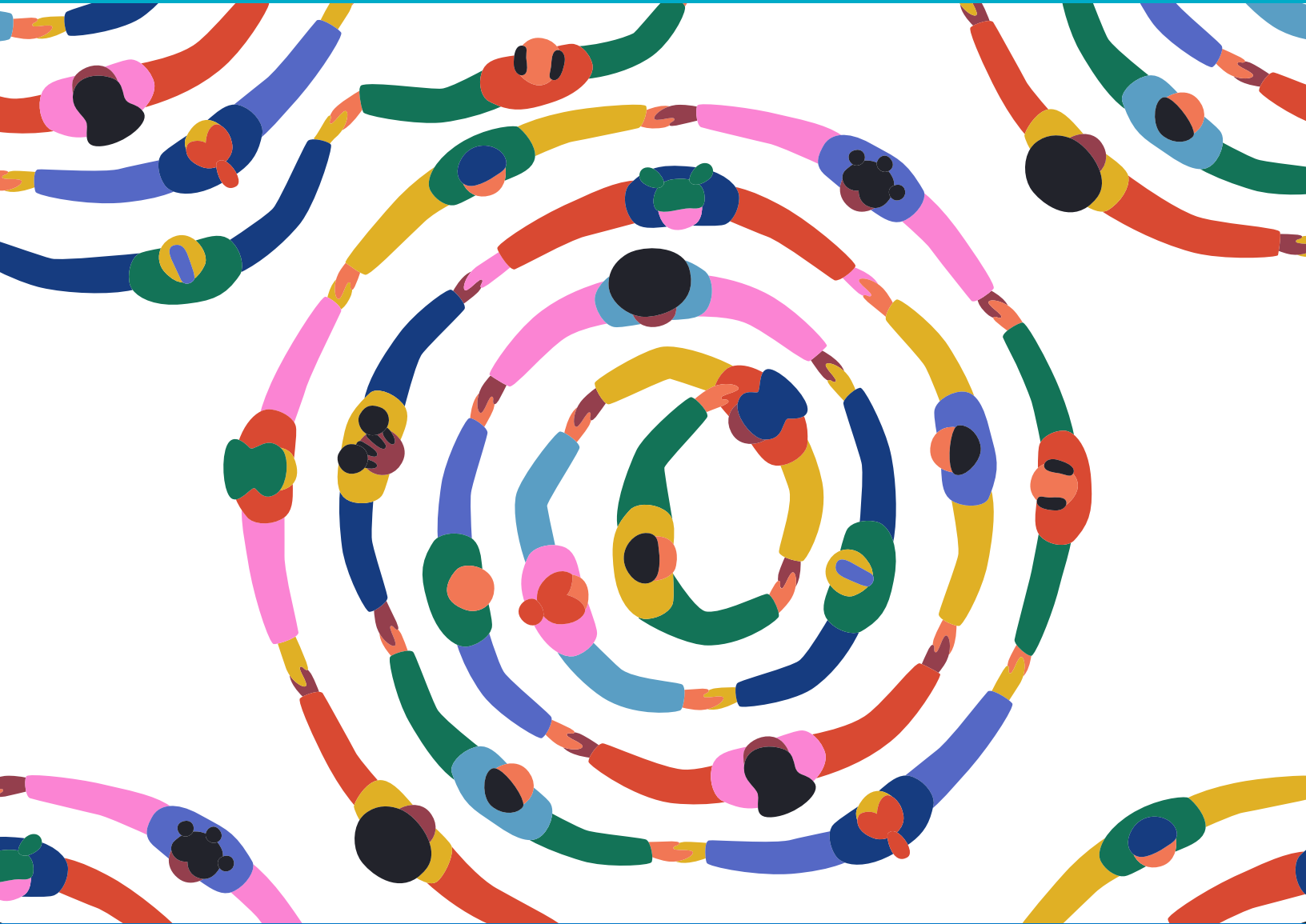


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Fostering Collaboration to Advance Shared Goals for Representativeness in Clinical Trials



healthpolicy@duke.edu

AUTHOR

Sandra E. Yankah

Valerie J. Parker

Cameron Joyce

Caleigh Propes*

Rebecca Ray*

Trevan Locke

Andrea Thoumi

Marianne Hamilton Lopez

**former Duke-Margolis staff*

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Introduction

Clinical trials conducted within the United States (U.S.) face structural and systemic complexities that can result in failure to address critical research questions accurately, equitably, and efficiently across a range of treatment and disease areas.¹ Data collection burdens on providers, sometimes onerous study protocols, and pressure to enroll narrowly defined patient populations, can limit the location of clinical trials to well-resourced centers, such as large academic medical centers, due to concerns around feasibility. Additionally, trial participants often encounter significant burdens beyond the confines of trial design, including logistical challenges (e.g., transportation), financial obstacles (e.g., fair compensation for participation), and stigmatization (e.g., implicit bias), which further exacerbate disparities in trial enrollment and participation rates. These factors complicate the breadth, quality, and generalizability of clinical trial evidence due to the lack of representation within the trials, which can increase inequities. In addition, under- or unrepresented populations often experience systemic exclusion and harbor institutional mistrust. As needs for rapid, rigorous, and generalizable evidence grow along improved technology supports to enable that evidence generation, a growing impetus exists to reimagine clinical trial conduct and advance trial representation without compromising vital research standards.

To address these issues, the Duke-Margolis Institute for Health Policy conducted a multiphase research study encompassing a landscape review of existent literature and published materials, multiple convenings, and structured stakeholder interviews with key experts across the clinical trial enterprise including researchers, pharmaceutical representatives, and patient advocacy organizations. This work was conducted between October 2022 and Spring 2024 with interviews taking place primarily in Spring 2023. Public workshops were hosted in July 2023 and March 2024.^{2,3}

This paper endeavors to highlight evolving policies and recent initiatives in the clinical trial space and explore strategies for fostering greater representativeness in recruited patient populations, through shared stakeholder goals. By harnessing insights from diverse stakeholders, and identifying avenues for collaborative action and strategic intervention, we encourage measurable improvements in the clinical trial landscape, ensuring clinical trial design and conduct help advance health care for all.

Key Concepts

Providing clear definitions related to representation can create a foundation for understanding among stakeholders and address the complexities often associated with this topic. Moreover, defining these concepts provides a basis for critically evaluating emerging solutions, challenging their scalability, feasibility, and applicability across diverse health care contexts and settings.

What do we mean by representation?

An equitable clinical research infrastructure should ideally be comprised of clinical trials and studies that accurately match the demographics of the disease burden under study.⁴ Such trials should be adequately powered to answer meaningful questions about safety and efficacy in underrepresented subpopulations. Shifting evidence

generation to efforts aligning with population level evidentiary needs can help answer these questions. This shift requires stakeholders to acknowledge the underlying systemic factors (e.g., structural racism) influencing care disparities and representation deficits in clinical trials.⁵ Additionally, clinical research should be a two-way street with patients and communities contributing to question identification and prioritization. Representativeness is a broad reaching category, not only inclusive of race, ethnicity, and gender, but also geographic location, disability, and socioeconomic status.

Published disease burden often fails to accurately characterize disease burden in marginalized populations because of systemic factors that hinder the documentation of population health challenges within these groups.⁶ These factors, including socioeconomic disparities, limited access to health care, and cultural barriers, can result in underrepresentation or complete omission of marginalized communities in formal diagnosis disease surveillance systems. Consequently, the published data may not accurately reflect the true prevalence, incidence, or severity of diseases within these populations, further exacerbating the underrepresentation of these groups in clinical trials. In such cases, using census data or other available information can help to ensure better representation. Meanwhile, addressing these systemic barriers is crucial to creating an equitable trial infrastructure.

Systemic barriers to representativeness: Systemic barriers rooted in social, economic, and institutional factors actively perpetuate the persistent lack of representation in clinical trials. This can create significant obstacles to equitable trial participation.⁷ These obstacles have the most profound impacts on marginalized populations, underscoring the importance of addressing systemic inequities and biases across all levels of the clinical trial enterprise. In addition to reimagining the design and execution of trials, real change necessitates reevaluating policies and practices of funding, recruitment, data analysis, and reporting. Examples of systemic barriers that affect trial representation include:

- **Trust.** Ongoing feelings of mistrust within certain segments of underrepresented communities serve as significant barriers to achieving representative clinical trials.¹ Both current and historical injustices, including unethical medical experiments and persistent disparities in health care access and outcomes, have contributed to deep-seated mistrust of medical institutions and providers among many individuals.² This mistrust is compounded by ongoing experiences of discrimination and neglect within health care systems, resulting in skepticism about the intentions and integrity of clinical trials among these segments of underrepresented communities.² Addressing this mistrust requires genuine acknowledgment of both current and historical injustices, along with meaningful efforts to build genuine relationships with patients, community members, leaders, and organizations.³ Sponsors, providers, and health systems should also prioritize transparency and inclusivity in trial recruitment and conduct.¹
- **Implicit Bias.** Rooted in structural racism, implicit bias impedes representation in clinical trials by influencing the decisions of healthcare providers, researchers, and other stakeholders in the clinical trial enterprise.⁸ Specifically, unconscious attitudes and stereotypes have the propensity to impact who is offered opportunities to be part of trials. Important ingredients for facilitating trust-building and combating implicit bias are a diverse workforce and strong ties with both disease and regional communities. These components are often missing in current trial design.
- **Accessibility.** Some participants are unable to engage in clinical trials because of barriers that prevent them from easily interacting with the medical system.⁶ For example, many individuals lack transportation, are uninsured or underinsured, have limited access to health care, or have challenging work schedules. Furthermore, language and information barriers, such as the format of trial information, and traditional funding structures in academic settings that require identification (e.g., driver's license) or information such as social security numbers, impede participation.

- **Awareness, education, and health literacy.**

Increased awareness and better access to information on clinical trials could encourage more underrepresented groups to participate, by helping patients know if they are eligible and understand the trials' benefits and risks.⁹ Relatedly, providing education to health care providers can better equip them in engaging and interacting with patients while being aware of their own biases.

- **Measurement.** A lack of standardized metrics exists to gauge representation deficits and facilitate progress tracking in efforts aimed at improving representation in clinical trials, and little data exists to support such metrics. The clinical trial enterprise would benefit from key performance indicators that operationalize goals for representation, create clear benchmarks, and enable the identification of evidence-based strategies for improving trial representation.

The Current Trial Representativeness Landscape

A landscape review of current practices in clinical research showed that most trial cohort demographics are still not sufficiently representative.¹⁰ However, the extent of these deficits varies significantly across disease areas. Underrepresentation is attributed to both individual and systemic factors such as those noted above.⁷ Additionally, many studies do not publish or report data on race/ethnicity, sex orientation and gender identity (SOGI), and other demographic variables that make it challenging to accurately quantify the full extent of representation deficits. This challenge is compounded by the fact that post-marketing studies have been shown to be less transparent and representative than pre-market studies, further hindering the ability to accurately measure and address representation deficits.^{11,12}

A report from the National Academies in 2022 emphasized the ongoing difficulty in recruiting underrepresented racial and ethnic populations.¹⁰ Findings revealed that White patients are overrepresented in trials, indicating minimal progress in diversifying participant demographics in recent decades.¹ Despite making up 39% of the U.S. population, historically underrepresented racial and ethnic groups—including Black and Latinx populations—comprised between 2% to 16% of the patients in trials.¹³ In 2020, according to FDA's Center for Drug Evaluation and Research's (CDER's) Drug Trial Snapshots only 8% of the 32,000 participants in new drug trials in the U.S. were Black, 6% Asian, and 11% Hispanic.¹⁴ These figures reflected a regression in progress since 2019.¹⁵ In 2021,

the FDA changed the formatting of Drug Trial Snapshot reporting, acknowledging that approved therapies span a wide range of medical conditions that either solely or disproportionately affect demographic subgroups (e.g., pediatric patients, conditions affecting only males or females), as well as rare and orphan diseases with a small number of patients.^{16,17} The agency concluded that, given the varied conditions being targeted for tracking, examining representation by individual drug or therapeutic area provides a clearer indication of trial representation than summary statistics. Still, the most recent report published in 2022 is reflective of ongoing disparities in the representation of ethnic and racial minority populations across both drug and disease areas.¹⁸

Moreover, underrepresentation deficits extend beyond race and ethnicity. Significant disparities based on gender and sex persist in trial representation, with females from underrepresented racial and ethnic groups particularly affected. Pregnant individuals are often excluded from trials altogether, resulting in a lack of evidence-based guidance on the use of various medications use during pregnancy.^{19, 20, 21, 22}

Individuals over the age of 65 also are frequently excluded.²³ For example, of the 32,000 participants in new drug trials in the U.S., in 2020, only 30% were aged 65 and older.¹⁴ Similarly, individuals with comorbidities or those from lower socioeconomic backgrounds are frequently underrepresented in clinical trials.^{24, 25} An absence of data

that adequately incorporates these intersections of identity and enables disaggregation by subgroup results in a reduced understanding of the safety and efficacy of drugs, devices, and vaccines within these populations.²¹

The lack of clinical trial diversity raises concerns for both public health and social justice, as unrepresentative trials hinder the generalizability of research findings

and exacerbate existing disparities in health access and outcomes. Improving the representativeness of the clinical evidence base is critical to ensuring the most effective use of new therapies and promoting uptake of those therapies in populations that might most benefit from them.

Key Federal Activity

Legislative and executive branch efforts have played a pivotal role in encouraging progress to improve representation in clinical trials. However, the impacts of the efforts are varied and additional efforts are needed to close the gap for many demographic groups (e.g., ethnic and racial minorities, and pregnant individuals). Measuring the impact of these initiatives can span decades, and quantifiable improvements have been limited. The following examples highlight some key efforts.

Legislation, such as the National Institutes of Health Revitalization Act of 1993 and the 21st Century Cures Act, has contributed to some improvements, particularly in the representation of women in trials, but has not led to major improvements in overall trial representation.^{26, 27}

National Institutes of Health (NIH) policies do not apply to the private industry-sponsored trials that account for most premarket studies of investigational products. Furthermore, NIH reporting requirements for researchers are often not enforced, as evidenced by the limited reporting of race and ethnicity data. Extant research has demonstrated that the majority of trials on clinicaltrials.gov over the past 20 years have failed to report race/ethnicity data.²⁸ These findings indicate that additional progress is needed to ensure that ethnic and racial minority populations have equitable representation in clinical trials.

In 2014, the Affordable Care Act Provision requiring insurance coverage of clinical trials by private insurers went into effect.²⁹ This followed the National Coverage Determination by the Centers for Medicare & Medicaid

Services that required Medicare coverage for clinical trial care costs.³⁰ More recently, the Clinical Trial Treatment Act that was passed by Congress in 2020 and went into effect in 2022, requires all state Medicaid programs to cover routine costs associated with qualifying clinical trials.³¹ Though these policy changes should nominally increase access to clinical research, some research has indicated that cracks in coverage exist, especially for Medicaid beneficiaries, that may limit ability to participate in trials. Additional work is needed to ensure these policies have their intended effect.³²

Under the Food and Drug Omnibus Reform Act (FDORA) of 2022, the Food and Drug Administration (FDA) will require drug sponsors to submit diversity action plans for their trials in the early stages of clinical development.³³ These diversity action plans must outline trial enrollment goals based on key metrics including age, sex, race, ethnicity, geographic location, and socioeconomic status along with plans for meeting their enrollment goals. While FDA is not yet receiving diversity action plans as mandated under FDORA as of the writing of this paper, the Agency is receiving diversity plans based on current draft guidance for review, including in areas such as oncology.³⁴ These diversity action plans, if well-implemented and monitored by the FDA, have the potential to advance change in industry-based trials, but significant work remains to determine the elements of a good diversity plan and what successful execution of those plans look like.

Notable Initiatives

In addition to congressional and administrative action at the federal level, stakeholders across the clinical trials enterprise—including drug developers, academics, and payers—have proposed and implemented solutions to address the issue of representation in clinical trials, with varying success. These initiatives have largely centered on improving community engagement, diversifying the workforce, and implementing additional accountability. Emerging initiatives also have emphasized opportunities to rethink the traditional explanatory trials and opt for more pragmatic approaches to clinical research. Here we highlight just a few of these initiatives.³⁵

Research Groups

Research groups engaged in community-based participatory research have developed strategies for working with community partners, and some of these strategies are aimed at recruitment of more representative trial enrollment. For example, the Just Ask Program is a training program that educates clinicians on implicit bias and community engagement for trial staff to try to improve trial representativeness.³⁶

Other initiatives, such as Good Pharma Scorecard by Bioethics International, focus on the idea of public accountability for drug sponsors by rating the representativeness of their trials.³⁷ They have found that low-scoring organizations tend to improve practices in response to low ratings, which can lead to quality improvement in sponsor companies.

In Durham, North Carolina, a partnership between North Carolina Central University—one of the Historically Black Colleges and Universities—and local community colleges has allowed students from minoritized populations to participate in the clinical research staff training programs. Broader awareness of clinical research as a career option, as well as developing a pipeline of diverse trial staff, can help create an inclusive environment that may foster patient trust.³⁸ Another notable initiative in Durham is Duke University's Project ENTRUST, a joint initiative between Duke Health and the local community.³⁹ The program will engage in an initial research phase that employs a longitudinal mixed-method approach to comprehensively understand and address factors contributing to mistrust and perceived lack of trustworthiness in health care and

medical research at Duke Health. It will then develop and implement interventions, practices, and policies while actively involving community members and patients in crafting solutions to repair mistrust and bolster trust in health care and research settings. Ultimately, Project ENTRUST hopes to foster a more inclusive, transparent, and trustworthy health care and research environment at Duke Health.

Other groups have released reports on the status of clinical trial representativeness. In 2022, the National Academies released a report titled, *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups*.¹⁰ In 2023, the Clinical Trials Transformation Initiative (CTTI) released recommendations for improving diversity in clinical trials and a corresponding maturity model.^{40,41} FasterCures released “Mapping the Journey: Building a Mutual Understanding for Health Equity in Clinical Research” in 2023.⁴² It details practical recommendations for achieving health equity at different types of trial sites and offers a visual illustration of how a patient might experience a typical clinical trial. Additionally, the Diversity Convergence Project, initiated by the CTTI, FasterCures, the Multi-Regional Clinical Trials Center of the Brigham and Women's Hospital and Harvard, and the National Academies of Sciences Engineering and Medicine, has sought to align stakeholder efforts in this space.

The Reagan-Udall Foundation for the FDA, in collaboration with FDA's Office of Minority Health and Health Equity, launched the Real-World Accelerator to Improve the Standard of Collection and Curation of Race and Ethnicity Data in Healthcare (RAISE) project.⁴³ RAISE aimed to improve the quality of health care and medical products through community workshops and the development of a multi-dimensional tool for improving the capture and curation of race and ethnicity data.

Pharmaceutical Industry

Commercial actors within the drug development space have engaged in voluntary efforts that address clinical trial representation, such as holding investigator training programs, establishing a wider variety of trial site settings, creating tools and templates for trial design, and implementing workplace diversity programs.⁴⁴

The Advancing Inclusive Research (AIR) Site Alliance, a collaboration between clinical research centers and Genentech, aims to encourage the representation of historically underrepresented patients in oncology and ophthalmology clinical trials.⁴⁵ By partnering with six oncology and three ophthalmology centers, Genentech and its allies rely on data-driven strategies to improve the recruitment and retention of historically these patients. The alliance creates educational resources for patients and health care professionals, develops regional health equity symposia, and integrates inclusive practices into study budgets. Other efforts including Abbott's 2030 Sustainability Plan; Beacon of Hope, led by Novartis and the Novartis US Foundation as well as other sponsors; and the Equitable Breakthroughs in Medicine Development (EQBMED) program funded by PhRMA at Yale University in collaboration with Morehouse and Vanderbilt Schools of Medicine, are also all aimed at improving trial representation.^{46, 47, 48}

Community Organizations

Many faith- and community-based organizations, including local businesses like barbershops and salons have increasingly connected their communities to clinical research.^{49, 50, 51} These initiatives are often very local, though new non-profits and companies are increasingly emerging to empower these community efforts.⁵²

For example, Our Health Ministry (OHM) is an inter-denominational and interfaith initiative that fosters connections between faith-based organizations (FBOs) striving to elevate the health and well-being of their congregations and various stakeholders, including community members, health care entities, government agencies, and academic institutions.⁵³ The organization also partners with influential stakeholders and grassroots advocates, including pastors, health ministries, and community health workers to achieve their aim of advancing health equity and eradicating health care disparities in underserved communities of color.

Similarly, Diverse Research Now, Inc. is a nonprofit organization dedicated to addressing the under-representation of minorities in clinical research trials.⁵² Recognizing the significant impact of this disparity on health outcomes within minority communities, the organization was founded in 2020 with a mission to drive meaningful change within the clinical trial enterprise.

The organization focuses on empowering underserved communities through education and support throughout the clinical trial process. By fostering a shift in attitudes and responses within underserved communities toward clinical trial participation, Diverse Research Now, Inc. aims to promote inclusivity and equity in medical research for the betterment of all.

Payers

Interventions at the payer level have attempted to improve trial representation by strengthening community-academic relationships. One initiative between Harvard Catalyst, Harvard University's clinical and translational science center and Blue Cross Blue Shield of Massachusetts' Community Coalition for Equity in Research is providing input to specifically address diversity and equity on research proposals.⁵⁴

Anthem, Inc. collaborates with the All of Us Research Program, a pioneering initiative led by the National Institutes of Health (NIH) aimed at revolutionizing health care through inclusive research.⁵⁵ Departing from traditional approaches, the All of Us program has established a diverse database with the potential to enhance understanding of disease risk factors and personalized treatment efficacy across patients from various backgrounds. Additionally, the program facilitates tailored clinical study connections for individuals within the database. Participants are empowered to contribute according to their comfort level, ranging from basic background information to genetic data. Ultimately, the program aims to usher in a new era of individualized health care, with the overarching goal of reducing health care costs and improving health outcomes for underserved populations.

Collectively, these initiatives highlight the complexity of addressing deficits in trial representation, and the importance of addressing this challenge across various sectors within the clinical trial enterprise. Advancing trial representation will require collaborative cooperation and concerted efforts across legislative, regulatory, financial, research, and educational, domains. By identifying and implementing shared goals, stakeholders across the clinical trial enterprise can make greater strides in ensuring that clinical trials accurately reflect the diversity of the population.

Shared Goals in Trial Representation: Strategies for Coordinated Action

The identification and implementation of shared goals is a key strategy for comprehensively addressing the multifaceted barriers associated with achieving representation in clinical trials. Although the diverse array of legislative actions and notable initiatives aimed at improving representation in clinical trials have resulted in some strides, current deficits suggest the need for a more coordinated approach to reduce duplicative efforts and improve mechanisms for tracking, measurement, and accountability. We propose the following goals for achieving a coordinated approach to addressing trial representation:

- **Adopt and Scale Community Engagement Standards**
- **Develop and Scale Innovative Trial Infrastructure and Processes**
- **Address Financial Considerations for Inclusive Practices**

Through each of these goals, we encourage collaboration among key stakeholders to facilitate a coordinated approach. Each of these overarching goals contains specific recommendations for different stakeholder groups along with overall guidance to help achieve the goal.

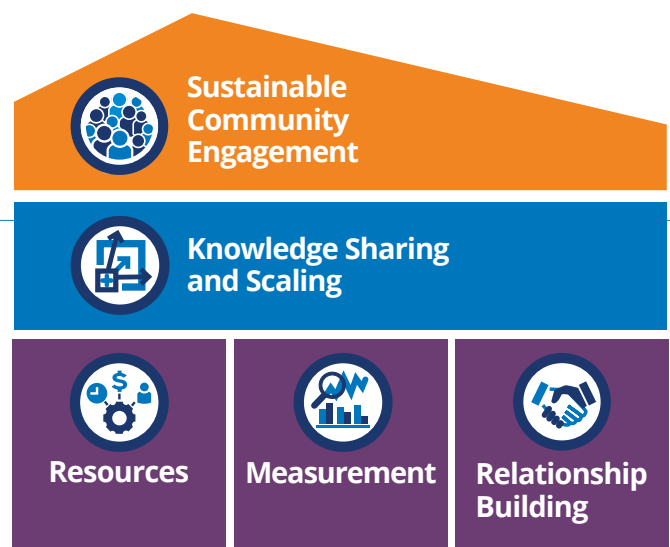
1 Shared Goal 1: Adopt and Scale Sustainable Community Engagement Standards

In order to increase representativeness consistently, the first shared goal is to adopt and scale sustainable community engagement standards. Community engagement involves building relationships within a community to foster trust, community building, and investment in local resources. Each potential trial participant is a part of a community, whether that be based on their geographic location such as a city or town, or by other interest or identifying factor such as a religious organization or local affinity group. Because patients exist in their own community networks, it is important to meet the patient where they are. While community engagement is not a new concept in clinical trials, the emphasis of this goal is not one-time community

engagement or outreach for an ongoing or upcoming trial, but lasting community engagement, whether or not a trial is active. We propose building and adopting community engagement standards to help bridge the silos of work currently being conducted.

To fully actualize the goal of sustainable community engagement, a number of essential foundational actions and subsequent supportive actions are required, **as depicted in Figure 1 and described on the next pages.**

Figure 1 | Framework for Sustainable Community Engagement



Foundational Pillars

To achieve sustainable community engagement, a number of essential foundational actions are required. Resources, measurement, and relationship building are all necessary to provide essential support and connections for effective initiatives.



- **Resources:** Adequate financial resources are essential for establishing long lasting and meaningful engagement across geographic and disease communities. Securing reliable and flexible funding streams has historically been a challenge for scaling many successful community engagement initiatives stifling the progress of these initiatives and impeding widespread implementation. These resources must be aimed towards lasting total care initiatives, not one-off efforts to achieve the goals of individual trials. Adequate funding for community health workers and community-based organizations is paramount. Stakeholders with the resources to create these funding streams include: government agencies, philanthropic organizations, pharmaceutical companies, and health care institutions. Collaborative, and ideally pre-competitive, efforts among these stakeholders are crucial to ensure sustained support for initiatives aimed at improving representation in clinical trials. *We further detail potential funding solutions in Shared Goal 3: Address Financial Considerations for Inclusive Practices.*



- **Measurement:** Research and metrics are key for ensuring that viable initiatives are established to foster long-term impact. The metrics measured should not be focused on arbitrary, process-specific, or marketing-specific definitions of engagement, but should instead track evidence-based strategies that are designed to make tangible impacts on relationship building within specific geographic and disease communities. By collecting and analyzing data as a core element of improvement initiatives, organizations can refine existing strategies, identify new strategies with maximum benefits for particular geographic and/or disease communities, and create standardized methods for demonstrating the value of related investments. Example measurements might include: trial accrual time, overall trial representation, and trial retention rates. Such measurements can enable comparisons of trials with versus without specific community engagement efforts.”



- **Relationship Building & Establishing Community Partners:** Nurturing strong relationships within the community and forging partnerships with local stakeholders are essential for sustainable community engagement. Building trust and rapport with disease and geographic community members creates the foundation for meaningful collaboration and ensures that initiatives are responsive to their needs. These relationships shouldn't solely be prioritized when trials are ongoing but should involve ongoing communication and collaboration efforts. Community engagement frameworks from other health settings can be instructive here.⁵⁶



Building on the Foundation: Knowledge Sharing and Scaling

Knowledge sharing, capacity building, and scaling are important support elements for disseminating insights and practices that maximize the impact and reach of successful community engagement strategies. For maximum effectiveness, knowledge sharing should be a multi stakeholder effort involving the continual exchange of insights, best practices, and lessons learned to enhance collective understanding and effectiveness among regulators, policymakers, funders, community organizations, health care organizations, and drug developers. Capacity building focuses on empowering individuals and organizations with the skills, resources, and infrastructure needed to implement and sustain community engagement initiatives long term. Scaling involves the replication and expansion of successful approaches to reach broader audiences and maximize impact. Together, these elements form a robust support system that amplifies the outcomes of community engagement efforts, fosters collaboration, and drives positive change across diverse communities and contexts. Incorporating educational and training opportunities for all stakeholders as part of this pillar is critical to ensure best practices are being employed and that equity is always a primary consideration.



Complete the Structure: Sustainable Community Engagement Standards & Best Practices

The end goal of this structure is sustainable community engagement standards and best practices, which is only possible through research, resources, and relationship building done to establish community partners, and through knowledge sharing and subsequent scaling of best practices identified. Many of the individual building blocks for this structure exist, but coordination among and continued investment from well-resourced stakeholders is needed to achieve lasting success. This foundation engagement work is critical to enabling the next goal necessary to increase representativeness: developing and scaling innovative trial infrastructure and processes.

2.

Shared Goal 2: Develop and Scale Innovative Trial Infrastructure and Processes

Modifying the traditional clinical trial structure by developing and scaling innovative approaches to clinical trials that can address systemic inequities, has the potential to increase representation in clinical trials by increasing access to clinical research opportunities. For example, point-of-care trials seek to enable clinical research as part of routine clinical care. Collecting the relevant data for the clinical trial while the patient visits their provider simplifies the requirements of participation and reduces the burden on trial participants. Other increasingly used trial types such as decentralized trials are also providing easier ways to participate in research, even sometimes delivering study therapies directly to patient homes. Duke-Margolis has explored many considerations for advancing these innovative trial approaches, including in a [companion paper](#) released in tandem with this one.

In addition to innovative approaches to trial design, ongoing efforts to revise inclusion and exclusion criteria for clinical trials are opening doors to participation by a wider array of people, including participants that are older, HIV+, pregnant and lactating, or have other traditionally restrictive comorbidities.

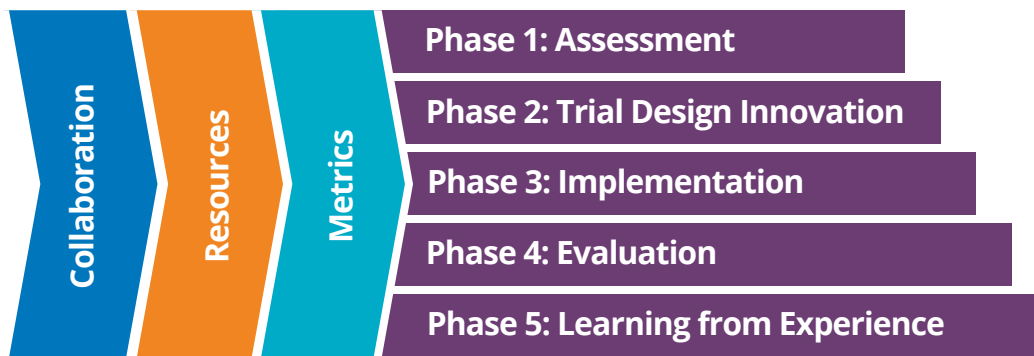
For all the innovative trial designs discussed and more, sustainable infrastructure is crucial to support and pilot these initiatives. Efforts are underway by federal agencies and partners to establish data infrastructures to enable the collection of high quality, interoperable data from real-world settings. More work is needed to expand strong data infrastructure to non-academic clinical sites that are less resourced. Likewise, physical infrastructure (e.g., sites equipped to participate in clinical research) is lacking in many places across the U.S. that face broader lack of access to health care facilities.⁵⁷

Likewise, the processes around clinical trials need to be simplified. The complexity—and therefore, cost—of clinical trials has grown without always having reasonable justification. Stakeholders need to work together to identify what elements of clinical trial conduct are essential for rigorous research and what elements can be simplified, revised, or altogether eliminated. Resources like the Good Clinical Trials Collaborative’s Guidance for Good Randomized Clinical Trials provides instructive principles for evaluating these process considerations.⁵⁸

In addition to the infrastructure and process considerations above, the trial workforce also is a concern. Any approach to modernizing clinical research should minimize the burden on patients and providers and health care leaders should strive to create cultures that support involvement in clinical research. Academic and non-academic settings alike need to update their incentive models for providers to support more participation in research. More broadly, initiatives like Beacon of Hope that fund scholarships and grants at historically black colleges and universities need to proliferate to improve the overall diversity of both the clinical research and overall workforce.⁵⁹ Currently, the health care workforce lacks diversity which can create barriers to equitable access to health care and clinical research.⁶⁰

Building on these examples to implement innovative trial structure, below we detail how stakeholders can each support clinical trials throughout the implementation process.

Figure 2 | Develop & Scale Clinical Trial Infrastructure and Processes



- **Collaboration:** Partnerships between community organizations, health care systems, regulatory agencies, drug developers, and researchers can foster development and implementation of innovative trial infrastructure and processes for inclusive trials. This collaboration ensures that the most pressing research questions are answerable through the efficient generation of practically relevant evidence.

- **Resources:** Allocation of resources enables and scales trial infrastructure for representative trials. Drug developers and federal agencies are best placed to provide funding for trial infrastructure that facilitates representativeness as well as support pilot studies to assess the feasibility of different innovative trial designs and updated processes. By conducting these pilot studies, researchers can demonstrate whether an innovative trial design fosters increased representativeness in comparison to traditional trial models. Some promising efforts by federal agencies (Advancing Clinical Trial Readiness Network Survey; Common Fund – Network for Research in Primary Care Settings) are already in development that could achieve these goals, but input from all stakeholders is vital to success.^{61, 62} **See Shared Goal 3: Address Financial Considerations for Inclusive Practices for additional recommendations.**

- **Metrics:** Like community engagement, measurement of progress is vital for evaluation of new infrastructure and related trial processes. Where possible, specific metrics for success should be leveraged to identify learnings and scale effective interventions as appropriate. Potential metrics include time or travel saved for patients; investigator/provider time saved, trial retention rates, trial costs, impact of evidence from innovative trials on decision making; and trial participant demographics in innovative trial designs compared to traditional trial designs.

- **Phases:** Each phase is built on a foundation of collaboration, adequate resourcing, and relevant metrics and each phase represents a step in the development and scaling of clinical trial infrastructure in a given disease area. Working through these phases should be a collaborative effort among drug developers, regulators, researchers, and potential participants.

- **Phase 1: Assessment**

- Conduct a comprehensive assessment of current clinical trial infrastructure and processes to identify barriers to inclusivity.

- Review existing trial protocols and procedures to pinpoint aspects that may exclude certain patient populations.

- Phase 2: Trial Design Innovation Phase

Consider innovative trial designs such as point-of-care trials and decentralized trials, including the viability of integrating clinical trial conduct with electronic health record (EHR) systems to conduct the trial in usual care conditions, to address systemic inequities.

- Phase 3: Implementation

Implement pilot studies to test the feasibility and effectiveness of new trial designs and related processes in increasing representativeness.

- Phase 4: Evaluation

Evaluate the impact of new infrastructure and processes on trial representativeness through rigorous research studies and by gathering feedback from stakeholders, including patients, providers, drug developers, and regulatory agencies.

- Phase 5: Learning from Experience

Use findings from evaluations and feedback to refine trial infrastructure and processes continuously, while staying updated on emerging best practices and technologies in inclusive trial design to incorporate.

As noted in each of the first two goals, one additional shared goal is critical to enable collaboration among stakeholders: addressing financial considerations for inclusive practices.

3. Shared Goal 3: Address Financial Considerations for Inclusive Practices

To achieve and fully implement the prior shared goals and recommendations, adequate and sustained funding is needed to reach the overall objective of increasing representativeness in clinical trials. Additionally, business cases must be developed and shared to encourage investment of resources by drug developers, foundations, and hospitals. Though some stakeholders will have more resources everyone has a role to play in creating the financial foundation for representative practices. During the March 2024 Duke-Margolis convening, expert panelists described current challenges to ensuring the financial foundation of representative clinical trials and highlighted successful funding and business model examples.

In addition to approaches already described above, insurance providers can play an important role in addressing barriers to participation from denied claims for out-of-network care in clinical trials. One potential solution is a “gold card” system that helps payers identify patients in clinical trials for payment approval and authorization, but such an approach would need buy-in from providers

and communities. Some available evidence suggests that these patients on trials are cheaper on a per person basis than patients not in trials for Medicare, but additional research is needed to demonstrate the potential cost savings of clinical trials to drive new policy development in this space.⁶³

As noted above, developing cultures of research in non-academic settings is important and requires buy-in from health system senior leadership. However, building trial capacity requires funding from conducting trials, but in order to get trials to conduct, there must be capacity. Resources from federal agencies, drug developers, or foundations, should be leveraged to create on-ramps that support systems interested in providing research as a care option. These catalytic investments in early capacity building can form the foundation of sustainable trial capacity in a wider range of settings that can ultimately be funded by stakeholders interested in running trials using this new capacity after the initial investments have run their course. Having this capacity can be a boon for health

systems through attracting more patients and keeping patients within a given system, even for relevant clinical research. Foundation- or philanthropic-based funding may be the most feasible option for many systems, though initiatives from ARPA-H or NIH may provide much needed catalytic support as well. Success from similar government spending initiatives can be seen in the National Cancer Institute Community Oncology Research Program, which has supported community-based cancer research for decades.⁶⁴

As we noted above, drug developers have made public commitments in recent years to invest in more expanded trial types and focus attention on intentional inclusion of underserved populations within their research and trials. While these investments are encouraging, drug developers could make further contributions by pooling resources and harmonization expectations for trial sites to pre-competitively solve problems that would enable more broadly accessible clinical research. Drug developer commitment to investing in representative trials will be critical for sustained success, and collaborative investments should be a priority as efforts to implement diversity action plans expand. On a specific trial level, dedicated budget line items for community engagement have increased to ensure that those resources are available. Intentional budgeting for trials by including line items like this will remain a key component to sustain engagement efforts.

Another important financial consideration for increasing representativeness in clinical trials is creating financial

incentives for inclusive practices which can act as a catalyst for increasing representativeness. These incentives can take a variety of different forms and can target various parts of the clinical trial process. For instance,

- **Create Tax Credits or Grants:** Providing tax credits or grants for organizations demonstrating proactive efforts towards representative enrollment can help sustain success. These financial incentives could help to offset the costs associated with implementing recruitment strategies and create improved mechanisms for compensating or reimbursing individuals and groups that are sometimes hard to support through existing grant processes (e.g., community health workers, community-based organizations). This in turn contributes to the lasting and sustainable community engagement shared goal described above.
- **Remove Costs to Participants:** Trial participants are often still expected to be responsible for non-health related costs associated with participating in clinical research (e.g., transportation and parking costs, child and pet care, and additional time away from work). Where possible, clinical sites should directly remove costs (e.g., providing free parking). Elsewhere, clinical trial budgets should proactively include reimbursement for these costs to provide more equitable access to clinical research. Furthermore, updates to regulations can ensure that compensation for trial participation doesn't imperil a participant's eligibility for Medicaid or other benefits or increase their tax burden.

Conclusion

By fostering collaboration to achieve the shared goals described above, we propose that clinical trials can be made more representative in a lasting and durable manner. Each stakeholder has a role to play in this multifaceted approach. Building on promising advancements to advance representativeness in clinical trials, future work can improve on approaches that span across disease areas, populations, and geographies. As new regulations to ensure representative trials are implemented, now is the perfect time to build a better, more equitable clinical research enterprise that improves health for all.

Appendix: Public Convening Participants

We sincerely thank the following individuals for contributing their insights and expertise to one or both of our public convenings, as noted below, during this project.

Amanda Wagner Gee,² Milken Institute

Barbara Bierer,² Brigham and Women's Hospital & Harvard Medical School

Bridgette McCullough,² ACIRAH Health

Carla Rodriguez-Watson,¹ Reagan Udall Foundation for the FDA

Carolyn Shore,² National Academies of Sciences, Engineering, and Medicine

Donna O'Brien,² Manatt Health

Grail Sipes,² Office of Science and Technology Policy

Jennifer Miller,¹ Yale School of Medicine

Jennifer Byrne,² Javara

Jennifer Gibson Levy,² Henry Ford Health System

Kirsten Bibbins-Domingo,¹ JAMA; University of California, San Francisco

Lola Fashoyin-Aje,¹ Oncology Center of Excellence, FDA

Martin Mendoza,² National Institutes of Health

Megan McKenzie,^{1,2} Genentech

Michel Reid,² GSK

Mimi Fenton,² Walmart Healthcare Research Institute

Nadine Barrett,^{1,2} Wake Forest University School of Medicine

Pamela Tenaerts,² Medable, Inc.

Perla Nunes,^{1,2} Perla Nunes Consulting

Priscilla Pemu,² Morehouse School of Medicine

Salimah El-Amin,² Duke University

Salina Waddy,¹ National Center for Advancing Translational Sciences

Sara Calvert,¹ Clinical Trials Transformation Initiative

Silas Buchanan,^{1,2} Institute for eHealth Equity

Sneha Dave,¹ Generation Patient

Yasmeen Long,¹ FasterCures

¹ Advancing Representative Enrollment in Clinical Trials

² Fostering Collaboration to Advance Representative Enrollment in Clinical Trials

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