Role of the Research Institution: Clinical Trials
Transformation Initiative Diversity Project
NIMHD Inclusive Participation in Clinical Research Workshop

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CTTI Diversity Project Purpose

Demonstrate the clinical, scientific, and economic impact of:

- Increasing diversity in clinical trials, and
- Adopting organizational-level practices that increase inclusion of diverse patient populations throughout the development lifecycle of medical products
CTTI Diversity Project Scope

- Inclusion of women, racial minorities, and ethnic minorities in clinical trials
  - These groups, with historical underrepresentation in clinical research, were selected to enable development of focused recommendations and products
  - Individuals and populations are not monolithic, and it is important to consider intersectionality of demographic, disease, and socioeconomic factors that contribute to inequitable access and inclusion in clinical trials
Interviews: Organizational-Level Diversity & Inclusion

36 Senior-level leaders at 20 organizations

- 8 pharmaceutical and medical device companies (12 representatives)
- 4 patient advocacy organizations (9 representatives)
- 5 academic institutions (9 representatives)
- 3 non-academic medical care centers (6 representatives)

Interview Topics

- Organizational-level practices that promote and support diversity and inclusion in clinical trial populations
- Key motivations for creating the practices
- Related short- and long-term investments their organization made to support these practices
- Perceived subsequent return on investments
Motivations for organizational-level diversity and inclusion practices
Deterrents to investing in organizational-level diversity and inclusion processes

- Cost and Time
- Impact Not Immediately Measurable
- Employee Unfamiliarity with Diversity & Inclusion Processes
Organizational-level diversity and inclusion processes

Staff investment most common approach mentioned:

- Supporting full-time positions
- Funding staff time to work on specific programs/initiatives
- Establishing smaller teams, cores, centers, taskforces to focus on D&I initiatives
- Maintaining a representative and diverse staff
- Hiring strategically, with a priority to hire diverse staff to mirror intended study populations
Return on investment from organizational-level diversity and inclusion processes

**Investment in Organizational Level Diversity and Inclusion Processes**

- Better Science
- Better Treatments
- Improved Patient Trust
  - Leads to improved recruitment & retention
Benefits evident – sustained commitment needed to realize and maintain success

Cultural shifts needed – embed actions into strategy and operations of organization

All stakeholders required for change
Finalizing Recommendations

CTTI Recommendations & Maturity Model
Draft Recommendations: Organizational Strategies

Organizational Culture

Clinical Trials Ecosystem Collaboration

Sufficient and Sustained Investment

Designated Personnel

Data-Driven Strategies

Leadership Commitment, Support, and Participation

Bidirectional Community Partnerships

Patients & Patient Group Engagement
Diversity Maturity Model Purpose:
Provide a guide for research organizations to:
- assess their current organizational infrastructure for increasing diversity in clinical trials, and
- identify a desired future state

What is a maturity model?
- A subjective, yet structured way to evaluate progress
- A holistic view of the major areas that are important for progress
- Give practical ways to
  - Measure in the absence of hard metrics
  - Establish goals
  - Gain organizational buy-in

Maturity Model for Organizational-Level Strategies

Level 1
Initial

Level 5
Optimizing
<table>
<thead>
<tr>
<th>Level 1 Initial</th>
<th>Level 2 Early</th>
<th>Level 3 Developing</th>
<th>Level 4 Implementing</th>
<th>Level 5 Optimizing</th>
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</thead>
<tbody>
<tr>
<td>Community stakeholders not identified</td>
<td>Study-by-study efforts to identify &amp; engage community stakeholders</td>
<td>Strategy for creating community partnerships and collaborations is being developed</td>
<td>Regular settings and practices created to discuss the needs of the community, share the organization’s commitment to, and investment in, diversity in clinical trials</td>
<td>Bidirectional community partnerships exist in the operation of clinical trial diversity efforts and the design and planning of clinical trials.</td>
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<td>Approach for partnering with communities served by the organization does not exist</td>
<td>Community engagement is not coordinated within organization and is not linked to patient engagement activities</td>
<td>Numerous clinical trials are collecting community input, but a study-by-study approach may still occur</td>
<td>Outreach on design, planning, and conduct of clinical trials is completed through established community partnerships</td>
<td>Community included in research strategy discussions</td>
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<td>Occasional community outreach for study recruitment</td>
<td>The organization is seeking advisement on requisite infrastructure to support community engagement activities.</td>
<td>Partnerships and insights are not communicated within organization or reflected in clinical rial diversity program strategy</td>
<td>Efforts at the program-level to identify community stakeholders.</td>
<td>Ongoing organizational strategy for community partnerships is in place including standard procedures, plans to identify partners, investments, maintenance, and coordination. Iterative learnings from coordinated efforts across the organization are in place.</td>
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Maturity Model Example – Bidirectional Community Partnerships

Yale Center for Clinical Investigation (YCCI)
- Over a decade of community collaboration & listening
- Community priorities inform YCCI’s priorities – including COVID reprioritization
- “Help us discover” clinical research awareness campaign
  - Database of volunteers
  - Cultural Ambassadors
  - Advertising and media
  - New clinical research recruitment call center
  - Integrate community practices
  - Community based health fairs and clinics
  - Epic telehealth engagement
  - Radio shows focused on health
  - Social media outreach

Health Equity Implications

- Improve diversity and inclusion in clinical trials
- Better and more generalizable evidence
- Improved trust
- Increased access and uptake of approved medical products
- A component of improving health outcomes and advancing health equity
Next Steps

- Publication available: Enhancing Diversity and Inclusion in Clinical Trials. Clin Pharma and Therapeutics, [https://doi.org/10.1002/cpt.2819](https://doi.org/10.1002/cpt.2819)

- Finalize recommendations and maturity model

- Launch publicly in Q2 2023

- Developing concept proposal to convene related efforts around aligning work to achieve diversity in clinical trials
# CTTI Diversity Project Team

## Team Leaders
- Bernadette Siddiqi* (MJFF)
- Dawn Corbett (NIH)
- Luther Clark (Merck)
- Richardae Araojo (FDA)
- Tesheia Johnson (Yale)

## Executive Committee Champion
- Robert Temple (FDA)

## Social Science Lead:
- Amy Corneli (CTTI/Duke)

## Communications Lead:
- Rae Holliday (CTTI)

## Project Manager:
- Sara Calvert (CTTI)
- Kimberly Fisher (CTTI**)

## Team Members
- Arisha Ali (Amgen)
- Beverly Lorell (King & Spaulding)
- Cassandra Beisel* (Melanoma RF)
- Cassandra Smith* (J&J)
- Cecelia Belmonte* (Amgen)
- Christina Brennan (Northwell Health)
- Coleman Obasaju (Eli Lilly)
- Dinorah Villanueva (J&J)
- Diana Foster (SCRS)
- Glendon Zinser (Susan G. Komen)
- Heidi Pereira (Novartis)
- Jaime Arango (CITI)
- Jamil Rivers (Individual Patient)
- Jane Williams (Syneos Health)
- Jeff Sherman (DIA)

## Team Members (cont.)
- Jerrihlyn McGee (U Kansas MC)
- Julia Yegorova (Genentech Roche)
- Karlin Schroeder (Parkinson's Foundation**)
- Katy Sadowski (TrailSpark)
- Kaveeta Vasisht (FDA)
- Kelley O'Donoghue (U Rochester)
- Kimberly Fisher (Janssen)
- Melania Boyce (EMD Serono)
- Patricia Hurley (ASCO)
- Ruma Bhagat (Genentech)
- Susan Burriss (GSK)
- Suzanne Maahs (Novartis)

*Former project team member  **Former affiliation
Questions about CTTI Diversity Project?
Contact sara.calvert@duke.edu

THANK YOU

www.ctti-clinicaltrials.org