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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

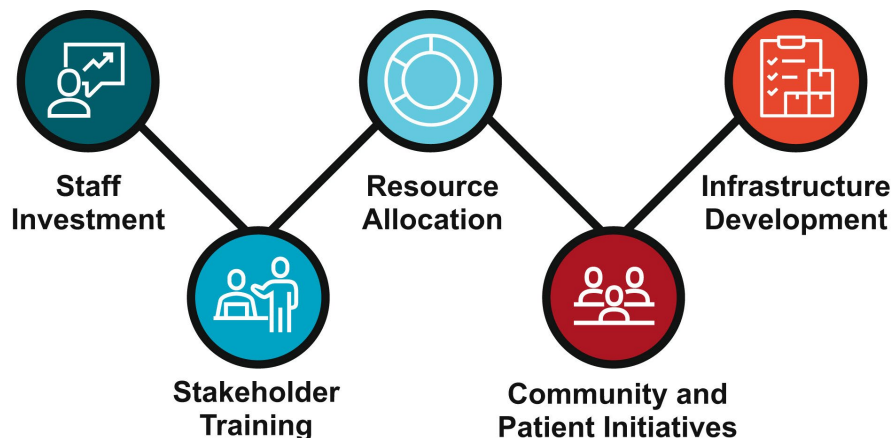


**Impact Not
Immediately
Measurable**



**Employee
Unfamiliarity with
Diversity & Inclusion
Processes**

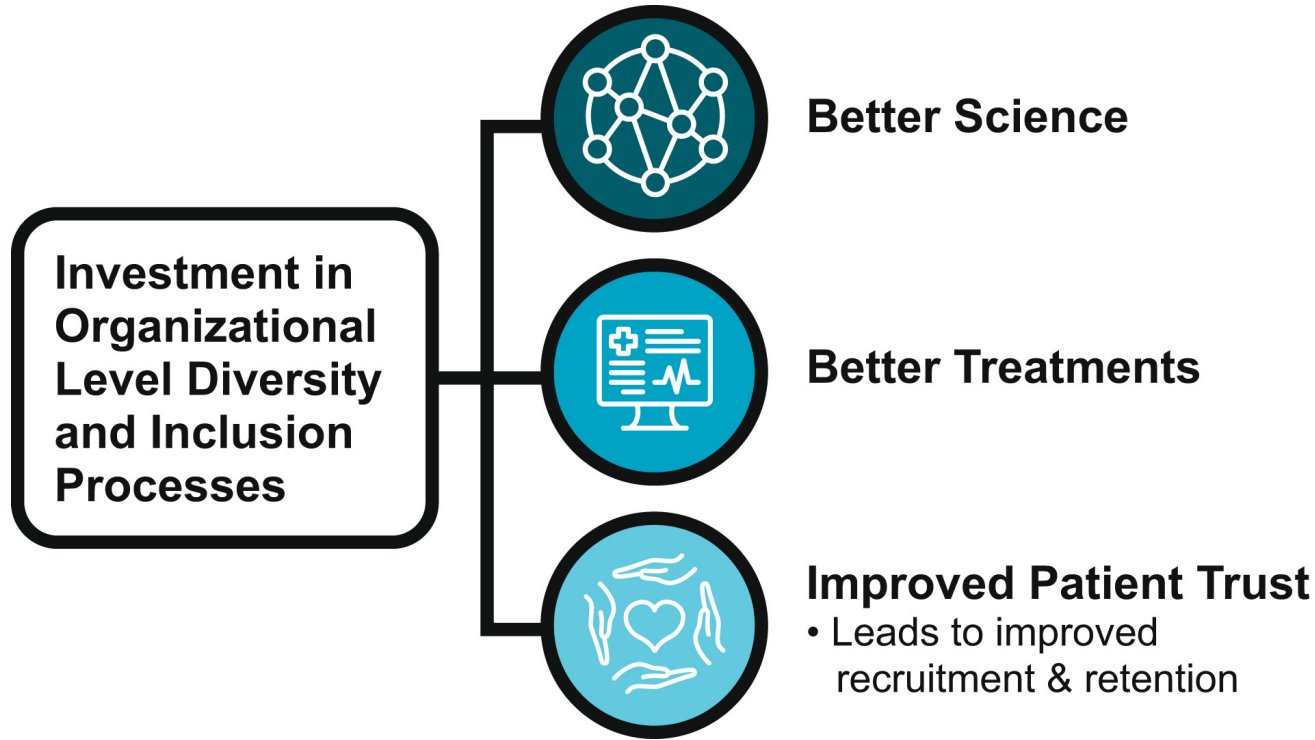
Organizational-level diversity and inclusion processes



Staff investment most common approach mentioned:

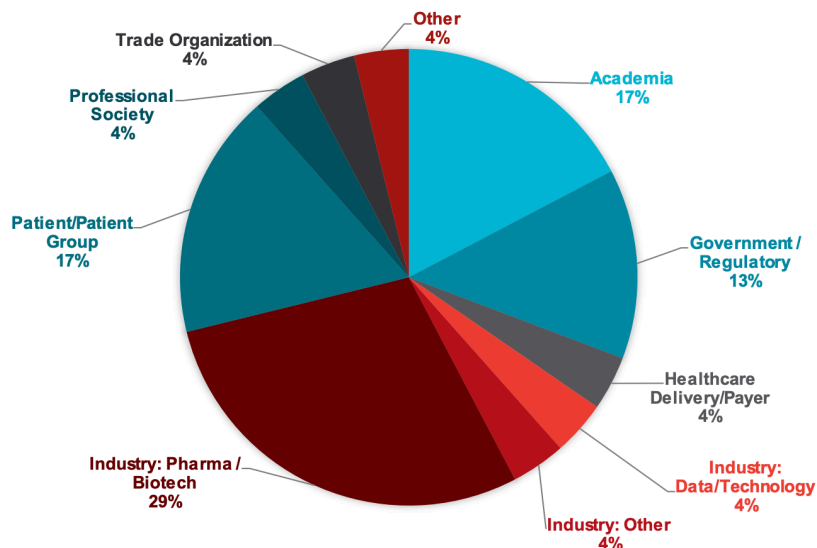
- Supporting full-time positions
- Funding staff time to work on specific programs/initiatives
- Establishing smaller teams, cores, centers, taskforces to focus on D&I initiatives
- Maintaining a representative and diverse staff
- Hiring strategically, with a priority to hire diverse staff to mirror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

Return on investment from organizational-level diversity and inclusion processes



October 2021 Virtual Expert Meeting

REPRESENTED STAKEHOLDER PERSPECTIVES



53 Attendees

Meeting Themes



Benefits evident – sustained commitment needed to realize and maintain success



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



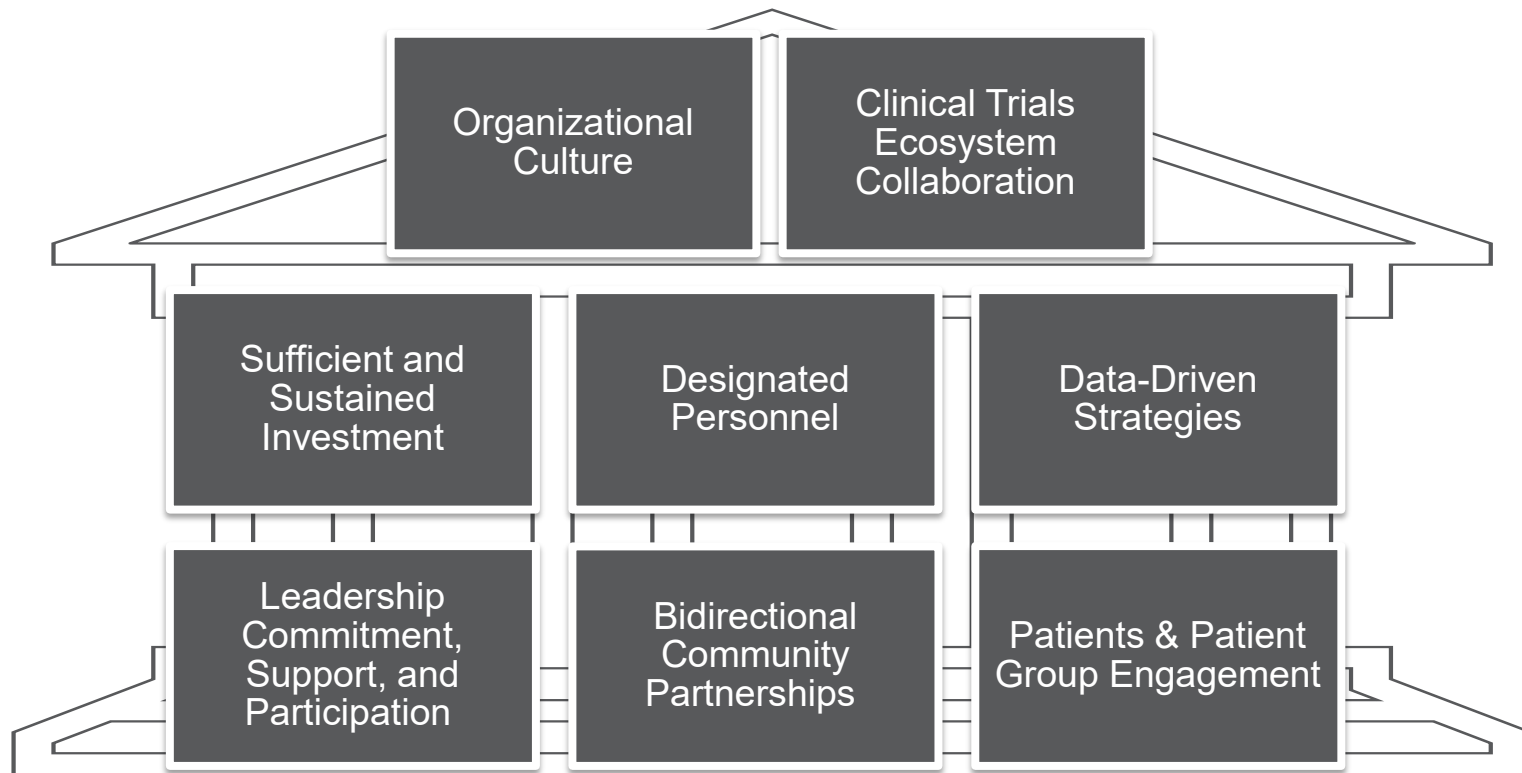
All stakeholders required for change

Finalizing Recommendations



CTTI Recommendations & Maturity Model

Draft Recommendations: Organizational Strategies



Maturity Model for Organizational-Level Strategies

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

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



Maturity Model Example: Bidirectional Community Partnerships

Level 1 Initial	Level 2 Early	Level 3 Developing	Level 4 Implementing	Level 5 Optimizing
<p>Community stakeholders not identified</p> <p>Approach for partnering with communities served by the organization does not exist</p> <p>Occasional community outreach for study recruitment</p>	<p>Study-by-study efforts to identify & engage community stakeholders</p> <p>Community engagement is not coordinated within organization and is not linked to patient engagement activities</p> <p>The organization is seeking advisement on requisite infrastructure to support community engagement activities.</p>	<p>Strategy for creating community partnerships and collaborations is being developed</p> <p>Numerous clinical trials are collecting community input, but a study-by-study approach may still occur</p> <p>Partnerships and insights are not communicated within organization or reflected in clinical trial diversity program strategy</p> <p>Links with patient engagement activities are made but not coordinated across organization</p>	<p>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</p> <p>Outreach on design, planning, and conduct of clinical trials is completed through established community partnerships</p> <p>Efforts at the program-level to identify community stakeholders.</p>	<p>Bidirectional community partnerships exist in the operation of clinical trial diversity efforts <u>and</u> the design and planning of clinical trials.</p> <p>Community included in research strategy discussions</p> <p>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.</p>

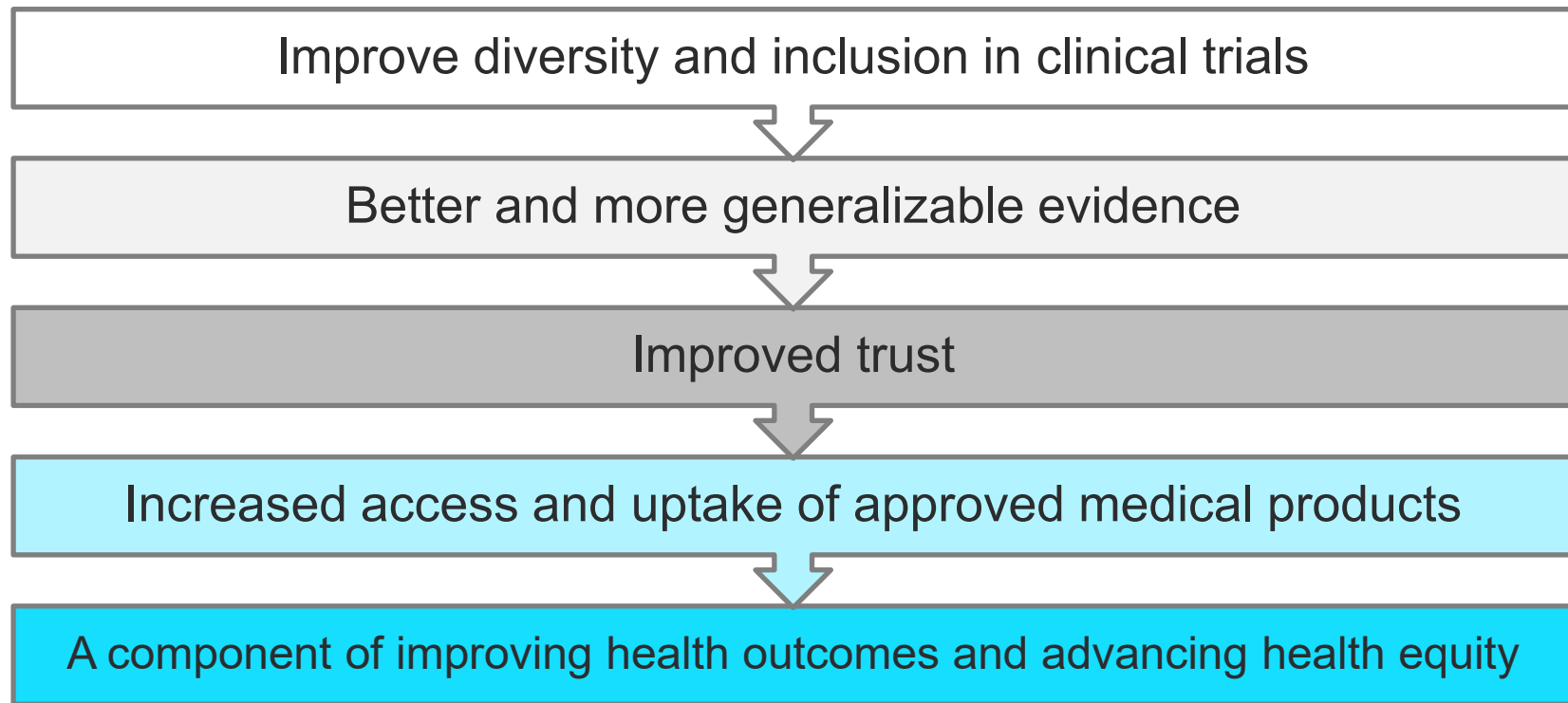
Maturity Model Example – Bidirectional Community Partnerships

Level 5 Optimizing

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



Next Steps



Publication available: Enhancing Diversity and Inclusion in Clinical Trials. Clin Pharma and Therapeutics, <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

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Glendon Zinser (Susan G. Komen)
Heidi Pereira (Novartis)
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Questions about CTTI Diversity Project?

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THANK YOU

www.ctti-clinicaltrials.org