

Clinical Trial Diversity

Advancing Scientific Discovery and Equity



A Report by the
Aspen Institute Science & Society Program





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Editors' Note

In late 2022, the Aspen Institute Science & Society Program convened a group of esteemed individuals for a moderated virtual discussion on how to increase diversity in clinical trial research. This report, publicly available to members of the scientific and medical communities, contains a summary of key points the participants made.

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The aim of this report is to synthesize and share perspectives from the discussion as a whole rather than to attribute any quotations or viewpoints to specific individuals. We are grateful to the following individuals (listed alphabetically by last name) for their participation in this timely and important discussion:

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Clinical Trial Diversity

Community–academic–industry partnerships: Promoting access to trials for underserved and historically marginalized populations

Tactical and strategic approaches to improve scientific literacy and access to clinical trials

Community–academic–industry partnerships are critical for making advancements in science, building trust, reaching diverse populations, and improving population health, particularly among those experiencing inequities. Equitable and mutually beneficial partnerships provide communities with education, facilitate capacity building within communities, and support the execution and dissemination of research designed to address real-world problems.¹ In this vein, roundtable participants explored both tactical and strategic mechanisms through which community–academic–industry partnerships could take shape to promote access to clinical trials for underrepresented populations, which, in this context, refer to “individuals from racial, ethnic, or linguistic groups not proportional to their share of the population meant to benefit from trial findings.”²

Organization-driven tactical approaches

Underrepresentation in clinical trials “perpetuate[s] disparities in outcomes and lead[s] to limited generalizability in practice,” with common barriers cited as being provider-, patient-, institutional-, and study design-related.³ Participants shared top-of-mind organizations and partnerships working to provide education about, and promote access to, clinical trials among communities that traditionally have low participation rates. These organizations spanned sectors and populations served, with examples including: the Lazarex Cancer Foundation, Tu Salud Tu Familia, the Michigan Center for Urban African American Aging Research, Acclimate, the California Health Care Foundation, and the Clinical Trials Transformation Initiative.

The [Lazarex Cancer Foundation](#)’s national IMPACT (IMproving Patient Access to Cancer Clinical Trials) program is designed to increase cancer clinical trials participation and retention among racial/ethnic minorities and underserved populations, improve access to trials, and reduce barriers to participation. IMPACT brings together cross-sector resources to help reduce the financial burden of clinical trial participation on populations identifying as underserved as well as their caregivers.

1. [Holton VL et al.](#) (2015). Measuring Community–University Partnerships across a Complex Research University: Lessons and Findings from a Pilot Enterprise Data Collection Mechanism. *Metropolitan Universities* 26(2): 99–124.

2. [Alhalel J et al.](#) (2022). How Should Representation of Subjects With LEP Become More Equitable in Clinical Trials? *AMA Journal of Ethics* 24(4): E319–325.

3. [Sae-Hau M et al.](#) (2021). Overcoming Barriers to Clinical Trial Participation: Outcomes of a National Clinical Trial Matching and Navigation Service for Patients With a Blood Cancer. *JCO Oncology Practice* 17(12): e1866–1878

[Tu Salud Tu Familia](#) (Your Health Your Family) is an award-winning, multimedia news program with short segments designed to reach and educate Latino/a/x populations and those with limited English proficiency.⁴ Hosted by physician-researcher Dr. Fabian Sandoval, Tu Salud Tu Familia content is produced in Spanish language to help ensure that Latino/a/x populations are informed of the latest medical research, equipped with information to promote healthy living,⁵ and educated about “health issues, healthy behaviors, and the importance of participating in clinical trials.”⁶

The [Michigan Center for Urban African American Aging Research](#) (MCUAAAR), founded in 1998, has been a long-standing and collaborative research, community outreach, and faculty mentorship program based at Wayne State, Michigan State, and the University of Michigan. The program works to “enhance the diversity of the future scientific research workforce [and to mentor] promising new faculty and research scientists from under-represented groups for sustained careers in aging-related behavioral research.”⁷ According to one roundtable participant, MCUAAAR has a pool of over one thousand Black/African-American older adults eager and willing to participate in research.

The Huntsville, Alabama-based company, [Acclinate](#), offers a tech-driven approach to clinical trials recruitment by working with Clinical Research Organizations (CROs) and pharmaceutical and healthcare companies to integrate “culture and technology to achieve more inclusive clinical research.”⁸ A roundtable participant noted that in the past, the organization had an interest in working with mayoral associations to facilitate increased engagement in urban areas. Understanding the value tech can bring to clinical trial participant recruitment and diversity, researchers have been partnering with tech and biotech firms to address this issue.⁹

The [California Health Care Foundation](#) (CHCF) is an organization dedicated to improving the health of underserved and historically and continually marginalized and oppressed communities.¹⁰ It was noted during the discussion that CHCF “has strong leadership and understands the value of research, mechanisms of funding research, and connections to healthcare clinics and hospitals and providers”—enabling a built-in network equipped with available resources from their research partnerships.

4. [Medidata](#) (September, 2022). Medical Education TV Show Sponsored by Medidata Wins Third Capital Emmy® Award.

5. [National Institute on Minority Health and Health Disparities](#) (n.d). Telemundo series: Tu Salud, Tu Familia

6. [Medidata](#) (September, 2022). Medical Education TV Show Sponsored by Medidata Wins Third Capital Emmy® Award.

7. [Michigan Center for Urban African American Aging Research](#) (2023). About us.

8. [Acclinate](#) (2022). Acclinate is achieving diversity in clinical research trials.

9. [Clark B & Tepp R](#) (2010). Community engagement is key to clinical trial recruitment and diversity. STAT.

10. [California Health Foundation](#) (2022). About.

The [Clinical Trials Transformation Initiative](#) (CTTI) was highlighted during the discussion. A public-private partnership between Duke University and the U.S. Food & Drug Administration (FDA), CTTI's mission is "to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials."¹¹ As one roundtable participant noted, "CTTI provides people with recommendations and tools on how to make diversity and clinical trials happen, and [with] new recommendations being released soon."

Strategic approaches to improve access to clinical trials

Beyond tactical approaches, action on the part of cross-sector (public, private, non-profit) organizations was also recommended. Key themes arising during the conversation included language justice and community engagement.

Considering a language justice lens to foster participation

In addition to spotlighting specific organizations, the group's attention was drawn to a recent systematic review of 14,000+ clinical trials with English language proficiency as an inclusion criteria.¹² The subsequent discussion focused on applying a language-justice perspective in the design of study protocols to ensure that participants who may otherwise be eligible are not excluded because of their limited English proficiency. Building on the discussion, a participant shared that their organization's patient materials are automatically translated into Spanish, and that when determining study site locations, they collect linguistic information and proactively encourage CROs to ask sites about said languages. Moreover, for sites that require more support and/or do not have language concordance between staff or physicians and patients, the organization has employed mobile, on-demand translation services through an on-site translator or via mobile devices (e.g., smartphone, tablet). Language concordance has been shown to improve trust between patients and physicians, optimize health outcomes, improve care, advance health equity for diverse populations, and serve as a window to broader social determinants of health that disproportionately yield worse health outcomes among patients with limited English proficiency.¹³

A counterview by another attendee presented the notion that merely knowing how to speak a language such as Spanish (native or otherwise), having a translator, and providing written materials does not fully address language justice. It was argued that rigor and accuracy are paramount and that "many interpreters are not familiar with the language of clinical trials." Complex early-phase clinical trials and the concept of randomization were given as examples. Established translation methodologies, such as back translation (also called reverse translation) and the requirement to have formalized certifications or training were described as being critical. Furthermore, some of the legal requirements for language to be included in consent forms is above the recommended grade level. Evidence sug-

11. [Clinical Trials Transformation Initiative](#) (2022). Who we are.

12. [Muthukumar AV et al.](#) (September, 2021). Evaluating the frequency of English language requirements in clinical trial eligibility criteria: A systematic analysis using ClinicalTrials.gov. *PLoS Med* 18(9): e1003758.

13. [Molina RL & Kasper J](#) (2019). The power of language-concordant care: a call to action for medical schools. *BMC Med Educ* 19(378).

gests that reading materials should be written between a 6th- and 8th-grade reading level.¹⁴ A participant voiced that to have these conversations and simultaneously have legal study documentation language requirements that potentially impede documents being written at an understandable level or in an understandable way is counterproductive.

It was expressed that organizations in the research community must begin to think about:

- How guidance around language proficiency may limit trial access and the eligibility of diverse subgroups who ought to be included in research
- Who is on the research team(s) and whether they are equipped with the necessary skills to engage effectively and inclusively
- The reading level of study documents.

Community engagement as a core element to address barriers to clinical trial participation

On-the-ground community engagement arose in the discussion as an important strategy for clinical trial participation. However, as a roundtable participant shared based on observations from their clinical trial site visits, “sponsors don’t think about the community first.” These visits with site staff entail inquiring directly about what they are doing to engage with the community, with some fully engaged of their own volition by attending football games, churches, and community centers, while others are not. Tu Salud Tu Familia was referenced as one of the endeavors “working at a level where others need to be,” with a comment that host Dr. Sandoval “is one of those physicians that does that really well on his own, which has been a game changer.”

14. The recommended grade level for research materials is between 6th and 8th grade ([Hadden et al., 2017](#)).



Moving the needle: Mechanisms for non-minority physicians and researchers to lead more inclusive and diverse clinical trials

Individual-level strategies

Physician and researcher “trust” surfaced as a major theme when trying to move the needle in creating more inclusive and diverse clinical trials. The concept of trust was discussed from the perspective of patients trusting physicians and researchers. A roundtable participant reflected that within the context of a “post-pandemic society,” there has been an increase in principal investigators referring to trust as a hurdle to clinical trial participation. Yet, as the participant also noted, “three independent companies successfully enrolled diverse populations in COVID-19 vaccine clinical trials, without coordinating across companies.” It was argued that physicians and researchers from non-racial and ethnic minority groups should move beyond “patient trust” as a default barrier. Instead, they should recognize their role in the chasm between physicians, researchers, and underrepresented populations. Furthermore, they should engage in practices that will help facilitate their perception as a trusted voice.

As explained by one participant, “a trusted voice means either the investigator understands the circumstances of the patient population, or [that] the physician/researcher can identify with the investigator.” For example, it was mentioned that at times, some physicians and clinical trial sites are not aware of their patient demographics, which has implications for who is part of their research team, physician/researcher/staff-patient language concordance, and community engagement. Other participants agreed and further noted that physicians in particular will oftentimes not inquire about patients’ interest in clinical trial participation, discount questions that patients ask about clinical trials, or make assumptions that some patients could not afford the costs associated with trial treatments and in turn not make a referral to the clinical trial.

Similarly, there tends to be a focus on the recruitment needs of individual trials as opposed to the individual needs of patients—and a lack of desire to uncover their knowledge, attitudes, and beliefs. Patient needs should be considered from the outset, and part of being a trusted voice means understanding individual-level determinants of clinical trial participation. This requires a shift in the physician/researcher’s perspective. Participants advised that physicians/researchers conduct an assessment of who makes up their patient population, talk to patients without judgments or assumptions, and consider the importance of—and strive to be—a trusted voice. There was a recommendation to be empathetic and “put yourself in the place of the patients that you want to be able to serve. Avoid those assumptions and you’ll be starting off at a much more positive place.”

A resource designed in partnership with the American Society of Clinical Oncology and the Association of Community Cancer Centers called [Just Ask™](#) was shared as a tool to better equip clinical trial research teams “to promote diversity, inclusion, and equity to improve the enrollment and retention of patients from African American/Black, Hispanic/Latino/a/x, and other groups who have been historically under-represented in clinical trials.”¹⁵ Just Ask™ is the first clinical trials-specific unconscious bias training for clinicians. In addition to this training, which was released in July 2022, the partners

15. [Association of Community Cancer Centers](#) (2022). Just Ask. Increasing Diversity in Cancer Clinical Research.

also created a self-assessment to enable clinical trial sites to review their own programs, policies, and procedures with the goal of determining how to best mitigate disparities in clinical trial enrollment.

Taking action: Community and structural strategies

The importance of community perspectives and community engagement could not be understated. It was voiced that “community member inclusion is important because they add an additional lens and lived experience. How are we developing our relationships with these communities? An understanding of this is critical in moving forward.”

While considered a standard or more traditional community engagement strategy, attendees advised conducting community seminars or town hall meetings. Other recommended community-level strategies included:

- Participating in conferences and convenings that directly engage with patient ambassadors and patient groups.
- Creating enduring alliances that involve collaborating with all physicians—particularly those of color—and working with cross-sector and cross-industry organizations and companies, such as drug stores and big-box stores, to make clinical trials more convenient and accessible.
- Asking questions when speaking with patients versus making assumptions about whether they would or would not have the interest or means to participate in a clinical trial.
- Inviting community stakeholders to be part of the research team (e.g., to have a professional role or join a community advisory board) and including them in the data interpretation process, which uncovers nuances that might not otherwise be known by the researchers.
- Moving away from “helicopter research” where research teams swoop into communities and collect data from residents, only to never return or share outcomes and impacts of their participation. Disseminating study results to the population under study provides communities with a sense of collaboration and an understanding of their role, contributions, and impact as research participants.



Structural strategies included:

- Complying with FDA requirements to develop a diversity plan at the initiation of planning a clinical trial which details how the research team intends to recruit a more diverse population. Guidance around the plan has strengthened incrementally since its first iteration in 2016.¹⁶
- Including investigator demographics in any peer-reviewed research publication referencing a clinical trial. This approach alludes to detailing who is doing the research and how well those investigators align with both the question and the study cohort a priori.
- Requiring researchers to identify how disease processes impact multiple different cohorts.

While reflecting on the community and systemic strategies shared by attendees, a participant posited that “if voluntary outreach and community engagement strategies don’t work, these other requirements now in medical publishing, and in registration, which is where the money resides, may make a difference.” Along these same lines, major financial commitments, strong leadership, buy-in from key stakeholders, and overall organizational support were expressed as indicators of support. Healthcare and pharmaceutical industries should not wait for things to become a requirement. Instead, they need to be proactive and recognize that the industry is evolving, which will ultimately lead to positive patient-level impacts.

16. [FDA](#) (October, 2016). Collection of Race and Ethnicity Data in Clinical Trials.

Decentralized clinical trials (DCTs): A strategy to remove historic barriers and gain public trust—or not?

The discussion opened with roundtable participants describing barriers to standardized care¹⁷ (e.g., minimized health care insurance, unemployment, trust, costs, transportation, and hours of operation), and how said barriers accumulate over time. It was argued that addressing these barriers will enable patients to be themselves, without bearing the burden of other influencing factors. It was expressed that once individuals realize that through clinical trial participation they could gain regular access to care and receive novel medications that they could not previously afford, they begin to fully understand the importance of clinical trials and the implications for improved quality of life. As a roundtable participant commented that historically, one reason that people do not participate in clinical trials is because until the COVID-19 pandemic, they did not know or understand where their medication had been developed. If people are educated about what the development process looks like and how they can be part of that innovation, as a way to start bridging equity gaps, that can change the discussion from experimentation and being a guinea pig to being part of the solution. There are business models, such as Walgreens' clinical trial business, that begin to address clinical trial access and diversity challenges, which is ideal given that nearly 80% of Americans reside within five miles of a location¹⁸ and noting that 51% of those locations are in socially vulnerable communities.¹⁹ Models such as these change how people learn about trials and shift the paradigm when it comes to who has access and who participates in clinical trials.

Decentralized clinical trials: A mechanism to increase enrollment or participant burden?

Decentralized clinical trials (DCTs) were described as a “next level” approach that improves access to clinical trials and enables research teams to go out into the community and recruit in spaces where people are living. As such, it was argued that the momentum around clinical trials is moving away from fully in-person activities (e.g., toward electronic informed consent, patients filling out the patient report) with patients performing study requirements remotely in the comfort of their own home. A roundtable participant further noted that DCTs have made it such that “conversations about enrollment in clinical trials are no longer limited to a patient’s doctor” and that “capturing observational data can be completely digital and involves no human interaction, no human touch.” When speaking about their proprietary DCT platform, an attendee shared that “there is an absolute need to make it easier for people to participate in clinical trials. My company uses technology to either deliver a clinical trial or to connect a local healthcare provider to the clinical trials so it can be easier for participants to enroll if eligible.” While reflecting, a participant voiced that some of the success of Operation Warp Speed Trials²⁰ for COVID-19 vaccine development was attributed to remote patient participation.

17. Standard of care is defined as “treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy ([National Cancer Institute](#), 2023).

18. [Walgreens](#) (2020). Facts and FAQs.

19. [Walgreens](#) (2022). Walgreens Launches Clinical Trial Business to Address Industry-wide Access and Diversity Challenges and Redefine Patient Experience.

20. [United States Government Accountability Office](#) (February, 2021). Operation Warp Speed Trials: Accelerated COVID 19 Vaccine Development Status and Efforts to Address Manufacturing Challenges. GAO-21-319.

As a contrasting point of view, it was also argued that DCTs may not actually minimize barriers and to some extent may place more burden on or require greater effort from patients. A participant further noted that “we must ensure that another level of bias is not introduced where people who don’t have access to technology cannot participate.” While DCTs may make learning about and enrolling in clinical trials easier, it is important to ensure that they are not catering exclusively to the digitally-enabled. In observing clinical trial sites, particularly in those studies serving elderly or rural populations, an attendee shared that “the [clinical trial] sites will tell us that patients will come back and sit in the lobby and do things for their e-consent or anything electronic because they don’t have Wi-Fi or it’s not working and they need someone to handhold them through the process.” It was cautioned, however, “not [to] fall into the trap of thinking that all underrepresented populations don’t have access to digital technologies,” as this is variable.^{21,22} Another participant further advised that the limitations of DCTs should be recognized more in the industry as there is greater realization that they “aren’t always capable of helping our patients that we want to serve.”

DCTs were perceived by one participant to be a “retention play more so than a recruitment play,” adding that they do not address the core issue of trust. The speaker argued that community engagement and the development of community partnerships with local organizations are the best methods for cultivating and fostering an environment of trust. As they noted, “relying solely upon DCT works counter to what we’re actually trying to accomplish with being visible and being sort of ‘local’ to many of the patient communities that we are seeking.” It was advised that, in reality, there is no one best approach and that “one size does not fit all.” What works for one group of people, such as recent immigrants, may not work for another, for example longtime residents. Per another roundtable participant, “If we involve more people in the community [who] look like the people who we would like to enroll in clinical trials, then that will help alleviate the trust issue.” Regardless of whether a clinical trial has a traditional brick-and-mortar study design or a decentralized study design, it was recommended to shift the conversation from questioning patient trust to reflecting on trustworthiness in the eyes of patients (i.e., trusted voice), and considering ways players are—or are not—engaging with them.

21. [Atske S & Perrin A](#) (2021). Home broadband adoption, computer ownership vary by race, ethnicity in the U.S. Pew Research Center.

22. “The vast majority of Americans are now online, as ongoing government and social service programs encourage internet adoption in underserved areas” ([Pew Research Center](#), 2021).

The clinical research ecosystem: Achieving sustainable, long-term impact

The culture of clinical trial research teams was a key theme in discussing diversity, equity, and inclusion (DEI). Little is known about what factors influence the recruitment decisions and the behaviors of clinical trials research teams.²³ As one roundtable participant noted, “the cultivation of a culture that understands the value of focusing on representation and diversity in clinical trials is still varied.” There is much work to be done with regard to “shaping and reinforcing the culture” of why research takes place and the need to prioritize representation. Participants agreed that it is time to move beyond the status quo. This means increasing participant diversity in clinical trials not only for the sake of fulfilling a requirement from a funder or sponsor, but because improving representation “is the important thing to do if we’re really going to address gaps in health equity and move the needle.” In addition to a culture shift, roundtable participants shared other recommendations centered on researcher-participant concordance, diversity training, designing clinical trials for justice, and making organizational investments to demonstrate commitment to achieving sustainable, long-term impacts.

Researcher-participant concordance

Furthering the discussion on representation, there was a shift in focus to the critical nature of diverse research teams and the question of “how we are cultivating a pipeline of researchers who represent historically underrepresented areas.” Acknowledging that while everyone has their respective expertise, “there’s something to be said about the lived experience of the researcher that provides an extra added protection and equity lens when they are conducting and designing the research study that might be missed by race discordant researcher-participant relationships.” The group was urged by a fellow roundtable participant to reflect on the diversity of their own teams—or lack thereof—and to be proactive with regard to connecting and working with researchers who represent the very same underrepresented populations that their studies focus on.

Diversity training

Research has demonstrated the value and efficacy of community clinical trial sites as a strategy for recruiting patients from underrepresented populations.²⁴ As one participant felt, based on their visits to community clinical trial sites, there is a critical need to invest in workforce development around DEI. Subsequently, the need to broaden training for clinical trial site staff was a recommendation from roundtable participants, as was the need to clearly explain the “why” and “how” of moving forward with effective diversity tactics. It was mentioned that community sites in particular—as opposed to large networked sites—may be aware of the FDA’s diversity guidance but remain unclear about why the FDA and/or sponsors are asking for diversity. Data have shown that “the capacity to acquire cultural knowledge about patients—their physical locales, cultural values, and environments in which

23. [Rai T et al.](#) (2021). Shifting research culture to address the mismatch between where trials recruit and where populations with the most disease live: a qualitative study. *BMC Medical Research Methodology* 21(80): 1–10.

24. [Heller C et al.](#) (2014). Strategies addressing barriers to clinical trial enrollment of underrepresented populations: A systematic review. *Contemporary Clinical Trials* 39(2): 169–182.

they live—is essential to recruiting culturally and ethnically diverse population samples.”²⁵ Thus, greater transparency is critical and those on the frontline in patient-facing positions may benefit from training in cultural humility along with efforts to uncover and address biases. This training would aid in making them feel comfortable enough to share feedback on what they are seeing and any challenges that persist. A roundtable participant referenced data from the [Society of Clinical Research Sites](#) (SCRS) and found that “most sites report that they are doing diversity efforts just fine,” which, “we know is clearly not accurate if we are not seeing it in the clinical trials.” It was further argued that clinical trial sites may not know what diversity is and looks like or may not understand how they can improve diversity within their own patient populations. In addition to training, they should be provided with information and resources (i.e., funding) to ensure that they are comfortable and capable.

Design for justice

While clinical trials are the “gold standard,” a lack of diverse representation in clinical trials has major implications for the validity of study findings, as generalizability and the capacity for research translation are at risk.²⁶ In addition to scientific validity, a roundtable participant posited that the issue of access is important because it is an issue of justice. To ensure that justice is a guiding principle, it was recommended to map out the clinical trial process from the point of ideation to the moment that either a study is published or a drug or new device is approved. Identifying and layering on all of the points that should be demanded or be measured will demonstrate that there has been meaningful thought given to the idea(s). The participant clarified that this would not be an attempt to weed people out, but rather an opportunity to design for justice and for representation—with consideration of delivery methods—from “the workforce behind the clinical trial, training, [and] communication with

25. [Wallington SF et al.](#) (2016). Enrolling minority and underserved populations in cancer clinical research. *American Journal of Preventive Medicine* 50(1): 111–117.

26. [Mindlis I et al.](#) (2020). Racial/ethnic concordance between patients and researchers as a predictor of study attrition. *Social Science & Medicine* 255: 113009.



possible participants, to creating welcoming environments.” The holistic approach of mapping the process out with a justice lens for sponsors, investigators, institutional review boards (IRBs), and/or scientific review committees (SRCs) may move the needle faster as opposed to focusing on just one particular aspect.

Organizational investment

The importance of senior leadership support was a persistent theme throughout the discussion and was viewed from multiple vantage points. As an example, one roundtable participant spoke about how their organizational and significant financial investments work toward achieving health equity, creating an environment that supports a diverse healthcare workforce, investing in culturally competent community care models, and creating enduring alliances with other organizations. Alongside these efforts, they stressed that ultimately, change requires that players “go beyond just having good ideas and good intentions” to impact people’s lives. They advised that platforms and opportunities such as the current roundtable enable a range of clinical trial actors to hear about what other organizations are doing and where they are making strides with measurable outputs.

A final comment by a participant rounded out the discussion with a focus on an overarching strategy that considers the multiple implications of clinical trial representativeness. “As we go forward, the only asset of value that any of us have is our health. And if we are going forward in a society where as many as 40–50% are not able to access their best health, then that limits our economic enterprise or political enterprise and quality of living.... This is the reality and the world we live in. We can’t go backwards. We have to be inclusive. The business models won’t work if we’re not inclusive, and we have to be reflective.... The ability to restore health based on science is a precious gift that all of us bring to the equation. So, strategically this is why we have to do this, and it should not be a debate.”

In closing, activating sustained and genuine DEI efforts to engage with subpopulations of interest throughout each phase of the clinical trial life cycle²⁷ plays a significant role in increasing representation. As documented throughout the report, roundtable participants revealed barriers and facilitators to clinical trial access at the individual, community, organizational, and structural level that can be enacted to facilitate trust, support community engagement, and improve clinical trial access. While intended for cancer trials in particular, the [American Society of Clinical Oncology \(ASCO\)](#) and [Friends of Cancer Research \(Friends\)](#) convened and developed recommendations to “optimize trial enrollment and ensure that benefits to patients and the broader scientific community are maximized.” Among the key recommendations is the guidance that all “patients be eligible for trials by default and excluded only when there is scientific rationale and/or evidence demonstrating that enrollment would compromise the patient’s safety” and that “trial participants more closely resemble the population intended to receive the therapy and no group is excluded without scientific justification based on current evidence.”²⁸ Consideration of these and other recommendations provided by roundtable participants may help ensure the generalizability of findings and accelerate scientific advances.

27. [VCCC Alliance](#) (2023). Clinical Trial Life Cycle.

28. [Kim ES et al.](#) (2021). Continuing to broaden eligibility criteria to make clinical trials more representative and inclusive: ASCO–friends of cancer research joint research statement. *Clinical Cancer Research* 27(9): 2394–2399.



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