



POLICY ISSUE BRIEF

A Call to Action for Diversity in Clinical Trials

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Introduction

FasterCures has initiated a body of work to advance system change within biomedical research to focus on and value diversity and representation within clinical trials. Following our report, [Achieving Health Equity: A Multi-Stakeholder Action Plan to Address Diversity across the Clinical Trials Enterprise and the Biomedical Research Ecosystem](#), released in November 2021, this policy brief highlights current and proposed policies with recommendations to reform an unequal research ecosystem. Throughout 2021, FasterCures delivered formal comments and recommendations for several pieces of draft legislation included in this brief. Other policies on the horizon are included to complete the picture of current legislative policies proposed to address diversity in clinical trials.

Issue

The COVID-19 pandemic has brought into focus the need to address longstanding inequities in the biomedical ecosystem among racial and ethnic minority communities.¹ Clinical trials are the primary means of determining if treatments are safe and effective; however, clinical trials historically don't represent the population groups bearing the greatest burden of poor health outcomes.² In 2020, 75 percent of US trial participants were White, 11 percent Hispanic, 8 percent Black, and 6 percent Asian, and these proportions remain consistent.³ More specifically, a decade-long review demonstrated that Black and Hispanic groups were consistently underrepresented in cancer

treatment trials when compared with cancer incidence and mortality trends in the US population.⁴ As a result of the greater attention to racial health disparities driven by evident COVID-19 inequities and racial justice activism in 2020, interest has arisen in replicating several lessons learned from vaccine and treatment development, which was accelerated as part of the emergency public health measures.⁵ At the agency level, several initiatives have promoted enrollment practices designed to lead to more representative clinical trials—primarily through broadening eligibility criteria and reporting enrollment targets.⁶ However, these initiatives have not moved the needle sufficiently, and barriers to achieving diverse, representative trials persist.

In the last year, policymakers have taken steps to address these barriers, introducing several key legislative proposals to address racial inequity in clinical trial development, enrollment, and recruitment (see Table). Critical to these proposed bills is addressing how trial sponsors, investigators, and clinical research itself can contribute to better engagement with historically excluded communities. We expect that defining barriers and best practices and evaluating progress on these critical priorities will advance participation and diversity in clinical trials.

Table 1. Recently Proposed Policies on Clinical Trial Diversity in the 117th Congress

Title and Sponsors/ Original Cosponsors	Introduction Date and Status	Description	Main Aims Related to Diversity in Clinical Trials
H.R.6000 Cures 2.0 Act US Representatives Diana DeGette (D-CO) and Fred Upton (R-MI)	Introduced in the House of Representatives 11/17/2021 Referred to Committee on Agriculture Subcommittee on Biotechnology, Horticulture, and Research 1/4/2022	To continue the acceleration of the discovery, development, and delivery of the 21st Century Cures Act, this bill will revolutionize how the US provides care to patients. Many of the 34 sections are aimed at speeding up the delivery of groundbreaking, new—and potentially lifesaving—cures, treatments, and innovations for those who need them most.	Updates reporting on inclusion of demographic subgroups, studies barriers to participation, carries out a public awareness campaign, and makes clinicaltrials.gov more user-friendly.

Table 1. Recently Proposed Policies on Clinical Trial Diversity in the 117th Congress (continued)

Title and Sponsors/ Original Cosponsors	Introduction Date and Status	Description	Main Aims Related to Diversity in Clinical Trials
<p>S.2706 and H.R.5030</p> <p>Diversifying Investigations Via Equitable Research Studies for Everyone (DIVERSE) Trials Act</p> <p>US Senators Robert Menendez (D-NJ) and Tim Scott (R-SC)</p> <p>US Representatives Raul Ruiz (D-CA) and Larry Bucshon (R-IN)</p>	<p>Introduced in the Senate 8/10/2021</p> <p>Read twice and referred to the Committee on Health, Education, Labor, and Pensions 8/10/2021</p> <p>Introduced in the House of Representatives 8/13/2021</p> <p>Referred to Committee on Ways and Means Subcommittee on Health 8/13/2021</p>	<p>This bill requires activities to increase diversity in clinical trials, expands reporting and data sharing related to COVID-19, and requires a study on data during public health emergencies.</p>	<p>Requires the Food and Drug Administration (FDA) to issue guidance on decentralized clinical trials including the role of digital health technologies. Allows the US Department of Health and Human Services to use grant funding to support community education, outreach, and recruitment activities and allow for reimbursement to patients without violating laws that address fraud and abuse in federal programs.</p>
<p>H.R.6584 Diverse and Equitable Participation in Clinical Trials (DEPICT) Act</p> <p>US Representatives Anna Eshoo (D-CA), Brian Fitzpatrick (R-PA), and Robin Kelly (D-IL)</p>	<p>Introduced in the House of Representatives 2/3/2022</p> <p>Referred to the House Committee on Energy and Commerce 2/3/2022</p>	<p>This legislation is aimed at boosting diversity in clinical trials through two main focus areas: requiring enhanced data reporting on clinical trial demographics and providing resources to improve access to clinical trials.</p>	<p>FDA to require trial sponsors to report specific demographic subgroup data targets, plans for meeting targets, and progress reports. Strengthens community engagement and capacity building in underrepresented communities to improve patients' clinical trial participation.</p>

Source: Milken Institute (2022)

Key Policy Recommendations and Implications for Practice

FasterCures' policy recommendations focus on three overarching priority areas:

- Reporting and progress evaluation
- Investments in structural barriers to clinical trial research
- Role of digital health technologies

Summarized below are selected provisions in each highlighted legislative proposal with corresponding recommendations to achieve diversity across the clinical trials enterprise.

Reporting and Progress Evaluation

Collection of accurate data on race and ethnicity is critical to more robust reporting requirements in support of an equitable clinical trial ecosystem. Provisions throughout the three proposed bills address the need for representative data and reporting. More action can be taken, however, to ensure data are collected in a way that allows for disaggregation based on racial and ethnic subgroups at clinical trial sites.

One of the barriers to existing data models is they are not sufficiently powered to detect nuances in enrollment by ethnicity. Leveraging real-world data and real-world evidence can help overcome this barrier to exploring health inequities, measuring safety and efficacy in the drug approval process, and allowing for regulatory application. In addition to the regulatory bodies already discussed within the proposed legislation, the critical role of Institutional Review Boards should be invoked to ensure racial and ethnic representation in the recruitment and enrollment of study participants.

Investments in Structural Barriers to Clinical Trial Research

Understanding and addressing the root causes of low participation in clinical research by underrepresented communities necessitates a multipronged approach engaging all stakeholders. The three bills all discuss the need to address structural barriers to representative, diverse clinical research; however, further effort is needed to address the drivers of inequity throughout the ecosystem. Starting with the investments that sponsor research, grant review committees must equitably represent the US population, and review protocols should include measures for accountability ensuring that diverse racial and ethnic representation is required on such committees. Further, plans should include specific measures to address explicit and implicit biases that may prevent funding of research, examining where such biases may generate inequity in funding decisions.

Financial support and investments in mentorship opportunities for professional workforce development should be increased to ensure equitable representation in community-based clinical research. Additionally, the establishment of a reimbursement model for health-care providers participating in clinical trials would allow for a permanent add-on payment if coverage for clinical trials were used as a continuum of care when other treatments were unavailable. Last, the study of the socioeconomic and environmental barriers that limit the participation of underrepresented communities in clinical trials must be considered in all discussions around community engagement and outreach. This could include provisions to allow trial sponsors to reimburse patients for their participation and for nonmedical costs associated with trial participation, such as travel and parking.

Role of Digital Health Technologies

Digital technologies play an increasing role in providing access to health care and clinical trials. Although much of the pandemic experience needs close study to ensure that all populations can access digital technologies, more evidence is needed before such technologies can be leveraged to increase access to clinical trials.

The bills in process can take full advantage of digital health technologies to incentivize change and improve inclusion, engagement, and participation in biomedical research and clinical trials. For example, making telehealth and electronic visits available for access to clinical trials could help make sure that clinical trials are more geographically balanced and thereby reduce the burdens of conventional trial participation. Leveraging digital health technologies and innovations, including novel, equitable data-collection methods, could help balance participation. Federal agencies have a large part to play in aligning the appropriate incentives to integrate such technologies.

Conclusion

The three main legislative proposals introduced during the 117th Congress offer a promising start to increasing diversity in clinical trials. Addressing gaps in and barriers to trial participation must continue as the key priority in devising new models for conducting clinical trials and achieving health equity across biomedical research. In addition to the proposed federal legislation, more efforts are required from all stakeholders across the biomedical research and innovation ecosystem to build trust systematically and overcome neglected health priorities among generations of historically excluded communities.

As a critical next step, FasterCures further recommends prioritizing, at the federal level, the establishment of a nationally coordinated, multisector, community-based clinical trials network. This would include the development of a unified strategy across the biomedical research and innovation ecosystem as well as collaboration with patient organizations and direct engagement with communities. FasterCures looks forward to collaborating across sectors on continued policy engagement to realize a national clinical trials network, thus achieving representative diversity in clinical trials.

About Us

About the Milken Institute

The Milken Institute is a nonprofit, nonpartisan think tank. For the past three decades, the Milken Institute has served as a catalyst for practical, scalable solutions to global challenges by connecting human, financial, and educational resources to those who need them. Guided by a conviction that the best ideas, under-resourced, cannot succeed, we conduct research and analysis and convene top experts, innovators, and influencers from different backgrounds and competing viewpoints. We leverage this expertise and insight to construct programs and policy initiatives. These activities are designed to help people build meaningful lives in which they can experience health and well-being, pursue effective education and gainful employment, and access the resources required to create ever-expanding opportunities for themselves and their broader communities.

About FasterCures

FasterCures, a center of the Milken Institute, is working to build a system that is effective, efficient, and driven by a clear vision: patient needs above all else. We believe that transformative and lifesaving science should be fully realized and deliver better treatments to the people who need them.

About the Center for Public Health

The Milken Institute Center for Public Health develops research, programs, and initiatives designed to envision and activate sustainable solutions leading to better health for individuals and communities worldwide.

About the Authors

Yasmeen Long is a director at FasterCures, a center of the Milken Institute. Her expertise lies within health equity, disparities, outcomes, policy, clinical research, patient engagement, and social determinants of health. Before joining FasterCures, Long served as the codirector of the Health Policy Fellowships and Leadership Programs at the National Academy of Medicine. These fellowships were designed for early- to mid-career national and international health-science scholars. She also served as a program officer at the Patient-Centered Outcomes Research Institute (PCORI), where she designed strategic objectives to advance patient and stakeholder engagement in patient-centered outcomes research. At PCORI, Long built key relationships with academic researchers, health-care providers, patient advocates, and policy stakeholders. Prior to PCORI, she directed global health policy programs in the US, Asia, and the Middle East at the Johns Hopkins Bloomberg School of Public Health in collaboration with the Bloomberg Philanthropies and the World Health Organization. She holds an MA in sociology and women's health from Suffolk University and a BSc in health sciences from Howard University.

Athena Rae Roesler is an associate director at the Milken Institute Center for Public Health. Her work champions and evaluates public-health policies, solutions, and partnerships to build a more equitable world. Most recently, she led a partnership with the DC government to understand better how cities can leverage food procurement to support nutrition, the environment, and equitable local economies. Roesler's experience in public health started literally from the ground up, teaching thousands of students about nutrition as a farm-based educator in Arizona, Washington, DC, and South India. Her graduate research centered on the human right to food, a dignified emergency food system, and strategies to reduce health disparities. She was part of a research team evaluating California's sugary drink tax and warning label policies. At Leah's Pantry, a nonprofit supporting California SNAP-

Ed, she furthered behavioral economics-based and trauma-informed nutrition security initiatives. Roesler holds a Master of Public Health in public health nutrition from the University of California, Berkeley and a BA in public health and educational studies from American University.

Jessica Marshall is an associate at FasterCures, a center of the Milken Institute. In her role, she conducts daily in-depth research for the COVID-19 Vaccine and Treatment Tracker, contributes to ongoing health-equity issues occurring across the biomedical ecosystem, and facilitates the development of trust within the health technology and data sector. Prior to FasterCures, Marshall was a graduate fellow at the Veterans Health Administration, where she aided studies focused on identifying veteran groups in the US experiencing health disparities and building trust to advance veteran health equity and knowledge of the COVID-19 virus. She holds a BS in biochemistry from The George Washington University and a Master of Public Health in global health policy from the Milken Institute School of Public Health at The George Washington University.

Endnotes

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