invited to trials but participated less frequently, suggesting that indirect costs like transportation, childcare, or lost wages create barriers that coverage alone does not address. While the Clinical Treatment Act of 2020 required Medicaid to cover routine clinical care costs in qualifying trials, indirect costs remain largely unaddressed.[20] A joint position statement from the American Association for Cancer Research (AACR), the American Cancer Society (ACS), American Society of Clinical Oncology (ASCO), and the National Cancer Institute (NCI) recommended collaboration among trial sponsors and federal agencies like the Centers for Medicare & Medicaid Services to systematically eliminate financial barriers to participation.[30]

A systemic barrier in terms of financial toxicity includes decreased federal research funding. Elimination of federal initiatives to promote diversity, equity and inclusion (DEI) has led to major changes in grant review and award processes, decreasing or excluding research that supports marginalized populations. The NCI serves as the U.S. government's principal agency for cancer research. A cross-sectional study from 2025 identified 181 terminated NCI funded grants, with a total award amount of $640 million and an estimated $317 million in unspent funds. Many of these grant terminations affected graduate students and junior faculty, causing disruption in their early research careers.[62] Another study showed that terminating National Institutes of Health (NIH) grants in the first half of 2025 affected around 74,000 participants enrolled in clinical trials, leading to disruption of randomized trials that inform evidence-based practice.[63]

Immigration Status

Immigration status introduces a relatively recent and often invisible barrier to trial participation in the United States. Changes to immigration and customs enforcement (ICE) by the current administration adds a new level to the barrier, increasing healthcare disruptions. The administration rescinded the longstanding "protected areas" policy in Jan 2025 that shielded designated areas like hospitals and clinics from immigration enforcement. This has led to missing appointments, delayed diagnoses and late-stage disease presentations due to fear of being detained and deported. Undocumented immigrants may also avoid research participation out of fear that it could expose them to immigration enforcement and subsequent deportation.[31] Hispanic immigrants, the largest immigrant group in the U.S. face increased concern given the current political environment surrounding immigration enforcement.[27] A California-based study examining the association between law enforcement experiences and healthcare access among Hispanic and AAPI immigrants found that delays in seeking care and avoidance of healthcare settings reflect a broader climate of fear.[32] Survey data from 2011 to 2016 further demonstrated that immigration enforcement activity was associated with decreased healthcare-seeking among Hispanic adults, in whom the perceived risk of deportation outweighed the perceived benefits of care.[33]

Legal immigrants also face obstacles related to restricted health coverage and difficulty navigating the research infrastructure.[34] These dynamics must be acknowledged in the trial design and consent process.

Language

Language barriers represent a structurally embedded obstacle to trial participation. A systematic analysis of more than 14,000 interventional trials registered on ClinicalTrials.gov revealed that nearly one in five explicitly required English proficiency as an eligibility criterion, while fewer than 3% made any affirmative provision for non-English speakers. The vast majority of protocols were silent on both counts, and those imposing a language requirement provided little standardized guidance on how proficiency would be assessed, leaving significant room for inconsistent and potentially discriminatory application.[35]

Translation costs represent a distinct and quantifiable barrier. A 2023 study published in *Nature* examined consent events at the Jonsson Comprehensive Cancer Center of UCLA and found that patients with limited English proficiency received consents at half the rate in non–industry-sponsored trials compared to industry-sponsored ones, reflecting the uneven distribution of funding for translation.[36] Time constraints in clinical settings further compound these challenges, with studies showing that physicians spend less time discussing trials with older Hispanic patients, contributing to lower participation rates.[37] For AAPI populations, who represent multiple distinct linguistic communities despite being grouped together, the absence of reliable interpreter services limits delivery of accurate and culturally competent trial information.[15]

Distance and Transportation

Transportation barriers disproportionately affect minority and low-socioeconomic-status populations and have measurable consequences for cancer care and research participation. Not having a mode of transportation, using public forms of transportation, relying on family members or friends to offer rides, living in a rural area with few clinics or hospitals are among the many ways this barrier affects patient care. A review of retrospective studies found that travel burden and distance from treatment sites were associated with more advanced stage at diagnosis, lower treatment adherence, worse prognosis, and diminished quality of life.[38] Among lymphoma patients at U.S. cancer centers, Hispanic and BAA patients reported significantly greater concerns about travel distance compared to White patients (34% and 31% vs. 14%). Female participants were significantly more likely to identify childcare availability (23% vs. 11%, $p = 0.004$) and flexible scheduling (62% vs. 43%, $p = 0.015$) as important facilitators of enrollment.[29] Strategies to reduce these barriers must be discussed during trial design, prior to and during patient enrollment.

Limited Access to Culturally Competent Care

The absence of culturally competent care within research settings serves as both a direct barrier to enrollment and a reinforcing factor for other barriers such as mistrust and poor communication. Clinical trial sites lacking diverse research staff, multilingual materials, and culturally sensitive protocols are less likely to engage minority populations effectively.[21,26] A joint statement from the ASCO and Association of Community Cancer Centers (ACCC) recommended that all individuals designing or implementing trials complete training in implicit bias, culturally competent communication, and the history of research abuses in the United States.[39] The research workforce also remains insufficiently diverse, particularly in leadership positions such as principal investigators.[40]

Collectively, these barriers highlight that underrepresentation in clinical trials is not driven by lack of interest alone, but by structural, cultural, financial, linguistic, and logistical challenges that limit access and opportunity. Addressing these gaps will require intentional, community-informed strategies that build trust, reduce practical burdens, and make clinical research more accessible to the populations it aims to serve.

Strategies and Solutions to Improve Equitable Clinical Trial Participation

Addressing disparities in clinical trial participation requires moving beyond identifying barriers toward implementing intentional, community-centered, and system-level solutions. Effective strategies must include trusted community partnerships, culturally and linguistically tailored education,

Table 1. Evidence-based strategies to improve equitable clinical trial participation among underrepresented populations.

Strategy	**Core Approach**	**Evidence / Impact**	**Ref.**
Community-Engaged Research and Co-Design	Use CBPR to build sustained, trust-based partnerships with community members from project conception through implementation.	CBPR improves recruitment, retention, and intervention effects in racial/ethnic minority populations; >85% of CBPR clinical trials in one systematic review reported statistically positive outcomes.	41,42
Oncology-Focused Community Partnerships	Combine community health workers, outreach campaigns, health fairs, and prevention education.	Multilevel liver cancer prevention initiatives improved liver cancer knowledge, viral hepatitis screening uptake, and community capacity for cancer research participation.	43
Patient Navigation Programs	Deploy trained lay navigators or community health workers to support awareness, eligibility, consent, logistics, and retention.	IMPaCT increased minority participation in therapeutic cancer trials from 9% to 16%; navigation programs show low refusal rates and improved reach into Hispanic, female, and minority populations.	44-46
Navigation for Supportive Care and Retention	Address quality-of-life, financial, and logistical barriers during trial participation.	Community health worker-led navigation improved health-related quality of life among low-income and racially/ethnically minoritized patients with cancer at 4 and 12 months.	47
Community-Based Outreach and Culturally Tailored Education	Deliver education through trusted settings such as churches, community centers, clinics, grocery stores, family networks, and local media.	Culturally tailored education improved knowledge, trust in researchers, and intent to participate in trials among Black and Hispanic communities; language-specific materials improve engagement in cancer care.	15,48,49
Workforce Diversity and Racial Concordance	Build research teams that reflect the communities being served,	Diverse and racially concordant research staff can reduce mistrust,	50

	including racially concordant coordinators and culturally competent investigators.	improve communication, and increase minority trial accrual.	
Language Access	Incorporate bilingual navigators, interpreters trained in clinical trial concepts, translated materials, and family-inclusive decision-making.	Interpreter training improved preparedness and confidence in discussing trials; expert panels recommend culturally informed, family-inclusive approaches for Hispanic and Asian patients.	51,52
Financial Reimbursement and Transportation Support	Offset trial-related costs, including transportation, lodging, meals, parking, and lost wages.	Financial reimbursement programs are feasible and may increase representation of non-White participants; transportation support improves satisfaction, visit completion, and retention.	53,54
Decentralized Clinical Trials and Telehealth	Use remote consent, telehealth, local treatment delivery, remote monitoring, and local providers for study procedures.	Decentralized trial models reduced travel burden and improved access for patients from economically disadvantaged zip codes; telehealth can support rural oncology access, though digital inequities must be addressed.	55-57
NCORP and Community-Based Trial Infrastructure	Activate trials in community practices where patients already receive care.	NCORP expands access to NCI-approved trials, improves rural and underserved participation, and has demonstrated strong minority enrollment in Hawai'i, including Chinese, Filipino, Japanese, and Native Hawaiian patients.	58,59

CBPR = Community-based participatory research, NCORP = The NCI Community Oncology Research Program.

proactive patient navigation, financial and logistical support, diverse research teams, and trial designs that reduce unnecessary exclusion. Together, these approaches can help shift clinical research from a system that underrepresented patients must struggle to access, to one that actively meets patients where they are and invites equitable participation (Table 1).

Community-Engaged Research and Co-Design

Community-based participatory research (CBPR) has demonstrated high rates of success in recruiting and retaining minority participants by building sustained, trust-based collaborations from within the community rather than imposing them from the

outside. This is accomplished by engaging community members as partners and collaborators instead of subjects.[41] A systematic review of CBPR clinical trials involving racial and ethnic minorities found that over 85% of studies employing these methods reported statistically positive outcomes, with key success factors including community partner participation in advisory committees, data collection, and intervention development.[41,42] In oncology, a multilevel initiative for liver cancer prevention incorporating community health workers, city-wide outreach, and community health fairs produced notable improvements in liver cancer knowledge and uptake of viral hepatitis screening while building broader community capacity for cancer research participation.[43]

Patient Navigation Programs

Patient navigators are trained individuals who guide patients through trial awareness, eligibility, consent and retention. They represent a consistently evidence-supported approach for improving accrual of the medically underserved population. One of the most compelling demonstrations of patient navigation's effect comes from the IMPaCT program, which introduced navigators within an NCI-designated cancer center to support BAA patients from initial awareness through trial completion. The program produced a meaningful shift in enrollment; BAA participation in therapeutic cancer trials nearly doubled over the course of the intervention (from 9% to 16%) and retention rates among patients who consented to receive navigation compared to those who did not was significantly higher (74.5% vs 37.5%, $p < 0.001$).[44] A broader review confirmed that navigation programs targeting BAA, Native Americans, and Native Hawaiians showed consistently low refusal rates between 4-6%.[45]

Another navigation program identified 429 oncology patients and demonstrated clear reach into underrepresented populations: program participants were more likely to be Hispanic (31% vs. 21%), female (52% vs. 48%), and from an underrepresented community (30% vs. 24%) compared to the underlying patient population, with 92% of enrolled trial patients receiving financial navigation to support retention.[46] In a multisite oncology randomized controlled trial, a community health worker–led intervention significantly improved health-related quality of life among low-income and minority patients at both 4 and 12 months post-enrollment.[47]

Although labor intensive, these studies show the effectiveness of a patient navigator who acts as a bridge between the medical system and the patient.[45]

Community-Based Outreach and Culturally Tailored Education

Educational interventions are most effective when delivered through channels that communities already trust. A culturally tailored program using trained community health educators to deliver presentations at churches, local clinics, and community centers increased knowledge about clinical trials, trust in medical researchers, and intent to participate among BAA and Hispanic participants.[48] Engagement through grocery stores, places of worship, print media, and the internet has proven effective, and involving English-proficient younger family members to advocate for cancer screening among older relatives has shown particular promise in AAPI communities.[15] A systematic review of interventions to increase cancer screening uptake confirmed that culturally sensitive, language-specific materials can improve understanding and engagement across diverse communities.[49]

Workforce Diversity and Racial Concordance

The composition of the clinical research workforce is a modifiable factor. A systematic review found that diverse research teams reflective of underrepresented populations can alleviate barriers, including the fear of being used as a "guinea pig" and that racially concordant study coordinators were associated with increased trial accrual.[50] Racial concordance between patients and providers not only improves communication, trust, and adherence but also builds a research workforce that reflects the populations it serves, which is essential to equitable engagement.

Language Access

Engagement of community members who speak non-English languages through bilingual navigators, trained interpreters, or community health workers should be a core component of any equitable research program. An example of an interna-

tional initiative in New South Wales, Australia, that trained healthcare interpreters specifically in clinical trial concepts, demonstrated significant improvements in interpreter preparedness and confidence, representing a scalable workforce-level solution.[51] An expert panel on enrollment of Hispanic and AAPI patients in gynecologic oncology trials further recommended inclusive family participation in decision-making and endorsed the ASCO/ACCC *Just ASK* training program to help sites identify their barriers to diverse participation.[52]

Financial Reimbursement

Financial support programs represent a high-impact intervention for minority participation and retention. A pilot financial reimbursement program (FRP) at two NCI-designated cancer centers achieved a 78% consent rate, with 51% of enrolled participants identifying as non-White compared to 28% at typical institutional trials, demonstrating that income-adjusted financial support can measurably shift the demographic composition of trial enrolled populations.[53] Direct transportation services have shown high rates of patient satisfaction and visit completion, and broad financial reimbursement programs can increase enrollment, particularly for low-income and racially/ethnically diverse patients.[54]

Decentralized Clinical Trials and Telehealth

Decentralized clinical trials (DCTs), incorporating remote consent, telehealth visits, remote patient monitoring, and local providers offer practical solutions to financial and logistical barriers. Evidence from a Stanford-led phase II study that relocated chemotherapy delivery into local community settings illustrates this potential: patients treated closer to home not only faced reduced travel burdens but were more likely to come from economically disadvantaged areas, suggesting that decentralization can actively shift the socioeconomic profile of enrolled populations toward those most historically excluded.[55] Telehealth holds significant promise for rural oncology care and trial participation,[56] though investigators must actively attend to digital access inequities, which could undermine outcomes if not explicitly addressed through device lending or technical support programs.[57]

The NCI Community Oncology Research Program (NCORP)

Effective strategies to improve equitable clinical trial participation are most impactful when implemented together within a sustained, multilevel framework supported by infrastructure such as NCORP. NCORP represents one of the most scaled solutions for expanding research access in underserved communities. Operating through a network of research bases and community sites distributed across the country, NCORP brings NCI-approved trials directly into the settings where rural and underserved patients already receive care, removing the need to travel to academic medical centers as a precondition for research participation.[58] The Hawaii Minority/Underserved NCORP program demonstrated that Chinese, Filipino, Japanese, and Native Hawaiian patients enrolled in cancer clinical trials at rates comparable to or exceeding those of White patients, affirming the effectiveness of community-based trial infrastructure as an equity strategy.[59]

An Integrated Multilevel Model for Scalable Action

The barriers and solutions to equitable clinical trial participation are well documented, yet translating awareness into sustainable, scalable action remains a critical gap. The following model proposes a repeatable framework that health systems and researchers can employ to move from disparity identification to measurable improvement. We illustrate this framework using CHIP research in AAPI communities as a case study (Figure 2).



Figure 2. Integrated multilevel model for scalable action to improve equitable clinical trial participation.

Using clonal hematopoiesis of indeterminate potential (CHIP) research in Asian American and Pacific Islander (AAPI) communities as a case study, this model outlines a six-step, community-engaged framework: identifying disparities, partnering with trusted community-based organizations, providing culturally tailored education, decentralizing screening and enrollment, supporting participants through navigation and specialty referrals, and sharing findings back with the community. This cyclical approach aims to move from documented disparities to measurable improvements in participation, retention, early detection, and precision prevention for cancer and cardiovascular disease.

Step 1: Identify the Disparity

Principal investigators, trial sponsors, and health systems should begin by analyzing existing enrollment data to identify who is absent and why. Although the FDA has recommended that trial sponsors set goals to enroll representative populations, no consensus exists on how to quantitatively assess this representativeness.[60] Methods such as the participation-to-prevalence ratio (PPR) – the proportion of trial participants with the disease divided by the total disease burden in the population – offer one approach, but are dependent on well-defined and accurately reported prevalence data, which may be unreliable in historically marginalized communities.[61] Therefore, the appropriate method must be matched to the intent and goals of each trial.

We have identified that the AAPI population is severely underrepresented in CHIP research. CHIP, a precursor to hematologic malignancies and incident solid cancers, is strongly associated with increased cardiovascular (CVD) risk.[12,13] However, CHIP's prevalence and clinical implications remain largely unexamined in AAPI population. This limits our understanding of cancer and CVD risk in communities for whom these are leading causes of mortality.[13,14] The study aims to evaluate the prevalence of CHIP and its relationship to CVD risk factors, generating novel biomarker data to support precision prevention strategies in AAPI populations.

Step 2: Partner with Trusted Community-based Organizations (CBO)

Once disparities are identified, health systems must establish trustworthy, bidirectional partnerships with CBOs rather than arranging top-down recruitment campaigns.

The CHIP project leverages a multidisciplinary team – including oncologists, preventive cardiologists, health policy specialists, molecular pathology experts, and community leaders – to develop a community based participatory research design. Partnerships with local organizations such as the AAPI Health Coalition, the American Heart Association of Greater Cleveland, and the Cuyahoga County Board of Health aim to decentralize research and embed it within trusted community networks. Using surveys and focus groups with Chinese, Filipino, Pakistani, Indian, and Afghan community members, the team identified major logistical barriers including transportation and childcare. Through strategic engagement of the AAPI community, we secured strong community backing by partnering with Federally Qualified Health Centers, the grassroots organization A.S.I.A. Inc., and the Filipino Nursing Association. Additionally, the American Heart Association has committed resources for language translation and culturally tailored educational materials, and blood pressure monitoring hubs have been identified to optimize AAPI out-

reach and participation. With community backing for the initiative, we strive to increase willingness among the AAPI population to participate in clinical trials.

Step 3: Provide Culturally Tailored Education

Working with community leaders and navigators, education must be linguistically appropriate, culturally sensitive, and delivered through trusted channels. For the CHIP project, education sessions are being developed to raise awareness of CVD in the AAPI community and to educate participants on the link between CHIP and elevated cardiovascular risk. Pre-existing CVD educational materials from the American Heart Association will be distributed during these sessions to improve health literacy and encourage engagement with CHIP screening and preventive care. Participants will also receive education about CHIP and cancer risk. The term "cancer" often carries stigma in Asian communities so educational sessions will need to be developed in conjunction with AAPI community health workers.[15]

Step 4: Decentralize Screening and Enrollment

Bringing screening and enrollment activities into community settings removes the logistical barriers like transportation, time off work, and childcare that disproportionately affect minority and socioeconomically disadvantaged populations. Decentralized models reimagine how, where, and when clinical research is conducted, extending study activities beyond the walls of research institutions and into patients' homes and communities.

Participants from AAPI communities in Greater Cleveland will be prospectively recruited through mobile research vehicles that will be deployed to different sites to ensure accessibility. Informed consent will be obtained by a clinical research coordinator on-site in the mobile research vehicle. Efforts will be made to have on-site translators available during the enrollment and consent process. Patients will go through Next Generation sequencing (NGS), a simple blood test. The study will assess the prevalence of CHIP generating novel biomarker data in AAPI populations.

Step 5: Patient Navigation and Referrals to Specialty Care

Once participants are enrolled, trained navigators must guide them through each step of the research process, troubleshoot logistical barriers, connect them to financial support programs, and facilitate timely referrals to specialty care.

To evaluate implementation effectiveness, the CHIP study will integrate a CBPR approach, actively involving AAPI community leaders and stakeholders in the research process. Regular feedback sessions and advisory input will help assess participant engagement, logistical challenges, and community-driven solutions to improve recruitment and retention strategies. Navigation bridges the gap between community-level outreach and the clinical infrastructure required for precision prevention, ensuring that participation leads to actionable health outcomes rather than data collection alone. By generating novel biomarker data and refining community engagement strategies, this study will inform evidence-based prevention strategies to reduce chronic disease burden, decrease healthcare expenditures, and improve long-term cardiovascular outcomes in AAPI populations. To ensure continuity of care, participants identified with CHIP-associated elevated CVD risk will be referred to preventive cardiology clinic for further evaluation and risk reduction interventions. Participants who test positive for CHIP mutations will also receive referrals to the CHIP clinic and be monitored with interval testing. This approach integrates early detection with targeted prevention, mitigating the long-term impact of cardiovascular disease and other chronic comorbidities.

Step 6: Share Findings with the Community

Equitable research is not extractive. Findings must be communicated back to community partners in accessible, culturally appropriate formats, reinforcing trust and sustaining the partnerships that make future research possible. Community events, translated summaries, and ongoing engagement with partner organizations are integral components of this model and distinguish it from traditional recruitment-only approaches.

Findings of the CHIP pilot study will be shared

with community partners, stakeholders, and research teams to refine study protocols and inform funding applications for expanding community-driven CHIP screening. Through this culturally tailored initiative, we aim to empower community members with knowledge, encourage participation in CHIP screening and preventive CVD care, and improve health literacy.

Policy and System Changes Needed

Closing the equity gap in cancer clinical trial participation will require structural and policy-level interventions that extend beyond the reach of any single institution or research team. Several priority areas emerge from the evidence reviewed here.

Mandatory Diversity Reporting and Accountability: Federal agencies, including the FDA and NIH, should move toward requiring, rather than merely recommending that trial sponsors submit and implement diversity enrollment plans with measurable targets and transparent reporting. Reporting disaggregated race and ethnicity data at the subgroup level should be a condition of trial registration and publication.[60,61]

Expanded Coverage of Trial-Related Costs: The Clinical Treatment Act of 2020 extended Medicaid coverage to routine care costs in qualifying trials, but indirect costs, transportation, lodging, childcare, and lost wages remain largely unaddressed. Policymakers should work with the Centers for Medicare & Medicaid Services and private insurers to develop standardized reimbursement frameworks for these expenses, consistent with the joint recommendations of AACR, ASCO, ACS, and NCI.[30]

Protections for Immigrant Participants: Federal and institutional policies should explicitly affirm that research participation does not trigger immigration enforcement, and trial consent documents should reflect these protections clearly. Collaboration between research institutions, legal advocacy organizations, and community health centers can help establish trust among undocumented and mixed-status communities who have been largely excluded from the research enterprise.[27,31–33]

Investment in Community Trial Infrastructure: Sustained federal investment in programs like NCORP, Federally Qualified Health Centers, and minority-serving institutions is essential to bring clinical trials to the communities where underrepresented patients already receive care. Expanding NCORP's reach and funding, particularly to sites serving AAPI, BAA, and Hispanic populations would accelerate equity in both access and accrual.[58,59]

Language Access Mandates: Regulatory bodies should require that clinical trials above a minimum size include translated consent documents and provide interpreter access as a condition of funding and approval, rather than leaving language accommodation to the discretion of principal investigators or the availability of industry sponsorship.[35,36]

Conclusions and Key Takeaways

Racial and ethnic disparities in cancer clinical trial participation are neither inevitable nor acceptable. This review demonstrates that barriers to equitable representation are multilevel, interconnected, and structurally embedded, spanning patient awareness, medical mistrust, financial toxicity, immigration-related fears, language exclusion, transportation burden, and the absence of culturally competent research environments. Critically, these barriers are modifiable. Community-engaged research, patient navigation, culturally tailored education, diverse research workforces, language access, financial reimbursement, and decentralized trial design have each demonstrated meaningful impact, and their effects are amplified when implemented together.

The CHIP pilot study presented here illustrates how a multilevel, community-rooted model can be implemented into practice — beginning with disparity identification, proceeding through trusted community partnerships and culturally tailored education, and ultimately connecting participants to navigation and specialty care. This framework is repeatable and adaptable across cancer types, populations, and geographic contexts.

Progress requires action at every level: researchers must design trials that center equity from the outset; health systems must invest in navigators, interpreters, and culturally competent staff; policymakers must create regulatory frameworks with meaningful accountability; and communities must

be engaged as genuine partners rather than passive recruitment targets. The ultimate goal is not representative enrollment as an end in itself, but a research enterprise whose findings are truly generalizable and whose benefits reach every population it is meant to serve.

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