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Towards A National Action Plan To Improve Representation In Clinical Trials

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The United States has some of the poorest health outcomes among high-income countries around the world, outcomes that are particularly striking for racial and ethnic minority groups and rural populations. Blacks, Latinos, Native Americans, and certain Asian groups die at two to three times the rate of White Americans as a result of the most prevalent disease conditions, including cardiovascular disease, stroke, diabetes, HIV/AIDS, cancers, and chronic kidney disease. Black populations, for example, are [30 percent more likely to die of heart disease](https://minorityhealth.hhs.gov/heart-disease-and-african-americans) and are [30 percent more likely to have high blood pressure](https://minorityhealth.hhs.gov/heart-disease-and-african-americans). Black populations experience higher rates of end-stage kidney disease, diabetes, heart failure, stroke, and breast cancer. Latino women are [40 percent more likely to be diagnosed with cervical cancer](https://minorityhealth.hhs.gov/cancer-and-hispanic-americans) and are [20 percent more likely to die](https://minorityhealth.hhs.gov/cancer-and-hispanic-americans)

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11135625/> from it compared to non-Hispanic White women. Rural Americans have a [shorter life expectancy https://pubmed.ncbi.nlm.nih.gov/24439358/](https://pubmed.ncbi.nlm.nih.gov/24439358/) and are [more likely to die from common chronic conditions https://www.cdc.gov/rural-health/php/about/?CDC_AAref_Val=https://www.cdc.gov/ruralhealth/about.html](https://www.cdc.gov/rural-health/php/about/?CDC_AAref_Val=https://www.cdc.gov/ruralhealth/about.html) —at a rate [nearly 21 percent higher for cardiovascular disease https://stacks.cdc.gov/view/cdc/109049](https://stacks.cdc.gov/view/cdc/109049), for example—than those living in urban areas.

These are the [same groups that are grossly underrepresented in clinical trials https://doi.org/10.1016/j.patter.2023.100713](https://doi.org/10.1016/j.patter.2023.100713). Of 339 Food and Drug Administration drug approvals between 2015 and 2021, 25 percent of trials included 1 percent Black participants or fewer, and 21 percent of trials included 1 percent Asian participants or fewer. Participation in clinical trials for Americans living in underserved rural areas remains low.

This lack of representativeness in clinical trials limits our scientific knowledge of the safety and efficacy of medical products and interventions for certain populations. Furthermore, low trial participation by underrepresented patient groups limits access to the latest scientific advances for these groups, as clinical trials are increasingly part of clinical care, particularly for oncology. The discrepancy in trial participation thus further widens existing gaps in quality of care. In this article, we explain the need for a national action plan to improve diversity, equity, and inclusion in US clinical trials. We outline such a plan, and we issue a call to action to all stakeholders to make progress on the goals and action steps presented below.

The Landscape: A Sense Of Urgency But A Lack Of National Coordination

The problems of health disparities and underrepresentation in clinical trials have been generations in the making. The COVID-19 pandemic illuminated the profound differential morbidity and mortality among minoritized populations and generated renewed urgency to address these systemic health inequities. In the past four years, dozens of reports, peer-reviewed publications, and white papers have been written about the lack of diverse representation in US clinical trials. Organizations across the clinical trials enterprise—biopharmaceutical companies, health systems, academic research organizations, patient advocates, foundations, public health institutions, and government agencies—are working to improve diversity, equity, inclusion, and access in clinical trials. A 2021 *Health Affairs Forefront* short series, “[Envisioning A Transformed Clinical Trials Enterprise For 2030](#),” laid out ideas for advancing a clinical trials

enterprise that is more efficient, effective, person-centered, inclusive, and integrated into the health delivery system of 2030 than is currently the case.

Despite these efforts, the US clinical trials enterprise continues to fall short of the public health need. Progress has been slow, uneven, and poorly understood.

In 2023, four organizations with established leadership involved in the national dialogue on these topics—the Clinical Trials Transformation Initiative (CTTI), the Multi-Regional Clinical Trials Center of the Brigham and Women’s Hospital and Harvard (MRCT Center), Milken Institutes’ FasterCures, and the National Academies of Sciences, Engineering, and Medicine (National Academies) Forum on Drug Discovery, Development, and Translation came together to accelerate transformation. We identified three essential gaps:

- Lack of accountability: Whose job is it to define and achieve diversity in clinical trials?
- Multiplicity of recommendations: What is the comprehensive set of work that needs to be done?
- The challenge of moving from strategy to tactics: What are the steps specific actors can take to drive change?

Working together, we saw an opportunity to use our platforms to advance a single unified national strategy and to move from recommendations to concrete action steps for all parties in the clinical trials enterprise.

To begin, we hosted a series of convenings from 2023 to 2024 to ensure that the strategy for achieving systems-level change to improve representation in US clinical trials represented the multiplicity of organizations and expertise already dedicated to this issue. The most recent convening was held by the National Academies on May 20, 2024, aligned with Clinical Trials Day. A crucial contribution of this work is the recognition that many of the necessary changes require sustained collective action, and that a single plan could inspire, guide, and accelerate more coordinated activity.

There is continued momentum at the national level to increase diversity in clinical trials. For instance, the White House Clinical Trials Forum held in June 2024 provided a platform for key stakeholders from across the clinical trials enterprise to tackle barriers to trial participation and highlight best practices in trial design, accelerating progress toward improving health outcomes for all.

Establishing Common Goals

In the convenings, more than 200 participants representing academia, patient organizations, government, and communities, were brought together through workshop discussions and questionnaires.

With input from these discussions, questionnaire results, analyses of existing research, and a review by CTTI, MRCT Center, FasterCures, and National Academies staff, eight domains and key collective actions were identified as necessary for achieving a diverse, equitable, and accessible clinical trials enterprise. The four organizations jointly [published <https://milkeninstitute.org/report/clinical-trials-diversity-national-framework>](https://milkeninstitute.org/report/clinical-trials-diversity-national-framework) a framework for a national plan based on these domains.

A single entity, organization, or institution cannot achieve these goals alone. Transformative and sustained change requires the involvement of every sector: academia, industry, sites and care delivery, patient organizations, government, communities, and the public. A national action plan with defined, high-priority goals and measurable objectives serves as a call for stakeholders to propel the US research enterprise toward shared accountability and more diverse, equitable, inclusive, and accessible clinical trials. It focuses on the following eight areas.

Prioritize Public Awareness And Communication

The public is not broadly familiar with clinical trials, the critical role they play in bringing new products to market, and the channel they provide to interventions that are under development. Those who are aware of the research enterprise are likely to know about historical breaches in ethics that disproportionately affect minoritized populations. Research entities—especially sponsors, commercial research organizations (CROs), and academic research organizations—and federal funders of research should create a sustainable, scalable, and measurable national campaign involving communities from historically underrepresented communities. The goal of the campaign should be to increase awareness of clinical trials so that individuals can make informed decisions about their participation.

Engage And Invest In Communities

Developing community-driven partnerships, alongside predictable and sustained funding mechanisms, can empower communities to articulate their research needs, engage with investigators, and benefit from implementation of research results. Examples of this, such as mechanisms for transparent communication of research results and community action plans that include bidirectional training opportunities, must be shared, assessed, and scaled.

Enable Clinical Trial Sites

Better representation in trials requires more sites, with appropriate resources, in more different geographies and health care settings. Sponsors and CROs could provide adequate funding and training, nimble and intuitive technologies, and access to experienced researchers to encourage new sites.

Cultivate A Representative Clinical Trials Workforce

There is a large workforce around trials, from the principal investigator to the research professionals that manage recruitment, investigational products, data, and other critical functions. Sponsors, funders, professional associations, and others can help educate the public about this career path and ensure that appropriate supports (for example, funding, training, mentorship) are in place to make these rewarding opportunities. Examples such as clinical research path learning modules and leadership development programs showcase how, although outcomes are not yet studied.

Design Clinical Trials For Equitable Access

Trials often ask a lot of participants, although researchers can engage with communities and patients to get input on design elements that will make participation feasible, even appealing, for more people. For instance, ensuring participant and caregiver/supporter expenses are reimbursed during trial participation and deploying decentralized trial elements (for example, apps, portals, wearable technology) can increase the feasibility of participation. The design of clinical trials must address barriers to participation by reducing burdens.

Allocate Resources For Clinical Trials

Beyond awareness, access, and logistical feasibility of participation, there are also financial implications connected with taking part in a trial. Sponsors should explore adequate reimbursement of expenses and compensation for time. Federal and payer entities must ensure that insurance coverage, copayments, and associated tax consequences are straightforward and fair, and support participation.

Establish Shared Accountability

As described above, the lack of representativeness in clinical trials is well documented and understood. To drive and scale progress, we need to measure both investments made and the outcomes they produce.

Importantly, we need a national report card to share progress toward established metrics and shared goals.

Call To Action

The time is now to meet the moment, respond to inequities in the clinical trials enterprise, and align on a shared plan of action as a country. Diversity, equity, inclusion, and access in US clinical trials cannot be achieved by individual entities, organizations, or institutions, each pursuing only its own priorities. Alignment on a national action plan would enable every sector—academia, industry, sites and care delivery, patient and other nonprofit organizations, government, communities, and the public—to work toward common goals and take collective actions to achieve system-level change. It is incumbent upon stakeholders to make commitments toward advancing progress in one or more of the domains and action steps listed above that are consistent with both their own mission and a national action plan. Moving forward, the Diversity Convergence group will continue to leverage our organizational platforms to inspire and track these commitments, learn from successes and failures, foster accountability, and catalyze investments at scale for interventions with demonstrated outcomes.

Authors' Note

This article represents the opinions of the authors and does not necessarily represent the views of any particular organization.