Leadership Roundtable Summary Report
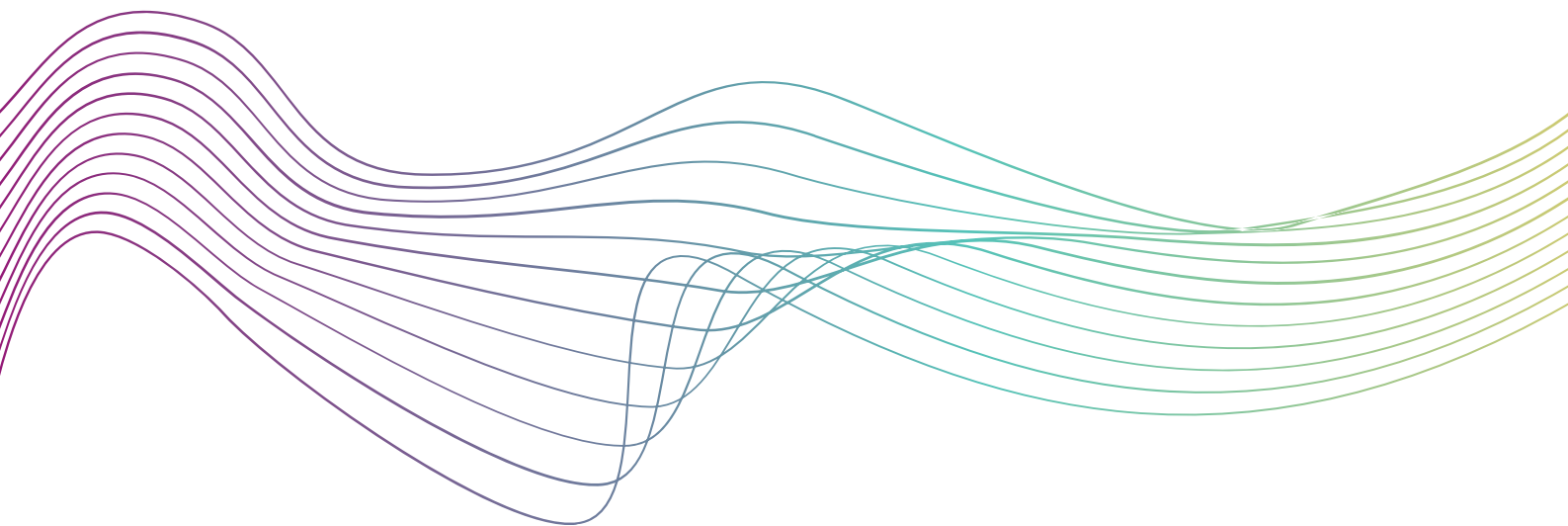
ADVANCING HEALTH EQUITY: THE IMPACT OF PATIENT ADVOCACY AND ENGAGEMENT

Introduction

In April 2023, VOZ Advisors (VOZ) and the Cancer Support Community (CSC) convened a leadership roundtable for patient advocacy and engagement leaders to share experiences and insights. Participants identified action-oriented solutions to advance health equity, driving change that furthers the inclusion of patients in therapeutics decision-making. The roundtable brought together a diverse group of committed stakeholders representing industry, patient and community advocacy organizations, healthcare systems, and regulatory agencies with a focus on three prioritized health equity pathways: **leading with a health justice mindset, investing in community relationships, and building inclusive clinical research models.** Each health equity pathway featured a speaker who introduced the topic followed by a combination of formal responses from patient advocacy group leaders, breakout group sessions, and a large group discussion.

This summary report provides key findings and recommendations from participants committed to a deeper understanding of the role that patient engagement and advocacy can and should play in advancing health equity. The enthusiasm and sense of purpose was palpable, demonstrating shared interest in continuing to engage with each other as well as a wider stakeholder group to co-create solutions that drive action. VOZ and CSC are grateful to all who invested their time and contributed their insights and experiences in the spirit of collaboration as we strive to create a world where all people have the opportunity to live their healthiest lives.

Leading with a Health Justice Mindset

Foundational to furthering health equity is a commitment to a health justice mindset. Philip Alberti, PhD, founding director of the Center for Health Justice at the Association of American Medical Colleges (AAMC) proposed a set of "vital conditions" that must be met for health equity – ensuring that every community receives and provides the basic, vital conditions we all need to thrive – to be realized. Central to this approach is constructing meaningful community relationships that strengthen partnerships and alliances, expand knowledge, improve healthcare programs and policies, and ensure communities can flourish.

A crucial building block to creating meaningful community relationships and establishing effective partnerships is trustworthiness. The AAMC "Principles of Trustworthiness" co-created with and endorsed by community stakeholders, serves as a roadmap for establishing trust and opening the door to building these relationships. These principles were instrumental in informing the roundtable conversations, and aligned with the insights that were shared, as outlined on the following page. [1]

Insights and Action

Adopt and demonstrate a "whole *person*" mindset. This mindset means acknowledging and addressing more than the individual's immediate medical need and instead supporting the entire individual with a focus on patient-centered strategies that acknowledge the biological, behavioral, social, and environmental factors that influence health.

Recognize that one size does not fit all. There is tremendous diversity within communities and populations which needs to be embraced and incorporated into engagement efforts. Time and effort must be taken to fully understand individuals of each community with which one wishes to engage.

Acknowledge and address implicit bias. Unconscious attitudes held against historically marginalized individuals are widely acknowledged within the provision of health care. This bias impacts communication, care decisions and organizational practices; it requires evidence-based professional education and training as well as institutional change to address policies and systems that perpetuate bias.

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[1] Association of American Medical Colleges. The Principles of Trustworthiness. https://www.aamchealthjustice.org/our-work/trustworthiness/trustworthiness-toolkit#principles. Accessed September 5, 2023.

AAMC Principles of Trustworthiness

Deserving trust is crucial to equitably partner with the communities you engage and to achieve health justice.

Remember, though, **the process of engagement is as important as the product**. Here are 10 principles that community stakeholders endorse as the guiding compass on your journey to establishing trustworthiness.

1 — **The community is already educated; that's why it doesn't trust you.**
Words matter. Be mindful of how you frame your relationship. It is not your job to teach to the gaps you assume the community has. Mistrust is a rational response to actual injustice. The community knows what it doesn't know and will ask when it thinks you have answers it can trust. (This goes for "empowering" the community, too.)

2 — **You are not the only experts.**
People closest to injustice are also those closest to the solutions to that injustice. (That is probably not you or your organization and, even if it is, there's a power imbalance.) Listen to people in your community. They have deployed survival tactics and strategies for decades — centuries, even. Take notes. Co-develop. Co-lead. Share power.

3 — **Without action, your organizational pledge is only performance.**
Walk the walk, please. Deploy resources. Coordinate across your organization. Hire someone to the C-suite and a network or coalition of experts to be responsible for transformation because transformation is not a one-person job. Be authentic. Don't just say you're committed to the goal of health equity; do the work to achieve it.

4 — **An office of community engagement is insufficient.**
One full-time employee doesn't cut it. Don't jam this work into your existing diversity and inclusion office, either. Trustworthiness is not a "minority tax"; we are *all* responsible. This is systemwide, all-hands-on-deck work and, as such, should be acknowledged, incentivized, and promoted in material ways.

5 — **It doesn't start or end with a community advisory board.**
Running your thoughts by a group of self-appointed community leaders for a thumbs-up does not suffice. Take to the streets to get some unfiltered opinions. And then work together with the community to put that wisdom into the work. Make it clear to all you've done so, and explain the benefits accrued.

6 — **Diversity is more than skin deep.**
We are diverse within our diversity. Do not rely solely on matching skin tones to make a difference. Think intersectionality and multiple identities, but remember: humility and honesty are the foundation for earning trust.

7 — **There's more than one gay bar, one "Black church," and one bodega in your community.**
Not all gay people go to the club, and not all people of color go to the same church (or go at all). Know *all* of your community's assets. Visit them. Meet the patrons. Meet the leaders. Break bread and share a meal — at their tables.

8 — **Show your work.**
The community does not think you are perfect, and the past is always present. So be transparent about your limitations, your biases, your goals, your funding, and the outcomes that matter to you. Then ask the community to do the same. Identify the "win-win" for all parties. No secrets, no surprises.

9 — **If you're gonna do it, take your time, do it right.**
Demonstrating trustworthiness is not a one-and-done proposition. Keep at it. Be mindful. Remember, it takes a long time to build trust and only a split second to destroy it. Pace yourself.

10 — **The project may be over, but the work is not.**
Do not drop in and drop out. Share results. Partner on next steps. Close the loop. The community is constant — it is not there only for the duration of your grant or initiative. Be there for the community, always, and it is more likely to want to be there for you.

Association of American Medical Colleges

Engage in small, outwardly visible gestures of support. Trustworthiness is established through simple gestures that indicate that an individual is seen, welcomed, and understood (i.e., displaying a rainbow flag at a clinical research site). These outwardly visible gestures of support must be carried through behaviors and actions.

Understand and articulate the business case. A business case should demonstrate shared focus on the corporate and scientific value of expanding reach into marginalized communities as well as overall corporate social responsibility for reducing health care costs and improving health outcomes.

> *"Whether it is having a rainbow flag in your office or an affirmative statement in your elevator, it all can make a difference… We are living in a desert and we as a community are just looking for a little bit of water."*
>
> **– Scout, Executive Director, National LGBT Cancer Network**

Investing in Community Relationships

Building and sustaining authentic, impactful relationships with members of historically marginalized communities is critical to furthering health equity. Yasmeen Long, Director, Faster Cures, shared insights from her portfolio of work aimed at understanding and providing recommendations pertinent to all stakeholders within the health and biomedical research ecosystem. *A Call to Action for Health Equity: Solutions from the Front Lines for Local and National Efforts* focuses on four areas for action: partnerships, data sharing, work force diversity, and accountability. This report summarized findings from a convening by FasterCures and the National Civil Rights Museum in Memphis, Tennessee with leaders in biomedical research, community-based organizations, and health care, together with local and national policy stakeholders with a focus on health as a civil right.

Insights and Action

Develop a "whole *community*" mindset. Recognize that a community is an ecosystem with interrelating dependencies that impact overall health and quality of life. Supporting healthy communities requires a broad effort that includes understanding and engaging in civic issues of importance and investing in the local economy through hiring and business relationships.

Build relationships early. Get to know and authentically engage the community. Listen to community leaders in determining the best pathways in developing mutually beneficial, impactful relationships. Be transparent about past community engagement efforts that have not been successful and why. This is an essential step to toward co-creation.

Co-create with the community. Co-creation is engaging in a purposeful relationship in order to build something together. Co-create congruent solutions that address both short-term and long-term goals, mutually agreed upon roles and responsibilities, and clear accountability measures.

Build capacity. Provide community groups with unrestricted funding to support the infrastructure needed to advance shared program goals. Invest in workforce training and education (medical education, research fellowships, patient navigators, etc.).

Create a forum for continual cross-collaboration and sharing progress.
Develop a mechanism for consistently sharing ideas and best-practices and leverage opportunities to share these findings with all community stakeholders. Share study progress and results with participants and the larger community using content and language that is accessible.

"Indian country supports practice-based evidence, which may be a bit different than what you are used to. We have traditional healings that do not have that much data or information to back it, so maybe try to be more open to engage with our experts than just sticking to what Westernized research tells us."

**– Francys Crevier, CEO,
National Council of Urban Indian Health**

Building Inclusive Clinical Research Models

Regulatory agencies, such as the U.S. Federal Drug and Food Administration (FDA), play a central role in setting the pace for innovations and uptake of strategies to further health equity. Luckson Mathieu, MD, Senior Clinical Reviewer, FDA Oncology Center of Excellence shared FDA diversity and inclusion initiatives, with a focus on the April 2022 draft guidance, *Enrollment of Participant from Underrepresented Racial and Ethnic Populations in Clinical Trials* that is to be required by mid-2025. This guidance recommends a framework for developing a Race and Ethnic Diversity Plan to "enroll representative numbers of participants from historically underrepresented racial and ethnic populations [to] be submitted to the investigational new drug (IND) application . . . ." To achieve increased diversity in clinical trials, this framework includes enrollment goals, an enrollment and retention action plan, and enrollment status.

Insights and Action

Employ an FDA interagency approach. The FDA has done significant work in furthering diversity and inclusion in clinical research as well as patient engagement in therapeutics development. FDA efforts would benefit from an interagency approach that is coordinated across these work streams.

Look beyond race and ethnicity. While current FDA Diversity Plan guidance encompasses race and ethnicity, it is critical that study sponsors seek diversity in clinical trial enrollment beyond populations defined by race and ethnicity through the inclusion of other demographically defined underrepresented populations.

Develop continuum-wide diversity plans. Start diversity planning at early discovery level and continue this through Phase IV, including but not limited to post-market research. Early discovery allows for attaining the unique perspective and identifying unmet needs of specific disease communities. Phase IV helps bridge the gap between clinical trials and real-world experience to improve understanding of a medicine or device impact on population health.

Develop cross-functional community engagement plans within companies. Internally, build mechanisms that foster strategy sharing across functional areas. Externally, demonstrate a unified front to the community to build credibility and trustworthiness. Include fair market value reimbursement for patient consultation and engagement, including diversity planning.

Leverage decentralized clinical trials. Intentionally build in mechanisms that reduce burdens and increase access to clinical trials by through partnerships with non-traditional sites (i.e., community health centers, households) and the use of technology. Ensure input from patients to decrease unforeseen burdens.

Recognize the strain placed on patient and community groups in the development of diversity plans. Patient and community groups have insights, reach, and credibility that could inform and accelerate clinical trial diversity planning and implementation. However, this may not be a priority or a capability for all groups. Collaborations must be built on mutual interests and organizations appropriately compensated for their efforts.

Engage the broader healthcare ecosystem. When focusing on furthering health equity through the lens of patient engagement in clinical research, it is critical to broaden the focus to include clinicians, hospital administrators, payers, and other essential influencers.

Recognize and support the unique needs of community health center study sites. Federally qualified health centers (FQHC) are well positioned to reach traditionally underrepresented communities, however, conducting trials at these sites creates financial burdens. There are opportunities to strengthen the infrastructure and build capacity at these sites so that research may be run more effectively.

> *"People believe clinical trials generate margins for community organizations but in most cases, they cost money to run. The administrative and financial infrastructure necessary to minimize losses and ensure full reimbursement, let alone generate margins, remains a big challenge.*
>
> *Community health centers represent the best opportunity for ensuring diversity within trials and maximizing their health equity impact.*
>
> *If we want equitable access to clinical trials sponsors should invest in developing infrastructure and providing underlying resources needed to effectively run research in community organizations."*
>
> **– Jonathon Rendina, Senior Director of Research, Whitman-Walker Institute**

Next Steps

Roundtable participants affirmed the value of providing forums like the leadership roundtable to share insights and learnings, as well as future opportunities for pre-competitive collaboration to advance health equity. There was also a shared commitment to turning roundtable insights into action. Next steps include:

• **Furthering collaboration** through the development and piloting of a multi-stakeholder model for pre-competitive collaboration

• **Increasing knowledge** through the creation, dissemination, and uptake of tools and resources based on key roundtable insights

• **Expanding capacity** by committing resources to building community capacity for patient engagement and advocacy

We thank each leader who participated in the roundtable for not only sharing their professional insights, but their lived experience and vision of what can be. Each of us plays a role, personally and professionally, in dismantling the barriers that prevent all people from living their healthiest life. Each conversation and resulting action pave the way for change.

Leadership Roundtable Participants

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VOZ
ADVISORS

Our vision is a world were all people have the opportunity to live their healthiest lives.

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