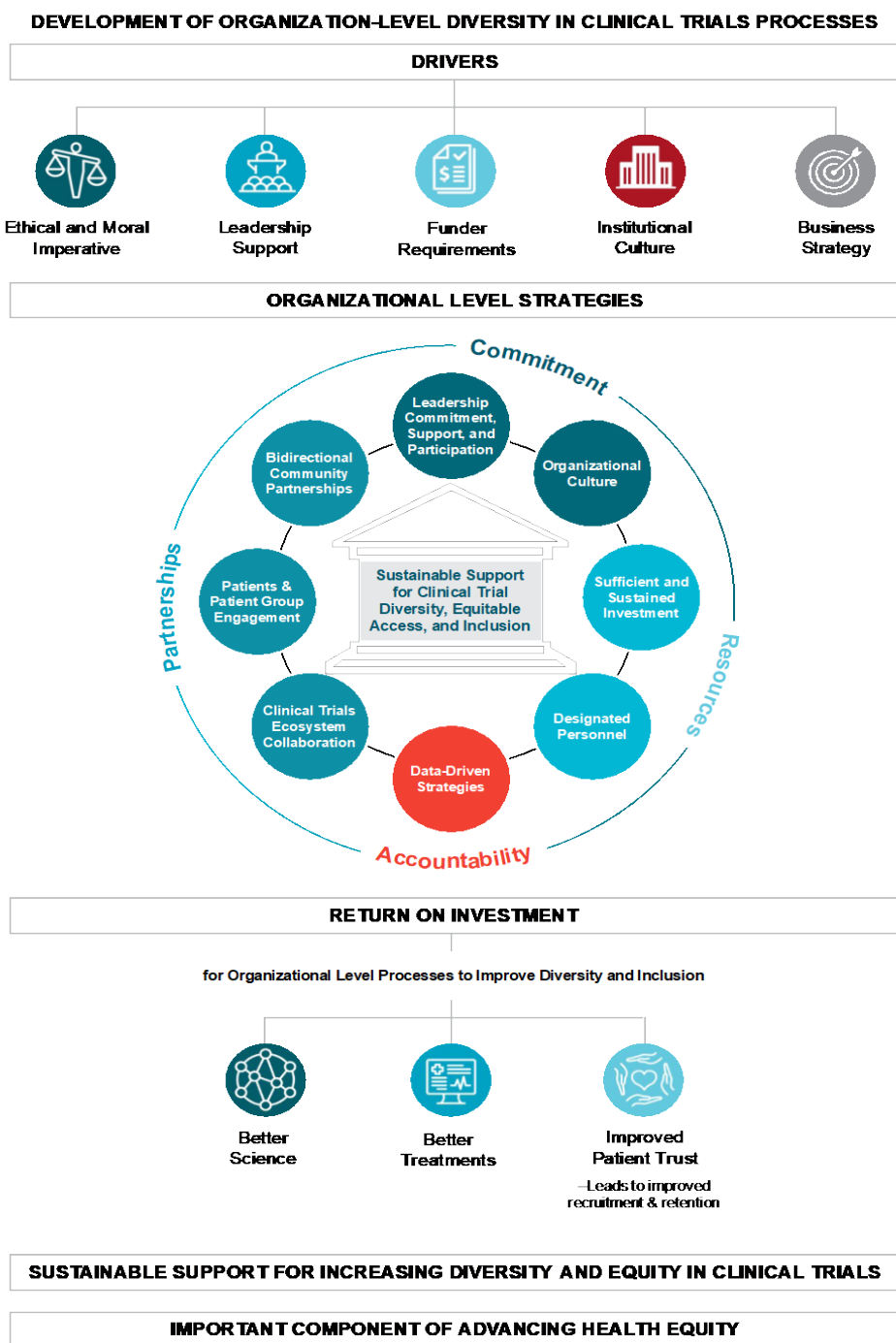


CTTI Recommendations: Increasing Diversity in Clinical Trials



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Experts and key stakeholders from across the clinical trials ecosystem developed these recommendations following CTTI's five-step methodology* designed to ensure the recommendations are actionable, evidence-based, and consensus-driven.

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For a summary of evidence gathering and the process used to create these recommendations see: <https://doi.org/10.1002/cpt.2819>

OVERVIEW

Inclusion and adequate representation of women and underrepresented racial and ethnic groups in clinical trials in the United States is both an ethical and scientific imperative. Enrolling diverse populations leads to more accurate and generalizable trial results by enhancing and expanding our understanding of the safety and efficacy of investigational medical products.¹⁻⁴ In addition, inclusion of all the populations who are affected by a condition can improve access to innovative and potentially life-extending or life-improving therapies, develop trust in clinical trial results, and facilitate uptake if the medical product is approved.⁵⁻⁸ Representative clinical trials increase the availability of evidence-based treatment guidelines for populations that are disproportionately burdened by disease.^{1,9-10}

At the start of the Clinical Trials Transformation Initiative (CTTI) Diversity Project in 2019, many efforts to increase clinical trial diversity focused on reactive, study-level strategies narrowly aimed at supporting the recruitment and retention of underrepresented populations. The far-reaching consequences of a lack of diversity in clinical trials were clearly underscored by the COVID-19 pandemic, leading individuals and organizations across the clinical trials ecosystem to call for deep, systemic change.¹¹⁻¹³ These CTTI recommendations seek to build on the growing recognized need for long-term, transformative strategies that are rooted in a deep organizational commitment to developing clinical trial research infrastructure that is more responsive to the needs of historically underrepresented populations.

Target Audience: Organizations that design and conduct clinical trials involving FDA-regulated medical products*, such as medical product companies, patient groups, academic and non-academic research institutions, contract research organizations, and sites.

Scope: Inclusion of women and people from racial and ethnic groups who have been historically underrepresented in clinical trials in the United States.^{11,14-16} Collectively these groups are referred to throughout these recommendations as *diverse populations*†.

Clinical trial diversity is an important component of a broad organizational culture and commitment to diversity, equity, and inclusion (DEI). While these recommendations are not intended to directly address broader workforce development and DEI initiatives, some recommendations may apply to, or be supportive of, such efforts.

These recommendations and [maturity model](#) are applicable for organizations at various stages in their development of organization-wide strategies for improving equitable access and participation of diverse populations in clinical trials. The recommendations describe best practices and the supporting [maturity model](#) is intended to guide organizations, including those starting to build organizational-level strategies, in the assessment of the current state of development and identification of their ultimate desired progress.

* Medical products include drugs, biological products, and medical devices.

† These *diverse populations* who have been historically unrepresented in clinical trials were selected to enable development of focused recommendations. Individuals and populations are not monolithic, and it is important to consider the intersectionality of demographic, disease, and socioeconomic factors that contribute to inequitable access to and inclusion in clinical trials. Organizations conducting research should seek diversity in clinical trial enrollment beyond populations defined by sex, race, and ethnicity, including populations defined by characteristics such as gender identity, age, geography, socioeconomic status, disability, pregnancy status, linguistic differences, and co-morbidity.

Draft Recommendations Summary

1. [Ensure Leadership Commitment, Support, Participation, & Visibility](#): Establish a strong organization-wide commitment, driven by and accountable to senior leadership, toward the implementation of programs that can improve equitable access and diverse participation in clinical trials.
2. [Build Bidirectional Community Partnerships](#): Develop and maintain bi-directional community partnerships that inform the creation of research strategies, the formation and operation of clinical trial diversity programs, and the design and implementation of clinical trials.
3. [Engage Patients & Patient Groups](#): Include diverse individual patient and caregiver representatives and patient groups in the development of clinical trial diversity programs and at all stages of medical product development.
4. [Ingrain Within Organizational Culture](#): Prioritize equitable access and inclusion of diverse populations in clinical trials as a key component of the organization's overall research strategy and culture of diversity, equity, and inclusion – embedding this commitment into activities at all levels of the organization.
5. [Invest Sufficiently and Sustainably](#): Create an organizational infrastructure – with allocated sufficient and sustained funding – that focuses on the development and consistent deployment of strategies to ensure equitable access to, and diverse participation in, clinical trials in a way that sustainably extends beyond the lives of individual clinical trials, programs, or grants.
6. [Designate Personnel](#): Designate personnel at all levels of the organization's hierarchy to be accountable for the design and deployment of clinical trial diversity strategy, share expertise, and facilitate strong, cross-functional coordination and collaboration across the organization.
7. [Utilize Data-Driven Strategies](#): Develop data-driven approaches to 1) help identify the needs and interests of diverse populations impacted by the disease area(s) of interest, 2) monitor the recruitment and retention of diverse participants in clinical trials and 3) continuously improve the organization's clinical trial diversity program.
8. [Collaborate Across Full Clinical Trials Ecosystem](#): Improving equitable access to and diverse participation in clinical trials will require all groups in the clinical trials ecosystem to work together towards the ultimate goal of clinical trial populations that are representative of the populations who will use the medical product, if it is approved.

RECOMMENDATIONS

1. **Ensure Leadership Commitment, Support, Participation, & Visibility:** Establish a strong organization-wide commitment, driven by and accountable to senior leadership, toward the implementation of programs and activities that can improve equitable access and diverse participation in clinical trials.

Senior leadership roles and responsibilities include the following:

- ▶ ensuring broad understanding within their organizations of the ethical and scientific imperative to increase equitable access and diverse participation in clinical trials – through coordinated employee outreach, education, targeted role-specific training, and regular collection and review of key diversity metrics
- ▶ engaging personally with internal teams and the external community, patient groups, and operational partners to better understand the available resources, specific capacity-building needs, and roadblocks that may limit the organization's ability to develop and resource effective long-term strategies for increasing clinical trial diversity
- ▶ designating a champion or multiple champions who are accountable for embedding the clinical trial diversity program into all departments and/or programs, tracking the program's success, and reporting program outcomes to senior leadership.
- ▶ establishing and utilizing performance goals and objectives that are linked to the 1) creation of and participation in clinical trial diversity initiatives and 2) the establishment of organization-wide goals and performance metrics
- ▶ setting benchmarks for the evaluation and measurement of the organization's clinical trial diversity programs and regularly reviewing the organization's performance and progress towards defined goals in order to ensure long-term sustainability of diversity programs
- ▶ communicating publicly about the organizational commitment to and progress towards conducting clinical trials that reflect the populations who may use the approved medical products, recognizing the contributions of community, patient, and research partners to the organization-level clinical trial diversity strategy, supporting reciprocal relationship building, and increasing the credibility of the organization's efforts

Example messages for senior leadership to convey within their organization include the following:

- It is incumbent upon the organization to ensure equitable access to and increase diverse participation in clinical trials as an important component of improving health outcomes and care options for the populations being served, as well as for the overall public.
- When diverse populations are not enrolled, the approved therapy may not adequately address or treat the condition being studied in those with the highest burden of disease. Enrolling diverse populations – that reflect the populations who may intend to use the intervention – leads to more generalizable trial results by enhancing and expanding our understanding of safety and efficacy outcomes in the included populations (noting that pooled data or innovative statistical methods may be needed for definitive subgroup analyses¹⁷⁻¹⁸).
- An organization's commitment to enrollment of diverse populations distinguishes them within the clinical trials enterprise from organizations without established and sustained clinical trial diversity programs.
- Sustained clinical trial diversity programs strengthen public confidence in the organization's commitment to serving diverse populations, which can lead to increased participation in clinical trials, improved trust in research results, and improved access to and uptake of approved medical products.

2. **Build Bidirectional Community Partnerships:** Develop and maintain bidirectional community partnerships that inform in the creation of research strategies, the formation and operation of clinical trial diversity programs and activities, and the design and implementation of clinical trials.

- ▶ Establish partnerships and collaborations with a range of community groups such as: consortiums, advisory panels, and councils, as well as academic organizations, local healthcare organizations, community healthcare providers, non-profits, medical product companies, faith-based organizations, professional societies, and local political leaders.

- ▶ Ensure partnerships with community groups are reciprocal, embedded into the operations of both organizations, and mutually beneficial in order to facilitate longevity and build trust.
- ▶ Build relationships with community partners well before planning for a specific clinical trial and before asking for research collaboration. These activities may be coordinated directly by the organization or in collaboration with research partners.
 - Create regular settings and practices to communicate with partners about the needs of the community and the organization's ongoing commitment to and investment in community activities that involve diversity in clinical trials.
 - Establish educational programs around topics like ethical research protections, basic science, health literacy, goals of clinical research, and contributing to protocol development.
- ▶ Develop strategies and standard procedures to identify, invest in, and maintain long-term community partnerships. Engagement should go beyond the short-term support of a specific trial, program, or grant.

Bidirectional, sustained engagement with community groups¹⁸⁻¹⁹:

 - builds trust between organizations and underrepresented populations
 - provides critical insight into the barriers limiting diversity in clinical trials, enabling clinical research organizations to create tailored strategies
- A point person or internal team should track community partnerships and coordinate outreach across the organization to minimize redundant interactions. This designated contact should also be available to receive inquiries from community organizations (i.e., 'front door'). In organizations with patient and patient group engagement programs, outreach should be planned with those teams, deferring to their established expertise in community outreach when present.
- Coordination of community partnerships and collaborations with other research partners is critical to share expertise, reduce burden on community groups, and avoid redundant activities. For example, a research organization can have direct partnerships with community groups; while other community partnerships may be established and maintained by other research partners such as patient groups, sites, community health centers, or CROs.

- ▶ Include community partners in the following activities:
 - organizational planning of research strategy and clinical trial diversity programs
 - designing, planning, and conducting clinical trials
 - creating materials and trainings that address diversity in clinical trials intended for patients, communities, investigators, and staff
 - planning and selecting methods for increasing community access to clinical trials (e.g., expanding research sites to include community health centers, utilizing non-traditional sites like pharmacies, utilizing patient navigators, increasing use of virtual study visits or hybrid onsite-virtual study visits)
 - establishing strategies for providing general education about clinical research and reaching out to potential research participants about specific clinical trials
 - regularly reviewing the organization's performance and progress towards clinical trial diversity program goals and planning improvements to the partnership and clinical trial diversity program
- ▶ Provide feedback to the community partners about how input is used and what results came from the co-created strategies and programs. For example,
 - how community input was used to shape research strategy
 - metrics on changes in inclusion of diverse populations in clinical trials
 - lay summaries for specific clinical trials

3. **Engage Patients and Patient Groups[‡]:** Include diverse individual patient and caregiver representatives and patient groups in the development of clinical trial diversity programs and at all stages of medical product development.

- ▶ In addition to including patients in the activities mentioned for community partners above, diverse individual patient and caregiver representatives should be engaged in program and trial level planning, such as:

[‡] CTTI projects use the term “patient group” to encompass patient advocacy organizations, disease advocacy organizations, voluntary health agencies, nonprofit research foundations, and public health organizations. <https://ctti-clinicaltrials.org/our-work/patient-engagement/patients-groups-clinical-trials/>

- formative research on clinical trial needs, logistical obstacles to trial participation, and preferences of potential participant populations (e.g., use of digital health technologies, transportation, translations)
- co-design of studies and co-development of study specific items (e.g., selection of endpoints, benefit/risk assessment, recruitment strategies and materials, trial design, protocol, consent forms)

Sustained engagement with diverse patients, caregiver representatives, and patient groups – as equal partners in the research process – increases trust, demonstrates commitment, and leads to better research questions and more meaningful, feasible studies.^{5, 20-21}

- ▶ Establish processes that create transparency, show appreciation, and provide feedback about how patient and patient group input is used and what results come from the strategies, programs, and individual trials.
- ▶ Plan for time needed to identify diverse patient and caregiver representatives, provide training on research, and complete necessary paperwork to provide patient and caregiver representatives with compensation for their time and expenses.
- ▶ Additional recommendations and tools for engaging patient groups in medical product development is available in CTTI's [Patient Group Engagement](#), [Quality by Design](#), and [Digital Health Technologies](#) work.

4. Ingrain Within Organizational Culture: Prioritize equitable access and inclusion of diverse populations in clinical trials as a key component of the organization's overall research strategy, and culture of diversity, equity, and inclusion – embedding this commitment into activities at all levels of the organization.

- ▶ Embed commitments to programs that improve equitable access to and diverse participation in clinical trials into the organization's mission, vision, core values, and/or strategic plan.
- ▶ Establish the expectation that people at all levels of the organization will incorporate diverse participant access and inclusion considerations into their daily work and activities.
- Strategies to improve equitable access and diverse patient participation should be integrated and not separate from other research planning programs. For example – planning and executing patient engagement should include diverse

perspectives (i.e., there shouldn't be separate patient engagement plans and a diverse patient engagement plans).

- Employees at all levels of the organization are accountable for incorporating strategies, measuring program outcomes, and participating in performance evaluations.
- Ensure the clinical trial diversity program is incorporated into the overall diversity, equity, and inclusion strategy to establish expectations at all levels of the organization.
- ▶ Establish and maintain diverse researchers and research teams by considering diversity and inclusion when recruiting and hiring as one component of building trust within the community and with the diverse populations who may participate in a clinical trial.
- ▶ Include supporting internal departments (e.g., institutional review boards, regulatory and legal departments) and external operational partners (e.g., sites, clinical research organizations, investigators) early in the creation and enactment of clinical trial diversity programs and activities, the planning of clinical trials, and the development of trial-related materials. These groups have perspective across studies, research programs, and – for external partners – multiple organizations, which can be critical for sharing knowledge and ensuring feasibility of strategies to increase equitable access and participation of diverse populations in clinical trials.

5. Invest Sufficiently and Sustainably: Create an organizational infrastructure – allocated sufficient and sustained funding – that focuses on the development and consistent deployment of strategies to ensure equitable access to and diverse participation in clinical trials in a way that sustainably extends beyond the lives of individual clinical trials, programs, or grants.

- ▶ Organizations should provide dedicated resources for the following purposes:
 - devoting staff positions and/or dedicated time to clinical trial diversity programs (see next recommendation)
 - guiding communication and partnership development with community and patient groups, including dedicated funding for engagement activities and dedicated personnel to serve as primary points of contact with specific external partners

- training and education for current faculty and staff, including programs focused on: the importance of diversity in trials, racial bias awareness, cultural competency, potential enrollment biases, and using a health and diversity lens when developing programs and activities
- investing in the development and training of new investigators and site personnel, especially:
 - in expanded settings such as community practices and rural geographies¹³
 - for early career professionals from diverse populations
- supporting sites with the resources they need to:
 - effectively communicate and engage diverse study populations
 - recruit study participants from underserved neighborhoods,
 - use telehealth/tele-research services, home health, and other decentralized or hybrid study approaches
 - customize study materials for diverse audiences, such as translations of participant-facing materials
 - provide financial reimbursement for expenses incurred due to participation in a clinical trial
- investing in tools, technology, and resources that allow for modern study operations (e.g., eCOA, eConsent, eSource, translation software)
- employing systems to track, monitor, and report on participation of diverse populations in clinical trials

Sufficient and sustained investments can⁵:

- provide effective and efficient clinical trials operations, as the ongoing infrastructure investment allows organizations to maintain engagement designed to meet the needs of patients and continuously build and improve trust; and
- aid in the recruitment and retention of employees who are committed to addressing issues of equitable access.

6. Designate Personnel: Designate personnel at all levels of the organization’s hierarchy to be accountable for the design and deployment of clinical trial diversity strategy, share expertise, and facilitate strong, cross-functional coordination and collaboration across the organization.

- ▶ The structure and number of dedicated personnel will differ depending on size of organization.

Common Attributes	Varies by Organization
<ul style="list-style-type: none"> ○ Part of, or with access to and direct supervision from, senior leadership ○ Personnel efforts effectively embedded into the organization’s standard operating procedures ○ Reserved time for work of clinical trial diversity program ○ Personnel selected based on skills, experience, and dedication to meeting the needs of historically underserved and underrepresented populations ○ Personnel who are from the communities the organization is trying to reach AND allies ○ Assigned champion(s), with appropriate training, who lead(s) and is/are accountable for embedding the clinical trial diversity program into all departments and/or programs, tracking success, and reporting outcomes to senior leadership 	<ul style="list-style-type: none"> ○ Staffing: one or more full-time employee(s), employees with a reserved portion of their time, and/or external services providers ○ Team organization: small teams, task forces, and/or centers ○ Roles needed based on organization type (e.g., navigator role at site)

- ▶ Examples of key responsibilities of dedicated personnel include, but are not limited to, the following:
 - Lead the development of a comprehensive external engagement strategy to build trust between the clinical research organization and diverse communities and raise awareness of the organization’s efforts to increase diversity in clinical trials
 - Facilitate strong cross-functional coordination and collaboration to identify capacity building needs and address organization-, patient-, investigator-, site-, and sponsor-level barriers to diversity in clinical trials
 - Ensure access to education and targeted training to increase awareness of the importance of diversity in clinical trials

- Provide support for clinical trial developers and facilitate organization-wide consistency in diversity plans to meet the recommendations of the FDA²² or other oversight agencies
- Engage in coordinated communication activities (e.g., community outreach events, conference presentations, journal articles, webinars) to reach a broad audience, ensuring that communication activities are guided by core messages developed with the community and patient partners and approved by senior leadership

7. Utilize Data-Driven Strategies: Develop data-driven approaches to 1) help identify the needs and interests of diverse populations impacted by the disease area(s) of interest, 2) monitor the recruitment and retention of diverse participants in clinical trials and, 3) continuously improve the organization's clinical trial diversity program.

Specific considerations for the development of data-driven strategies by leadership and clinical trial diversity champion(s) include the following:

- ▶ Develop processes to obtain data (gather or generate if not available) about the epidemiological incidence and/or prevalence of disease on populations impacted by the condition(s) being studied, the differential impact of disease on diverse populations, possible indicated differences in safety or efficacy across the population based on factors associated with race or ethnicity, and the populations cared for or served by the organization.
- ▶ Develop methods for gathering quantitative and qualitative data to identify the needs and priorities of patient representatives and communities and apply this data to inform the clinical trial diversity program as well as study-specific scientific questions and design.
- ▶ Collect qualitative feedback from trial participants on their experience in the trial and apply it to the design of future clinical trials.
- ▶ Apply gathered data to proactively set evidence-based goals for clinical trial participation that reflects the populations affected by the disease of interest, the populations served by the organization, and other relevant evidence. In medical product development programs, it is important to set goals and define the approach for generating data for a diverse population early in the program. The goals and

approach for gathering data can be used for measuring progress internally, providing information to funders, and/or developing diversity plans.²²

- ▶ Monitor the progress of each trial in achieving goals for enrollment and retention of diverse populations at each stage of development, as well as for the overall research portfolio, and adjust strategies when goals are not met.
- ▶ Sponsors should request data from operational partners on their ability, experience, and willingness to recruit diverse populations, the diversity of their staff, and their engagement with community groups and incorporate this data into partnership considerations.
- ▶ When available and appropriate, consider methods to identify new sites and principal investigators with the ability to enroll diverse populations.
- ▶ Monitor and evaluate the deployment of clinical trial diversity strategy across the organization and regularly review internal clinical trial data to determine areas where targeted strategies are most needed and opportunities for improvement exist.

8. **Collaborate Across Clinical Trials Ecosystem:** Improving equitable access to and diverse participation in clinical trials will require all groups in the clinical trials ecosystem to work together towards the ultimate goal of clinical trial populations that are representative of the populations who will use the medical product, if it is approved.
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Thank you to [the experts and key contributors](#) from across the clinical trials ecosystem who helped create this set of recommendations and resources, including the Diversity project team leaders and members, [expert Meeting participants](#), recommendations advisory committee members, and many others.

ABOUT CTTI

The Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the U.S. Food and Drug Administration, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Bringing together organizations and individuals from across the ecosystem—representing academia, clinical investigators, government and regulatory agencies, industry, institutional review boards, patient advocacy groups, and other groups—CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges. Many regulatory agencies and organizations have applied CTTI's more than 20 existing recommendations, and associated resources, to make better clinical trials a reality. Learn more about CTTI projects, recommendations, and resources at <http://www.ctti-clinicaltrials.org>.

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