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Toward a National Action Plan for Achieving Diversity in Clinical Trials

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Executive Summary

By any measure, increasing representativeness in clinical research is not a new concern. More than 30 years ago, the US Congress passed the National Institutes of Health (NIH) Revitalization Act, establishing guidelines for improving representativeness in clinical research funded by NIH, specifically for women, and for racial and ethnic populations. While some progress has been made, particularly in the representation of White women in clinical trials, participation in clinical research among racial and ethnic minorities remains low, even though such groups now represent nearly 40 percent of the US population. Health disparities were laid bare during the COVID-19 pandemic, with ethnic and racial minorities significantly underrepresented in early vaccine trials despite being disproportionally impacted by the disease. As a 2022 National Academies report stated, "the lack of equitable representation in clinical trials compounds disparities in health and will cost the United States hundreds of billions of dollars."[1]

Despite decades of work and recent progress—including passage of the Food and Drug Omnibus Reform Act of 2023, which established legislative mandates for increasing clinical trial diversity—there remains a need for collective action across sectors and organizations to align on goals for system-wide, sustainable change. To that end, members of the four organizations with established leadership in advancing diversity in clinical trials—the Clinical Trials Transformation Initiative (CTTI), FasterCures, the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center), and the National Academies Forum on Drug Discovery, Development, and Translation—coordinated a series of convenings in 2023 with the following aims:

- Align on domains for improving diversity, equity, and inclusion (DEI) in clinical trials that, if effectively addressed, would promote system-level change within the clinical trials enterprise.
- Describe common goals for each domain and key collective actions necessary to achieve those goals.
- Inspire organizations to work together toward common goals and commit to taking collective actions.
- Support organizations as they develop metrics to assess progress over time individually and collectively.
- Learn together.
- Drive accountability.

Attendees included more than 200 individuals representing academia, patient organizations,

government, and communities that, when brought together, can drive adoption, scalability, and accountability to improve diversity, equity, inclusion (DEI) in US clinical trials.

Diversity Convergence Project Convenings

- June 12, 2023: Virtual meeting hosted by the Clinical Trials Transformation Initiative
- September 22, 2023: Hybrid meeting hosted by the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
- November 8, 2023: In-person invited session hosted by FasterCures of the Milken Institute
- May 20, 2024: Hybrid public workshop convened by the National Academies Forum on Drug Discovery, Development, and Translation

Based on input from these discussions, survey results, analyses of existing research, and a review by CTTI, MRCT, FasterCures, and National Academies staff, a national action plan for accomplishing system-level change emerged. While this plan focuses on approaches to achieve ethnic and racial diversity in clinical trials, the goals and actions proposed here are also foundational for supporting other historically underrepresented communities and people with intersecting identities. In addition, these goals and actions are meant to complement existing and emerging plans that more specifically address the representation of communities such as people who are LGBTQIA+, people with disabilities, and people with limited English proficiency.

The path forward is clear: Achieving representative clinical trials in the United States requires coordinated and concerted action. By advancing the collective goals and actions laid out in the eight domains described herein, organizations and sectors from across the enterprise can work together toward a future clinical trials enterprise that is diverse, equitable, inclusive, and accessible to all.

We call on each of us from across the clinical trials enterprise to step forward and commit to working together to implement this national action plan and achieve representative clinical trials.

A Call to Action

This national action plan for achieving diversity, equity, and inclusion (DEI) in clinical research represents a living document that will evolve, grow, and mature over time as organizations continue to explore complex issues, ask challenging questions, grapple with uncomfortable truths, and invest in remediation. The document reflects the commitment of hundreds of collaborators who have contributed their expertise, wisdom, and time over the past year and, in many cases, for the past several decades.

A single entity, organization, or institution cannot take this on alone. Transformative and sustained change requires that every sector—academia, industry, patient and other nonprofit organizations, government, communities, and the public—work toward common goals and take collective actions to achieve system-level change. The following recommendations will not apply uniformly to each stakeholder, but instead are intended to anchor collaborative work that draws upon the expertise and resources of individual organizations. It is incumbent upon readers to locate themselves and their organizations within the recommendations and commit to action.

We call on each of us from across the clinical trials enterprise to step forward and commit to working together to implement this national action plan and achieve representative clinical trials.

Figure 1: Eight Domains to Achieve Diversity, Equity, and Inclusion in Clinical Research

Source: Diversity Convergence Project (2023)

National Action Plan: Priority Goals and Collective Actions

Domain A. Public Awareness and Communication

Mistrust in the US health and research systems, especially among African Americans, is long-standing. Historical events, notably the US Public Health Service Untreated Syphilis Study at Tuskegee from 1932 to 1972, imposed unethical and irreparable harms on individuals, families, and communities in the name of research. The legacy of scientific outcomes resulting from the unauthorized use and reuse of Henrietta Lacks' cells does not undo the wrongs done to her in the name of science. Nearly a century after these wrongs were first perpetrated, mistrust remains a primary barrier to participation in medical research among people of color—a barrier reinforced by social and economic inequities and ongoing experience of bias that persist in the health-care system today.

The COVID-19 pandemic provided an unprecedented opportunity to engage more deeply with the public about clinical research. Unfortunately, the scope and scale of misinformation that emerged in the presence of fear and uncertainty further undermined public trust in science and scientists. Recent data indicate that trust in science and medical scientists is now below pre-pandemic levels.[2]

Much effort is required to right wrongs, heal harms, and cocreate clinical research experiences that reflect community and cultural preferences, values, and needs. Several initiatives have worked to improve public awareness and communication about the value of clinical trials, but sustaining awareness beyond time-limited projects remains a challenge.

Public messaging must break through myths, clarify the benefits and risks of participation, and engender hope and healing for the intended audience. Effective messaging and communication strategies must involve the voices and perspectives of communities, which will require community partnership and investment.

GOAL: Create a sustainable, scalable, and measurable national campaign involving historically underrepresented people and communities, together with the clinical trial ecosystem, to increase awareness of and representativeness in clinical trials.

Collective Actions

A1. Inventory and understand existing campaigns, initiatives, and best practices with experience in effectively reaching historically underrepresented people and communities about health-related topics.

- Catalog existing and emerging initiatives, programs, and activities working to increase public awareness and understanding of clinical trials. Seek to understand the scope and scale of these activities, align opportunities to interconnect, and share lessons learned across the clinical trials enterprise.
- Identify the human resources, sustainable funding, and potential home for the inventory's database.
- Define processes for data collection, database structure development, and methods for continually accessing, maintaining, and updating the inventory.
- Design the inventory and database to be useful and usable by a broad range of users, including the public, communities, organizations, individuals, and researchers.

A2. Create national messaging and an iconic symbol that is collectively and intentionally informed by, and crafted with input from, the audiences with whom the messaging will be shared.

- Solicit ideas from those currently engaged in community-based DEI activities related to clinical trials to gather ideas for themes, images, and other messaging (e.g., video, audio, written).
- Set up listening sessions with communities to focus on lived experiences with clinical trials and how those experiences could be improved through system-level changes.
- Align events with national and global health observances supported by disease- and condition-specific groups and others that focus on broader public awareness opportunities related to DEI in clinical trials.[3]
- Proactively seek ongoing input through various community-based and focused channels, events, and opportunities.

A3. Disseminate messages, including narratives of lived experiences, using strategies that align with and across multiple groups and entities.

- Partner with trusted community-based leaders to assist in developing campaign storylines and messaging that align with

national health-related observances; cultural, geographic, and community observances; and federal and state observances.

- Identify private, public, and nonprofit partners (e.g., community health centers, federally qualified health centers [FQHC], faith-based organizations, and community-based organizations) for distribution of communications (through multimedia channels, foundations, libraries, art centers).

- Partner with government agencies that can align events, policies, legislation, and activities related to the national and community focused messaging campaigns.

A4. Ensure sustainability and equitable engagement of messaging and communication campaigns by establishing shared accountability among the clinical trials enterprise and communities.

- Codevelop with communities methods for monitoring and measuring effectiveness of public awareness and communications strategies.

- Gather data and feedback on messages and messengers to identify the strategies that resonate positively with a community and to those that do not.

- Cocreate processes with communities to develop public awareness.

Domain B. Community Engagement and Investment

Research has shown that study enrollment is more successful when patient communities, community organizations, and trusted community leaders partner with researchers at all stages of the research process, including trial design, implementation, analysis, and dissemination of results. However, acknowledging both community groups and leaders as key stakeholders within the clinical trial enterprise and integrating them into the research continuum remain challenging. Despite best efforts and intentions, researchers often approach community groups without understanding their needs and priorities and, instead of seeking community input, offer trials that are misaligned with community interests, which may lead to further harm.

GOAL: Establish sustainably funded, enduring community partnerships, communication, and engagement to support clinical research that matters to communities.

Collective Actions

B1. Define community partnership structures that empower communities to articulate their clinical research and partnership needs.

- Establish a process for building trust with community sites, community groups, and their trusted members. Earning trustworthiness requires listening and learning, understanding the history (including past and present traumas that perpetuate inequities), recognizing the attributes and values of a given community, and establishing long-term commitments on the part of principal investigators (PIs), research teams, and institutions.

- Develop a division of engagement focused on building long-term, sustainable, trusting relationships that is separate and distinct from recruitment of study participants. It is important to understand the unmet needs and priorities of the community, be present, and offer support before introducing research opportunities.

- Codevelop a structure with the community, including community clinics, community organizations, and individual trusted leaders, through which needs and preferences can be articulated for how the community would like to engage with the clinical trials enterprise. Once trusted relationships are established and the research focus is aligned, study teams can approach the community with research opportunities.

- Cocreate and implement a communications plan with communities to facilitate transparent and respectful bidirectional communication without hierarchical undertones. Provide a safe environment in which the community can articulate its needs, evaluate progress, and push back when its needs are not being met.

- Involve medical product industry sponsors and researchers, caregivers/families, patient advocates, and community groups in the research continuum, including review and authorship of research results as appropriate.

B2. Develop a community action plan and business infrastructure that are defined and directed by the community for engaging with researchers who are not from the community, and include methods to evaluate and measure the impact.

- Apply bidirectional training on topics such as research methods, and community engagement principles for researchers and research staff, develop strategies and methodologies that can mitigate hesitancy about the time required to build community relationships.

- Secure and support training on grant writing, philanthropic development approaches, and other strategies for funding that will sustain the organizational business infrastructure both during and beyond a research project.

- Involve community providers to guide and refer patients, and how to get involved in research by developing toolkits to guide community providers on how to get involved in research beyond patient referrals.

- Provide guidance on how community groups can measure the success of partnerships.

B3. Develop funding mechanisms and guidance to support community investment.

- Provide funding at the community level over an extended period, such as five years, to support community-identified needs, focusing on building relationships with the community in addition to the costs of the study.

- Provide equitable compensation to the community for time spent at all stages of the research process, including while jointly building research partnership infrastructure.

- Provide further guidance on what the medical product industry can and cannot pay for.

B4. Ensure transparent and broad communication of results, analyses, and plans for adoption, adaptation, implementation, and/or improvement.

- Return study level data in an understandable format promoting transparency and trust, allowing individuals to be more informed about their health.

- Develop a mechanism for sharing study (and individual patient) data, when available, in understandable and culturally and linguistically appropriate formats.

- Communicate the requirement or expectation that results will be shared, and provide detailed guidance on what will be shared, how, and when.

Domain C. Site Enablement

The ongoing COVID-19 pandemic demonstrates the need for US clinical trial sites to respond to, and anticipate, current and future public health needs. However, insufficient infrastructure, lack of funding, and limited coordination across sectors and organizations compromise readiness for clinical trials. Greater support across clinical trial sites of different types, sizes, and geographies is needed. In particular, the role of community practices and community health centers has become increasingly important and influential as the clinical trials enterprise expands beyond traditional academic research centers and professional research sites.

Access to clinical trials remains a challenge on two major fronts from the perspective of site enablement: (1) for frontline clinicians, investigators, and study staff who must navigate the requirements of, and dedicate incremental time to, research and (2) for people who are trying to identify and access trial opportunities and make informed decisions about participation. Clinical trial sponsors tend to use the same sites repeatedly, thus compromising the inclusion of underserved communities along with the generalizability of results. Additionally, initiating a trial is often hampered by inefficient, redundant, and complex documentation of qualifications from the trial sponsor.

Widespread adoption of common principles and site-readiness practices can improve consistency and enable sites that have not historically participated in clinical trials.[5]

GOAL: Enable more research sites, including community practices and community health centers, to develop or increase their capacity to conduct clinical trials.

Collective Actions

C1. Develop a flexible framework as a model for site development, recognizing the many ways to work in clinical research, highlighting nontraditional clinical site types (e.g., community hospitals and clinics, rural and community-based institutions) and focusing on stakeholders' strengths, not their deficiencies.

- Focus on cross-sector and cross-organizational approaches to engage key stakeholders and invite equitable input on the strengths different sites can offer based on key factors for the clinical trial process, including research team, infrastructure, study management, data collection and management, quality oversight, ethics, and safety.[6]

- Build on existing efforts that provide guidance and resources for clinical trial sites to improve the quality and efficiency of trials and were used to establish a core set of readiness practices that are applicable across trial sites, irrespective of size, geography, or clinical specialty.[7]

C2. Revisit site-funding models and provide necessary budgets to enable success in clinical research.

- Develop realistic budgets and design funding models to support the infrastructure and basic functions of a clinical trial site.

- Avoid under-budgeting by detailed planning that accounts for infrastructure, personnel, and other trial costs.

- Incorporate the costs of managing and monitoring technology, software, and data into the budget, ensuring that training, time, and effort are sufficiently represented in such costs.[8]

C3. Develop centralized, freely available training and resources for developing sites.

The principal investigator, sub-investigators, and other research team members should be qualified through experience, training, and mentorship to conduct clinical trials. Effective training and professional development, particularly for the highly specialized field of clinical research, are necessary for attaining the knowledge and practical skills to fulfill the requirements of a study.[9] While training and resources may build on existing programs, they will require collaboration across organizations and should affirm the input of community practices, leaders, and care providers as equal partners. Given the limitations on resources and capabilities of community and other developing sites, training and resources must be available, accessible, and flexible to the staff of these locations.

- Provide initial and follow-on training and education to all research team members. Core training in human participant protections and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) standards are required of all team members; additional training based on roles and responsibilities—and study specific requirements—should also be available.[10] The professional development path of each team member should be coordinated by a senior responsible individual who is knowledgeable in clinical trial requirements. Each team member should have access to mentorship and opportunities for growth.

- Include culturally competent training. The research team itself should reflect a diversity of skills and backgrounds.[11]

- Consult and refer to existing guidance and recommendations on training and resources for sites.

C4. Provide frontline clinicians with the resources needed to engage potential trial participants.

Engaging frontline clinicians in clinical trials requires that the value of trial participation aligns with health-care priorities. Additionally, the clinical trial process must be integrated into care delivery in ways that minimize time, burden, and distraction from the responsibilities of clinical care. Frontline clinicians should be consulted and invited to codesign resources to ensure that approaches are effective, consistent with practice, and sustainable.

- Offer fair reimbursement, rewards, and recognition for involvement. Both financial and nonfinancial incentives should reward the essential contributions of clinicians to the clinical trial system. The time that clinicians spend in training and education, the recruitment and retention of trial participants, and the conduct of the study, including data acquisition and documentation—all time away from compensated clinical care—should be reflected in compensation, professional reputation, authorship, and recognition.[12]

- Set policies and guidelines for managing clinician time and involvement with patients. Procedural expectations for serving as an effective liaison between clinical research and clinical care—while also providing evidence-based treatments in routine clinical services—are needed.[13]

- Offer training in clinical research methodology. Clinicians need adequate training in research methodology, data management, and biostatistics to build research skills.[14] Needs assessments could help identify ways for clinicians to support patients and potential trial participants better and focus training only on those areas that require additional skills and expertise.

- Provide training in the ethical foundations of research and the fundamentals of trial design and methodology. Like other members of the research team, clinicians need training in bioethics and participant protections, research methodology, the fundamentals of trial design, good clinical trial practices, and research and data integrity, among other subjects. The educational program(s) should follow a deliberative needs assessment to prioritize the training necessary for each clinical role.

C5. Enhance technology solutions to improve the efficiency and conduct of clinical trials.

- Identify incentives for medical-record vendors to use common demographic data standards.

- Subsidize medical record systems for

community-based sites and support data integration at academic medical centers and/or medical record companies.

Domain D. Workforce Diversity

A diverse and representative clinical trials workforce will help improve access to clinical research for patients and communities, decreasing health disparities.

Diversity in clinical trials begins with efforts to introduce clinical research as a professional choice, expose students of all ages to opportunities, and support training and practical experience. Such programs include internships, practicums, fellowships, pre- and post-doctoral programs, leadership development, and mentored clinical research training programs, in addition to on-demand learning modules and training. Mentorship training and time devoted to supervision and mentorship should be appropriately compensated.

GOAL: Cultivate and provide long-term support for a representative clinical trials workforce.

Collective Actions

D1. Establish equitable, general, and targeted opportunities for stakeholder supported pipeline/recruitment/cohort programs (e.g., clinical research career path learning modules, leadership development programs, internships, and fellowships with associated monies to support access to these opportunities.

- Identify opportunities to protect and advance science education and curricula in early grades.
- Add the principles of scientific reasoning, ethics, and clinical research to high school and undergraduate science curricula.
- Ensure placement of clinical research in public campaigns and social media to make it an understood, accessible, and desirable career path.
- Build on existing efforts that expand cross-sector pipeline programs to support and train individuals from underrepresented communities to consider career opportunities throughout the clinical trials continuum. Roles include clinical investigator, clinical trial coordinator, research nurse, data manager, project manager, and participant navigator. Re-envisioning an expanded research team will increase the participation of racial and ethnic minorities in the health professions.

D2. Create professional pathways for potential entrants into clinical research with job opportunities, support for their professional development once hired, and mentorship to promote their individual goals.

- Identify and support early-career scientists, clinicians, nurses, data scientists, and workers from underrepresented populations in other essential medical roles. Introduce medical and research career options to students as early as possible, and provide opportunities to work within the health-care industry, gain vital skills, and explore viable career opportunities, such as clinical research.

- Create entry-level and advanced positions and modify recruitment policies to allow hiring based on drive, promise, and experience—and not on educational attainment alone.

- Establish professional development and promotion based on experience and accomplishment, not on the highest educational degree attained.

D3. Develop human resource policies, processes, and funding mechanisms to support the representativeness and inclusiveness of clinical research personnel.

- Provide equitable wages, benefits, flexible work policies, and opportunities for advancement for principal investigators, clinical trialists, site support staff, and other personnel who support clinical research.

- Develop retention strategies, individualized plans, and professional development supports that are equitable, sustainable, and take into account the breadth of roles and responsibilities for personnel who support clinical research.

- Establish opportunities to share human resources best practices collaboratively with stakeholder groups across the clinical trials enterprise.

D4. Modify research funding opportunities to be more inclusive of early-career researchers and other entrants into the clinical research workforce from underrepresented populations.

- Expand funding opportunities to focus on individuals from underrepresented communities in clinical research as a necessity, and include sustained commitment, tailored training, and the provision of technology to maximize accessible participation.

- Allocate funds from academic medical centers and health systems for cultural-competency training and unconscious bias training for study investigators, research grant administrators, and institutional review board staff that takes into consideration DEI in community settings.

- Educate and train all persons engaging in clinical research to incorporate strategies to increase the recruitment and retention of diverse trial participants. Consider training a fundamental component of funding opportunities, budgets, and timely reimbursement of partnering agencies and organizations.[15]

- Encourage collaborative funding approaches by government agencies that support community research infrastructure and expand the capacity of community health centers and safety-net hospitals to enable a more diverse clinical trials workforce and better meet the needs of the patient populations they serve.[16,17]

Domain E. Design for Equitable Access to Trial Participation

Note that unlike the other domains in this framework, this domain on design for equitable trial access is focused on the level of specific trial planning and conduct (e.g., protocol development, site selection, recruitment, retention, post-trial access). It involves individual actions within organizations to reduce participant barriers to clinical trial access.

Although stakeholders across the clinical research spectrum have worked for years to reduce barriers to clinical trial access, progress has been uneven and remains incomplete. The recommendations below should become the default—planned, budgeted, and operationalized not only to reduce known barriers, but also to maintain accountability and serve as a backstop to collective actions in other domains of this national action plan. Progress can be assessed directly through the review of trial documents (e.g., study protocols and eligibility criteria, feasibility/site assessments, study- and site-specific communication plans, recruitment and retention plans); of budgets and expenditures; of accrual, retention, and withdrawal rates; and, importantly, by qualitative and quantitative data solicited from participants.

GOAL: Address barriers to clinical trial participation by taking actionable steps to reduce burdens.

Individual Actions

E1. Partner to establish, fund, and sustain bidirectional engagement with community members and advocacy groups to foster collaboration, discussion, and understanding.

- Involve patient and community representatives throughout the research process in the definition of the study question, trial planning and design, data collection, and meaningful and feasible trial endpoints. Engage with communities that are underrepresented in research to understand their health concerns and priorities, unique health needs, cultural and social considerations, and other factors that may affect health outcomes.

- Allocate funds specifically to enable community engagement and collaboration initiatives and the long-term sustainability of these initiatives. Community engagement is often funded on a per-trial basis and, when the trial ends, the engagement and community connections may be quickly severed. Community engagement is a long-term investment for all people involved, and there is a great need for sustainable funding that extends beyond single trials.

- Collect participant and community feedback about the experience of participation in clinical trials. Feedback should be standard practice to gain better understanding of areas for improvement in support of patients, participants, and communities.

E2. Provide resources to aid participants in finding trials and in navigating and affording participation.

- Develop and enable systems to help participants and clinicians find relevant clinical trials. This may require the development of technical platforms able to search efficiently and with precision. It may be necessary to provide participant navigators, who closely and routinely interact with participants and are described by participants as critical guides through the clinical trial process. Participants need such support and guidance not only early in the journey, when they are considering volunteering for a trial, but also throughout study participation, to transition to care at the end of the trial.

- Allocate funds and reimburse participant and caregiver/supporter expenses incurred during the trial. Such costs may include, for example, gas, parking, transportation, food, accommodation, childcare, or eldercare. Many trials reimburse these costs, but procedural differences exist, as well as categorical differences in reimbursable expenses (such as essential caregiver expenses).

- Allocate funds and provide reasonable compensation for a participant's time and burden. Travel, testing, appointments, and other requirements of clinical trials take time and should be compensated. The impact of opportunity costs (e.g., lost wages) is greatest for those at the lowest income levels.

- Provide incentives that help recruit and retain study participants.

- Develop, refine, and standardize processes further to pay participants readily and efficiently.

E3. Use plain and gender-neutral language that has been user tested and translated as necessary for all spoken communications and participant-facing materials.

- Make it easy for study participants to understand clinical research communications by using plain language and simplified numeracy principles. Apply these principles to all communication formats, including written, spoken, video, and electronic (e.g., apps and portals).

- Use culturally and linguistically appropriate language and imagery, which has been developed with the intended audiences. Do not use language that is discriminatory (to any group), and create welcoming physical and virtual environments.

- Establish a universal expectation and routine to communicate in accessible and respectful language that includes gender-neutral language and identity-neutral terms.

- Anticipate and budget for written translation and spoken interpretation. Because standards for the translation of participant-facing materials (e.g., recruitment materials, informed consent, study instructions) in clinical trials are inconsistent, translation and interpreter services should be anticipated and budgeted for. The US Census Bureau reports that 68 million people speak a language other than English at home, some of whom may not be comfortable trying to understand clinical trial information and communicate back their needs and wishes, in English.[18] Exclusion based on language alone is discriminatory.

- Incorporate principles of universal design (e.g., options for large font, closed captioning, and others) in all communications and media. Incorporate user-testing, which improves the accessibility of participant-facing materials for everyone. User-testing should include evaluation by people and organizations familiar with patient communities and people with disabilities.

E4. Optimize decentralized clinical trial elements and provide the necessary technology (e.g., apps, portals), devices (e.g., wearables, tablets), internet access and data plans, and technical support.

- Determine capacity to access and maximize the use of decentralized clinical trial (DCT) elements to support trials that are executed either in whole or in part remotely, through telemedicine, mobile technologies, local sites, and mobile health-care providers. Some elements of DCTs (e.g., local blood draws) have already been incorporated as components of clinical trials, but the growing use of digital health technologies, the increased research capacity of local pharmacies and imaging facilities, familiarity with remote monitoring, and other changes have broadened the use of DCT elements in trials. DCTs can expand geographical reach, decrease participants' burden, optimize participants' research schedules, and encourage greater participation by people from historically underrepresented populations. Trials should be reviewed to determine which requirements, research procedures, and outcomes, besides data minimization, can be reengineered for remote management.

- Collaborate with community organizations and with people with disabilities to define digital accessibility issues and test the usability of proposed technology (e.g., apps, portals) and devices (e.g., wearables, tablets). As the research community moves toward more rapid and decentralized clinical trials, it is essential to consider people who may be left behind by the new technology and how to demolish barriers. For example, people with visual impairment may be unable to use apps not developed with universal design. People in rural areas may be far from broadband internet.

- Provide any devices, software, and internet access/data plans required for the trial to participants who lack ready access, and ensure that all participants have access to technology support services.

E5. Help transitions at the end of a trial.

- Assess and plan for continued access to investigational medicines, devices, or other products used in a clinical trial, whenever applicable. It takes time for an investigational product to be approved, marketed, and reimbursed. Therefore, trial administrators should identify pathways to allow participants who benefited from the intervention to have extended access to the study therapy or transition them to appropriate alternatives and follow up. In addition, any accommodations (e.g., accessibility) provided during the trial should continue through ongoing access to the therapy. Site selection and recruitment

should occur only in locations with a plan to seek approval and market the tested intervention.

- Provide participants with individual and aggregate study results in a timely manner, in language they can understand, and in a format they can access. Participants volunteer for clinical trials largely for the benefit of society. They expect to have an opportunity to learn the trial results and, usually, their personal results; that information should be provided routinely. Aggregate results should be available to the involved community.

Domain F. Funding, Resources, and Support

Financial barriers hamper trial participation at the individual level (e.g., lack of transportation to trial sites; expenses for lodging, meals, child- and dependent-care; lost income from missed work), and structural barriers impede community involvement (e.g., lack of investment in community-based research infrastructure). Results of studies indicate that direct intervention to address financial barriers increases trial participation.[19] However, the full range of funding, resources, and support needed for clinical trial access has not been well characterized or prioritized with specific action steps.

Since the passage of an Executive Order on September 19, 2000, Medicare has covered costs that would typically be provided in the absence of a clinical trial, as well as costs defined as reasonable and necessary to diagnose and treat complications arising from participation in clinical trials.[20] Despite this provision, inconsistency remains widespread in the private insurance market regarding coverage of routine services for patients enrolled in clinical trials. The Affordable Care Act of 2010 required that most commercial health plans pay routine patient costs for items or services related to participation in clinical trials, which would otherwise not have been covered.[21] The nation's largest public health-care program, providing coverage for over 80 million Americans, including low-income adults, pregnant women,

older adults, and people with disabilities, did not provide uniform national policy for states until 2020. In 2020, Congress passed the Clinical Treatment Act, effective January 1, 2022, by which Medicaid programs are required to cover routine items and services for participants in a qualifying clinical trial.[22]

National policy on coverage for routine costs associated with clinical trials offers an important step to address financial barriers to patients; however, the lack of a consistent definition of what comprises routine care leads to denial of claims, cost-sharing requirements, or requests for prior authorizations that do not enable the timely provision of care. Patients' confusion about potential financial exposure leads many to decline participation in trials for which they are eligible.

Policies implemented by other federal agencies, such as the Internal Revenue Service (IRS), can further exacerbate financial barriers for low-income participants. The IRS requires that institutions file Form 1099-MISC for each person who has received at least $600 in income, including medical and health-care payments for participating in clinical trials.[23] This record is included in the taxpayer's annual return. For low-income individuals who participate in social welfare and public assistance programs subject to income requirements (such as food assistance, Medicaid, and housing programs), requirements for declaring very modest amounts can deter participation in trials.[24] The rare-disease community scored a win in eliminating this reporting requirement through the Ensuring Access to Clinical Trials Act, 2015, which permanently allows an exclusion under the Supplemental Security Income program and Medicaid for compensation provided to participants in clinical trials for rare diseases.[25]

Finally, limited and inconsistent funding of clinical trial infrastructure in community settings, investment in community organizations that support participation and engagement, and training and support for a diverse clinical research workforce further compound barriers to clinical trial access among members of historically underserved communities.

GOAL: Allocate funding resources for clinical trials to the appropriate study activities proven to increase diversity in clinical trials; identify and eliminate structural financial barriers to participation.

Collective Actions

F1. Establish insurance coverage policies (and associated beneficiary information) that support clinical trial participation.

- Remove the barrier for copays/deductibles (as a secondary insurance payment policy). Both Medicare and Medicaid provide coverage of routine medical services for individuals enrolled in clinical trials; in Medicare, however, such coverage is provided through the Original Medicare (Part A and/or Part B). Participants with secondary insurance must ensure coordination between the services that are covered with Original Medicare and those covered through secondary insurance. Lack of transparency on co-pays and deductibles continues to pose a barrier and increase financial exposure for participants.

- Define and agree upon common definitions and guidance from the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS) on reimbursable/payable services for equitable trial participation. Costs related to travel, lodging, meals, and child- and dependent care, among other obligations, are recognized financial barriers to trial participation. However, there are no common definition and agreement on the extent to which the range of support services may be reimbursed without exposing the trial sponsor to the perception of offering inducement or using coercion. In 2018, the FDA updated its guidance to state that reimbursement for travel expenses or costs associated with airfare, parking, and lodging does not raise issues of undue influence.[26] However, uncertainty around all eligible expense categories risks failure to reimburse participants fully. Guidance from FDA/CMS on agreed common definitions will allow sponsors clarity on services that are reimbursable or payable exempted from inducement.

- Eliminate the requirement for Form 1099-MISC (tax exemption for payment received for clinical trial participation). As described earlier, reporting of Form 1099-MISC for payments received for medical and health-care expenses, which applies to clinical trials, can impose an undue burden on low-income participants in public assistance programs. Exemptions provided to beneficiaries with rare diseases should be extended to any participant enrolled in a qualifying clinical trial.

- Develop a common standard for pre-authorization of services needed, in commercial insurance and for self-insured employers, as an incentive for clinical trial participation. The large scale of divergent policies for pre-authorization of services

and items covered during participation in a clinical trial gives rise to needless, time consuming complexity and burdens for both participants and clinical trial operators. To reduce administrative burden, develop agreed-upon standards on what constitutes routine care as well as covered categories of services. Employers can offer incentives in benefit programs to employees who participate in clinical trials, as often provided for wellness programs.

- Eliminate clinical trial payments from consideration in determining means tested eligibility determinations for federal and state programs.

F2. Develop processes to generate and/or reallocate financial, human, and physical resources to support diversity in clinical trials at the organizational or research-study level.

- Create a third-party, public-private partnership with sustained funding to address needs outside the clinical trial (e.g., wraparound services, community investment). Activities to stimulate engagement within the community, including outreach and education, are supported through partnership efforts between health-care and community organizations. Such partnership models should be developed with sustained funding to support the activities that address trust, disease education and awareness, health screenings, and outreach campaigns that fall outside clinical trials.

- Encourage and elevate philanthropy to fund diverse participation in clinical trials. Philanthropic funds are often used as catalysts to address issues for which public and commercial funding is unavailable. Sponsors often seek a social return on investment. Many nonprofit, disease-specific organizations that promote clinical research and disease awareness are supported through philanthropy. Such funding sources should examine the balance of health equity and disparities underlying the lack of participation in clinical trials for conditions that disproportionately impact racial and ethnic populations.

- Set DEI requirements for earmarking. Require funding for community engaged research to facilitate collaboration among principal investigators, research staff, and community leaders. Specific funding should be earmarked for diversity, equity, inclusion, and accessibility and be provided directly to community partners rather than only academic institutions. Funders (e.g., NIH) can require community partners as co-PIs when appropriate.[27]

- Create mechanisms to tie funding to DEI, data collection, transparency, and performance. Academic research organizations, clinical research organizations, community health centers, and community practices that conduct clinical trials should have funding linked to data collection on demographics for race and ethnicity by funders.

- Require reporting of race and ethnicity for regulatory review. The FDA should ensure accurate and complete data on race and ethnicity in its reporting requirements across all therapeutics, vaccines, devices, and biologics for regulatory review submissions.[28]

F3. Scale best practices for funding.

- Direct funding to community partners in underrepresented communities to strengthen recruitment at the local level. Programs such as the All of Us research program have developed best practices for engaging diverse communities and building trust as part of the strategy.

- Scale such programs and strategies to other sponsors and researchers seeking to involve underrepresented communities using engagement, outreach, enrollment, and retention strategies and tactics.[29]

F4. Bring additional stakeholders to the community table and compensate community members for their time.

- Increase participation in clinical trials by directly funding the community. Often, funding for studies is provided to academic research institutions or commercial research organizations. Sponsors and funders of research then rely on those partners to engage stakeholders in the community. This flawed model has led to persistent and chronic underfunding of community-based organizations that are critical to engaging diverse communities, building trust, and increasing the participation of those communities in trials.

- Reimburse community members and organizations for their time. Direct funding flow more directly to community stakeholders. Promote scalable models, such as navigation programs and community health workers.

- Plan for long-term sustainability of engagement at the community level, scope the community before the engagement to avoid helicopter research, and build long-term relationships and partnerships.

F5. Develop new models of funding sites and workforce.

- Fund new clinical trial sites and leverage existing programs through community health centers, FQHCs, and community hospitals as starting points.

- Fund workforce initiatives for outreach programs when research has demonstrated that agents of outreach, such as nurse navigators and community health workers, are effective in increasing outreach and enrollment.

F6. Provide financial support for underrepresented populations to enter clinical research careers (e.g., loan forgiveness, other financial incentives).

- Enforce diversity goals (and, potentially, workforce training incentives) across funders. Establish grant funding specifically for developing sites and new PIs that includes mentorship and knowledge transfer.

- Sponsor junior PIs and invest in loan-forgiveness programs, college and university fellowship programs, and mentorship opportunities. Create leadership training programs and focus on inclusive eligibility criteria and allyship.[30]

- Provide financial support to fund undergraduate and graduate student fellowships, as well as apprenticeships, to develop a diverse pipeline of researchers. Create partnerships with historically Black colleges and universities and minority-serving institutions.[31]

Domain G. Comprehensive and Consistent Data

The harmonized collection and reporting of demographic and non-demographic data are critical to allow for (1) better development of diversity plans and enrollment goals, (2) comparison of results from research and from DEI plans and initiatives, (3) data aggregation and interoperability, (4) analysis of consistent data variables, and (5) evidence generation. Most demographic variables exist as a continuum (e.g., age) or are heterogeneous (e.g., race and ethnicity), and are often influenced by social constructs and/or geographic location (e.g., ethnicity, language). Therefore, consistency in the use of common vocabularies (data dictionaries), standards in data collection, and defined metrics for measuring success in DEI efforts are challenges that must be addressed and, importantly, informed by collaborative input.

For data collection focused on race and ethnicity, there have been numerous efforts to standardize clinical research data collection and provide visibility into the challenges of doing so. Recent

(and non-exhaustive) efforts to complement these include terminology developed by the Clinical Data Interchange Standards Consortium (CDISC) to describe categories of race and ethnicity,[32] and the National Academies of Science, Engineering, and Medicine report on *Population Descriptors in Genomics Research*.[33] The FDA released Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products in January 2024 for public comment.[34]

Most people have intersecting identities, and racial minority populations can be more highly represented among other underrepresented populations. For example, while one in four people overall in the US reports a disability, that proportion rises to one in three for Black and Hispanic people.[35] Therefore, greater representation of racial minority populations is unlikely to progress without significant attention to intersecting identities and the breadth of lived experiences. While LGBTQ matters are not the immediate focus of this national action plan, it is important to acknowledge the burgeoning array of resources related to the collection of data surrounding sexual orientation and gender identity[36] as well as disability status.

Social determinants of health (SDOH; e.g., income, education, housing) also shape lived experiences, and some organizations are considering a greater focus on the collection of SDOH data to gain a better understanding of barriers to, and representativeness of, clinical trial participation. The World Health Organization,[38] Healthy People 2020,[39] and CMS[40] have proposed frameworks to standardize SDOH elements, but none are universally accepted (or necessarily globally appropriate), and none are routinely collected. Tools are available that provide a framework for data collection of SDOH, for academic medical centers and sponsors to work with when designing clinical trials or prospective research studies.[41]

Finally, the lack of consistency in the collection and reporting of the aforementioned variables is compounded by a lack of clarity as to whether and how different demographic and non-demographic variables should be collected in trials with sites outside the US, whether such data (with differing classifications of ethnicity, gender identify, educational level, etc.) are mapped to US data standards, and whether these data should be reported separately from data drawn from trials in the United States.

GOAL: Establish a national (and international), interoperable, and accountable system for collecting and sharing condition-specific demographic and non-demographic data.

Collective Actions

G1. Audit existing data sources to identify relevant variables (e.g., age, race/ethnicity, sex/gender) and variable response choices (e.g., for race White, Black or African American, and others) that meet data needs for informing diversity plans and enrollment goals. Consider both demographic and non-demographic variables.

- Identify a responsible party/ies and funding sources. Although there have been numerous calls for data mapping and a landscape analysis, leadership with the mandate and capacity to take on this effort has not yet emerged. Therefore, identification of responsible party/ies and funding sources will be of immediate importance, together with the choice of appropriate expertise (e.g., social science, data analysis, epidemiology, and community).

- Define existing internal and external data sources that collect data from participants (e.g., patient records, electronic systems, research records, insurance claims, census surveys) and identify the personnel responsible for these data sources. This identification of data sources and their data dictionaries is a critical step to clarify the availability of data. Among the early issues to address are identifying informative variables and values, and the degree to which data must be harmonized to be useful.

- Document the provenance, data origins, data quality, limits, and biases of each data source and data flow (e.g., data collection, analysis, and reporting). Researchers are often unsure which dataset to use because the provenance and attributes of each data source are not well known. Metadata, which explains where the data have come from, how old the data are, the explicit wording of numerators and denominators underpinning cited data (e.g., "1.5 percent of trial participants were African-American"), differences in how the data are captured compared to other datasets, and potential biases or limitations, is therefore very important to support shared understanding.

- Develop case studies of successful data collection and reporting on DEI. Such examples can be drawn from stakeholders and therapeutic areas, such as oncology, where there is a more extensive clinical trial portfolio and experience with data collection. Because qualitative data are often necessary to provide context for, and better interpret, quantitative data, examples of both would be informative.

G2. Drive collection, reporting, and analysis of patient and participant representation to enable continuous learning and improvement by trialists, sponsors, researchers, communities, and other stakeholders.

- Develop a standard set of fit-for-purpose data needs. The process of data collection begins with careful consideration of the purpose of the data collection. To increase consistency in how data are used, a standard set of fit-for-purpose "data needs" (e.g., to answer a scientific question, confirm study eligibility, support inclusion of diverse participants, and understand patient and family caregiver burdens and types of support needed) should be developed, including explanations of how the approach to data collection would differ for each purpose.

- Create a standardized list of time points during trials to collect and report demographic and non-demographic data. These time-point thresholds could include assessing demographics for the participants who were screened, who were deemed eligible, and who declined study enrollment; who withdrew, were withdrawn by the study investigator, were lost to follow-up; and who were retained and completed the study. Collection and reporting of demographic and non-demographic data at more nuanced time points (rather than only at the end of a study) are needed to observe whether participant engagement and subgroup representation change over the course of the trial(s). If changes are observed, further investigation is indicated.

- Partner with community representatives to ensure that their needs and preferences are represented. All participants want to be able to "see themselves" represented in the data and to understand the results, but the factors that people consider most important about their identity and lived experience are highly variable. The comfort and sensitivity of sharing certain data elements, as well as the method for requesting and soliciting such data, should be explored with community representatives. In addition, the trial outcomes that are most desired by a community may extend significantly beyond the safety and effectiveness of a medication. For example: Did the trial improve infrastructure, such as transportation to trial sites, in a community?

G3. Establish consistent terminology and data formatting for the DEI metrics, variables, and values to be used, in compliance with the latest regulatory guidelines.

- Gather expert consultation to determine those of the mapped data sources that need a common terminology and formatting, and the level of granularity in data needed for those data sources to be interoperable. Consistent terminology and data formatting are needed to permit empirical and comparative analyses across studies, geographies and populations, and time. Clinicians, data scientists, statisticians, and epidemiologists with experience integrating large datasets, alongside regulatory policy professionals, are among those who could be engaged to share insights and experience.

- Devise a shared, common data dictionary that aligns terminology, formatting, and structure for relevant data collection/sharing. Once the data infrastructure is understood, a data dictionary can be created to provide explicit wording for each variable (e.g., for race White, Black or African American, and others). Dictionary users then work from the same definitions, and data from one data source can be more reliably mapped to another.[42]

G4. Standardize data collection and reporting practices across departments, organizations, and site(s).

- Agree on which data should be shared, by whom, and how often. For example, should electronic health record vendors report summaries of demographic data, and if so, when? In developing these standards, consider the potential impacts on clinical research timelines and participant satisfaction with trial transparency. This would facilitate consistency across organizations and decrease administrative burden and expense.

- Generate cross-institutional training programs and resources to support capacity building around fit-for-purpose data collection, analysis/methodologies, and data harmonization. These training programs and resources/tools should incorporate the elements above, including descriptions of data-collection approaches that are fit for purpose; use of common variables, values, and data dictionaries; and regular tracking and sharing of these data at commonly agreed-upon time points in clinical trials.

- Establish periodic, systematic assessment of data collection and reporting systems in different types of trials, settings, and populations. Iterative improvement in

diverse representation and the processes and systems that drive representativeness can only be achieved with regular assessment of how data are being collected and dissemination of the lessons learned.

G5. Develop a comprehensive national database of detailed epidemiological data.

- Develop a comprehensive national database to capture patient demographic and non-demographic data associated with specific diseases and conditions. The demographic and non-demographic distribution of a clinical trial study population should mirror the population affected by, or at risk of, the disease or condition and for whom the study intervention is intended. While those data may be known, they are not generally available and, if available, not at the level of granularity (and intersectionality) needed (e.g., by race/ethnicity, by age and sex/gender). Further, the cost of access to whatever data are available is generally prohibitive. The data should be available in a format that allows analysis of incidence, prevalence, severity, and outcomes disaggregated by demographic and non-demographic variables, and in a way that allows further analysis of the impact of intersectionality.

- Put security, privacy, and confidentiality provisions in place for the database, which may be subject to additional protections, including controlled access through a trusted intermediary. The database will grow over time and should become an important source of high-quality data to direct estimates of appropriate participant representation in clinical trials.

Domain H. Accountability

Real progress in closing the gap in diversity in clinical trials and research cannot be achieved without accountability. There are no consensus metrics, enrollment targets, or alignment in data sources and references in measuring progress. How to drive accountability for a complex, multisector clinical research ecosystem—and where progress should be reported, monitored, and driven—are currently undefined. To make progress toward health equity, there must be accountability for improving the health outcomes of minority populations.

The December 2023 omnibus requirement for Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials represents one important step, but remains insufficient.[43] As an ecosystem of actors, we must assess and agree upon accountability measures through either "carrots" (i.e., incentives), or "sticks" (i.e., requirements, penalties, withdrawal of research funding) for poor performance on those agreed-upon measures.

GOAL: Establish standardized outcome measures tailored at the organizational and national levels.

Collective Actions

H1. Develop universal performance measures by domain, activity or program, stakeholder, and timing (e.g., create a scorecard or checklist) for overall performance measures to diversity goals.

- Establish metrics for each domain described in this national action plan, including Public Awareness and Communication; Community Engagement and Investment; Site Enablement; Workforce Diversity; Design for Equitable Access to Trial Participation; Funding, Resources, and Support; Comprehensive and Consistent Data; and Accountability. Examples of metrics could include the following:
    - gaps in acceptance rates of underrepresented groups within biomedical research and regulatory degree programs, NIH research grants, fellowship and mentorship programs;
    - progress toward target enrollment framework for clinical trials in the US; and
    - align goals and objectives towards a standard review of federal agencies with responsibilities within the US clinical trials and research ecosystem, including FDA, NIH, Centers for Disease Control and Prevention, Center for Medicare and Medicaid Services (CMS), Agency for Healthcare Research and Quality, Office of the National Coordinator for Health Information Technology, Department of Veterans Affairs, Department of Defense, and others.

H2. Establish a national reporting framework to share progress toward established metrics and goals.

- Develop an annual report designated by an office or agency (e.g., Office of Management and Budget, Government Accountability Office, Food and Drug Administration), and share this report with Congress and the public.

Summary of the Eight Domains: Goals and Collective Actions

DOMAIN A. PUBLIC AWARENESS AND COMMUNICATION	
GOAL:	Create a sustainable, scalable, and measurable national campaign with involvement of historically underrepresented people and communities and the clinical trial ecosystem to increase awareness of and representativeness in clinical trials.
COLLECTIVE ACTIONS:	**A1. Inventory and understand existing campaigns, initiatives, and best practices with experience in effectively reaching historically underrepresented people and communities about health-related topics.** **A2. Create national messaging and an iconic symbol that is collectively and intentionally informed by, and crafted with, input from the audiences with whom the messaging will be shared.** **A3. Disseminate messages, including narratives of lived experiences, using strategies that align with and across multiple groups and entities.** **A4. Ensure sustainability and equitable engagement of messaging and communication campaigns by establishing shared accountability among the clinical trials enterprise and communities.**

DOMAIN B. COMMUNITY ENGAGEMENT AND INVESTMENT	
GOAL:	Establish sustainably funded, enduring community partnerships, communication, and engagement to support clinical research that matters to communities.
COLLECTIVE ACTIONS:	**B1. Define community partnership structures that empower communities to articulate their clinical research and partnership needs.** **B2. Develop community action plan and business infrastructure that are defined and directed by the community for engaging with researchers who are not from the community, and include methods to evaluate and measure the impact.** **B3. Develop funding mechanisms and guidance to support community investment.** **B4. Ensure transparent and broad communication of results, analyses, and plans for adoption, adaptation, implementation, and/or improvement.**

DOMAIN C. SITE ENABLEMENT	
GOAL:	Enable more research sites, including community practices, to develop or increase their capacity to conduct clinical trials.
COLLECTIVE ACTIONS:	**C1. Develop a flexible framework as a model for site development, recognizing the many ways to work in clinical research, highlighting nontraditional clinical site types (e.g., community hospitals and clinics; rural and community-based institutions) and focusing on stakeholders' strengths, not their deficiencies.** **C2. Revisit site funding models and provide necessary budgets to enable success in clinical research.** **C3. Develop centralized and freely available training and resources for developing sites.** **C4. Provide frontline clinicians with the resources needed to engage potential trial participants.** **C5. Enhance technology solutions to improve the efficiency and conduct of clinical trials.**

DOMAIN D. WORKFORCE DIVERSITY	
GOAL:	Cultivate and provide long-term support for a representative clinical trials workforce.
COLLECTIVE ACTIONS:	**D1. Establish equitable, general, and targeted opportunities for stakeholder-supported pipeline/recruitment/cohort programs (e.g., clinical research career-path learning modules, leadership development programs, internships, and fellowships with associated monies to support access to these opportunities.** **D2. Create professional pathways for potential entrants into clinical research with job opportunities, support for their professional development once hired, and mentorship to promote their individual goals.** **D3. Develop human resource policies, processes, and funding mechanisms to support the representativeness and inclusiveness of clinical research personnel.** **D4. Modify research funding opportunities to be more inclusive of early-career entrants into the clinical trial workforce from underrepresented populations.**

DOMAIN E. DESIGN FOR EQUITABLE CLINICAL TRIAL ACCESS	
GOAL	Address barriers to clinical trial participation by taking actionable steps to reduce burdens and increase access.
COLLECTIVE ACTIONS:	**E1. Partner to establish, fund, and sustain bidirectional engagement with community members and advocacy groups to foster collaboration, discussion, and understanding.** **E2. Provide resources to aid participants in finding trials and in navigating and affording participation.** **E3. Use plain and gender-neutral language that has been user tested and translated as necessary for all spoken communications and participant-facing materials.** **E4. Optimize decentralized clinical-trial elements and provide the necessary technology (e.g., apps, portals), devices (wearables, tablets), internet access and data plans, and technical support.** **E5. Help transitions at the end of a trial.**

DOMAIN F. FUNDING, RESOURCES AND SUPPORT	
GOAL:	Allocate funding resources for clinical trials to the appropriate study activities that are proven to increase diversity in clinical trials; identify and eliminate structural financial barriers to participation.
COLLECTIVE ACTIONS:	**F1. Establish insurance coverage policies (and associated beneficiary information) that support clinical trial participation.** **F2. Develop processes to generate and/or reallocate financial, human, and physical resources to support diversity in clinical trials at the organizational or research-study level.** **F3. Scale best practices for funding.** **F4. Bring additional stakeholders to the community table and compensate community members for their time.** **F5. Develop new models of funding sites and workforce.** **F6. Provide financial support for under-represented populations to enter clinical- research careers (e.g., loan forgiveness, other financial incentives).**

DOMAIN G. COMPREHENSIVE AND CONSISTENT DATA	
GOAL:	Establish a national (and international), interoperable, and accountable system for collecting and sharing condition-specific demographic and non-demographic data.
COLLECTIVE ACTIONS:	**G1. Audit existing data sources to identify relevant variables (e.g., age, race/ethnicity, sex/gender) and variable response choices (e.g., for race, White, Black, or African American and others) that meet data needs for informing diversity plans and enrollment goals. Consider both demographic and non-demographic variables.** **G2. Drive collection, reporting, and analysis of patient and participant representation to enable continuous learning and improvement by trialists, sponsors, researchers, communities, and other stakeholders.** **G3. Establish consistent terminology and data formatting for DEI metrics, variables, and values to be used, in compliance with the latest regulatory guidelines.** **G4. Standardize data collection and reporting.**

DOMAIN H. ACCOUNTABILITY	
GOAL:	Establish standardized outcome measures tailored at the organizational and national levels.
COLLECTIVE ACTIONS:	**H1. Develop universal performance measures by domain, activity or program, stakeholder, and timing (e.g., create a scorecard or checklist) for overall performance measures to diversity goals.** **H2. Establish a national reporting framework to share progress toward established metrics and goals.**

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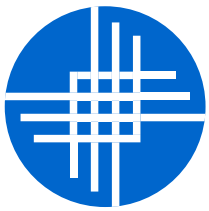
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