Diversity Convergence Project:
Toward a National Action Plan for Achieving Diversity in Clinical Trials

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- And thank you for inviting us.

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Diversity Convergence Project: History

We initiated the Diversity Convergence Project to drive system-level changes to achieve racial and ethnic diversity in interventional clinical trials in the U.S. These system-level changes cannot be accomplished alone. We want to to align our previous efforts on DEI and **move from dialogue to action**.

- MRCT Center:
  - Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document and Toolkit, Equity by Design Metrics Framework, IRB/HRPP DEI Toolkit, Accessibility by Design Toolkit
- CTTI:
  - CTTI Recommendations-Increasing Diversity in Clinical Trials, Diversity Maturity Model for Organizational-Level Strategies
- FasterCures:
  - Mapping the Journey- Building a Mutual Understanding for Health Equity in Clinical Research, Achieving Health Equity: An Action Plan To Address Diversity Across Clinical Trials and Biomedical Research
- NASEM:
  - Advancing Anti-Racism, Diversity, Equity, and Inclusion in STEM Organizations: A Consensus Study, Using Population Descriptors in Genetics and Genomics Research: A New Framework for an Evolving Field

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Diversity Convergence Project: Goals

- 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.

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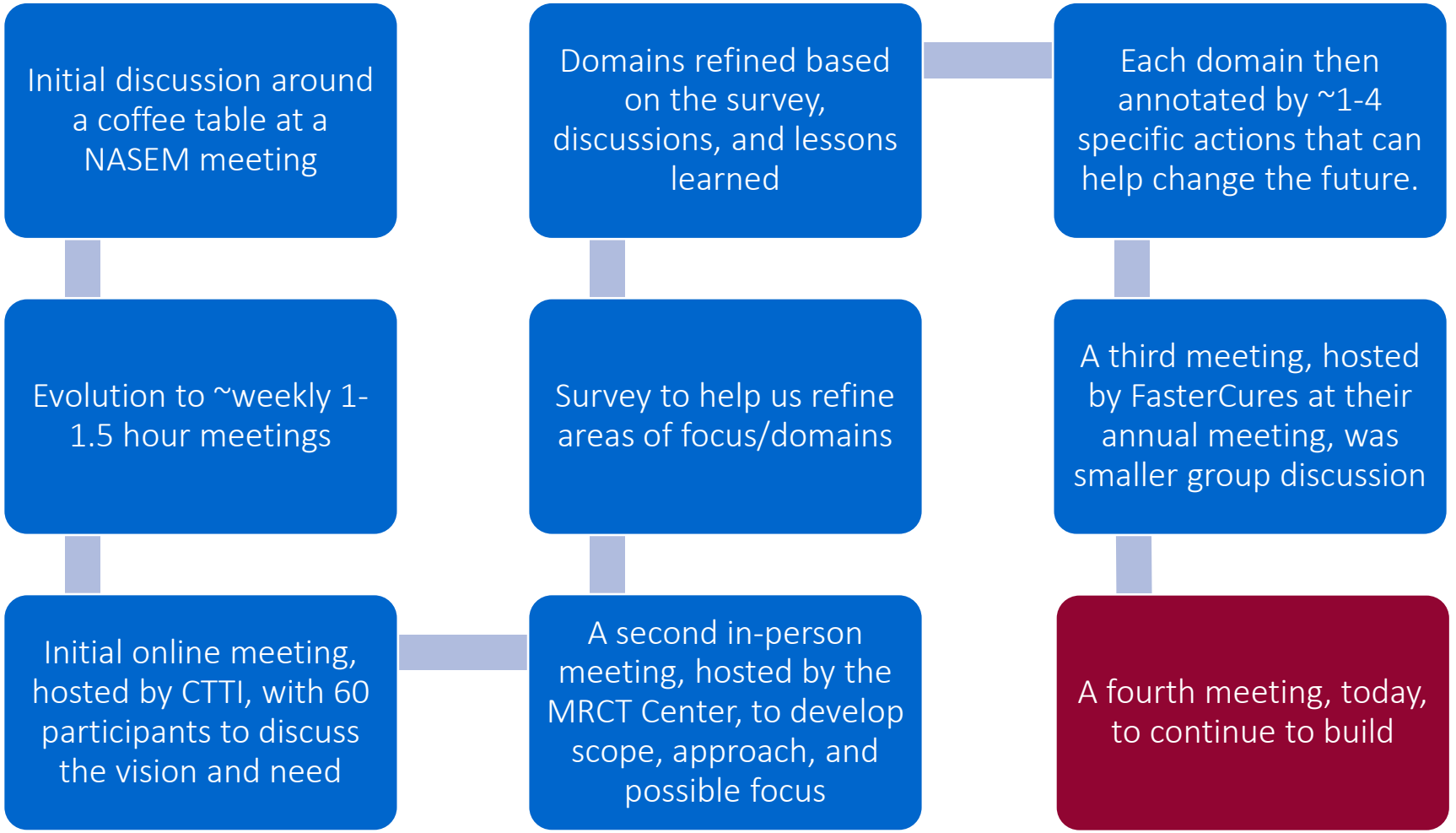
Diversity Convergence Project: Process



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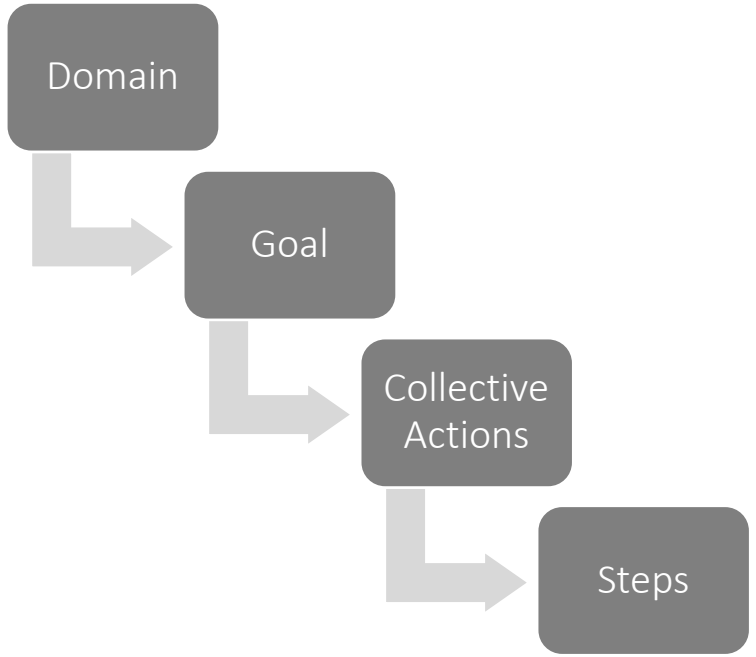
Diversity Convergence Project: 8 Domains

The Action Plan is structured for ease of use:



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A. PUBLIC AWARENESS AND COMMUNICATION. 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.

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

2. 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.

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

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

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B. COMMUNITY ENGAGEMENT AND INVESTMENT. Establish sustainably funded, enduring community partnerships, communication, and engagement to support clinical research that matters to communities.

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

2. 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.

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

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

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C. SITE ENABLEMENT. Enable more research sites, including community practices, to develop or increase their capacity to conduct clinical trials.

1. 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.

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

3. Develop centralized and freely available training and resources for developing sites.

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

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

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D. WORKFORECE DIVERSITY. Cultivate and provide long-term support for a representative clinical trials workforce.

1. 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.

2. 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.

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

4. Modify research funding opportunities to be more inclusive of early-career entrants into the clinical trial workforce from underrepresented populations.

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E. DESIGN FOR EQUITABLE CLINICAL TRIAL ACCESS. Address barriers to clinical trial participation by taking actionable steps to reduce burdens and increase access.

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

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

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

4. 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.

5. Help transitions at the end of a trial.

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F. FUNDING, RESOURCES AND SUPPORT. 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.

1. Establish insurance coverage policies (and associated beneficiary information) that support clinical trial participation.
2. 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.
3. Scale best practices for funding.
4. Bring additional stakeholders to the community table and compensate community members for their time.
5. Develop new models of funding sites and workforce.
6. Provide financial support for under-represented populations to enter clinical research careers (e.g., loan forgiveness, other financial incentives).

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G. COMPREHENSIVE AND CONSISTENT DATA. Establish a national (and international), interoperable, and accountable system for collecting and sharing condition-specific demographic and non-demographic data.

1. 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.

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

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

4. Standardize data collection and reporting.

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H. ACCOUNTABILITY. Establish standardized outcome measures tailored at the organizational and national levels.

1. 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.

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

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Next Steps

- Share opportunity for organizations and individuals to sign onto the Action Plan
- Disseminate template for organizations to make commitments to collective actions
- Foster collaborations across organizations dedicated to achieving equity in trials
- Host future convenings to facilitate sharing, learning, accountability
- Assess need for additional infrastructure to carry the collective work forward

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