Increasing Diversity in Clinical Trials
Recommendations Launch
Thank you for joining us!
This meeting is being recorded
All participants are muted upon entry
Questions will be entered via the chat box
The presentation and slides will be posted on the CTTI website
Clinical Trials Transformation Initiative

**MISSION**
To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

**VISION**
A high-quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based therapeutic prevention and treatment options

- **Multi-stakeholder** public-private partnership co-founded in 2007 by FDA and Duke University
  - Active collaboration with ±500 individuals and groups
  - Steering Committee with ±80 member organizations
  - All stakeholders have an equal voice

- **Evidence-based** research methods
  - Multi-method research
  - Systematic literature reviews
  - Expert meetings

- **Impactful** products and resources
  - Case Study Exchange
  - Policy adoption
  - Enterprise-wide engagement
CTTI Recommendations

Our multi-stakeholder teams develop actionable, evidence-based, consensus-driven recommendations designed to:

- Accelerate study start-up times & streamline protocols
- Leverage new technologies to improve efficiency of clinical trials
- Enhance the quality of clinical trials without adding undue burden
- Identify streamlined strategies to meet regulatory requirements
By 2030, clinical trials need to be:

- Patient-Centered & Easily Accessible
- Fully Integrated Into Health Processes
- Designed With A Quality Approach
- Maximally Leveraging All Available Data
- Improving Population Health

A critical part of the Evidence Generating System

https://ctti-clinicaltrials.org/who_we_are стратегический вид
Thank you - 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
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Patricia Hurley (ASCO)
Ruma Bhagat (Genentech)
Susan Burriss (GSK)
Suzanne Maahs (Novartis)

*Former project team member  **Former affiliation
## Agenda

<table>
<thead>
<tr>
<th>Time (EST)</th>
<th>Content</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>12:00 p.m.</td>
<td>Welcoming Remarks</td>
<td>Sally Okun (CTTI)</td>
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<tr>
<td>12:05 p.m.</td>
<td>Opening Remarks</td>
<td>RDML Richardae Araojo (FDA)</td>
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<tr>
<td>12:10 p.m.</td>
<td>CTTI Diversity Project Recommendations</td>
<td>Luther Clark (Merck)</td>
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<tr>
<td>12:25 p.m.</td>
<td>CTTI Diversity Maturity Model Overview</td>
<td>Dawn Corbett (NIH)</td>
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<tr>
<td>12:35 p.m.</td>
<td>Implementation Perspectives</td>
<td>Moderator: Sara Calvert (CTTI) Panelists:</td>
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<td>Ruma Bhagat (Genentech-Roche)</td>
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<td>Tesheia Johnson (Yale)</td>
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<td>Glendon Zinser (Susan G. Komen)</td>
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<tr>
<td>12:55 p.m.</td>
<td>Final Comments and Adjourn</td>
<td>Sara Calvert (CTTI)</td>
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RDML Richardae Araojo
Associate Commissioner for Minority Health
Director of the Office of Minority Health &
Health Equity (OMHHE)
U.S. Food & Drug Administration
CTTI Diversity in Clinical Trials Recommendations

Luther T. Clark
Executive Director, Patient Innovation and Engagement
Global Medical and Scientific Affairs
Merck
Inclusion of women and people from racial and ethnic groups who have been historically underrepresented in clinical trials in the United States

- These groups 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

- 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
Methods: In-depth Interviews & Expert Meeting

Interviews with 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)

Expert Meeting

53 Attendees

Represented Stakeholder Perspectives
Results: Drivers for creating organizational-level diversity & inclusion practices

DRIVERS

- Ethical and Moral Imperative
- Leadership Support
- Funder Requirements
- Institutional Culture
- Business Strategy
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
Recommendations: Organizational Strategies

- Leadership Commitment, Support, and Participation
- Organizational Culture
- Bidirectional Community Partnerships
- Patients & Patient Group Engagement
- Clinical Trials Ecosystem Collaboration
- Data-Driven Strategies
- Sufficient and Sustained Investment
- Designated Personnel

Sustainable Support for Clinical Trial Diversity, Equitable Access, and Inclusion
Recommendations

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.

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.
Recommendations (cont.)

- **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.

- **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.
Recommendations (cont.)

**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.

**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.
Recommendations (cont.)

- **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.

- **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.
Maturity Model Overview

Dawn Corbett
Inclusion Policy Officer
National Institutes of Health Office of Extramural Research (OER)
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 – desired levels of development may vary

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
- Gives practical ways to:
  - Measure in the absence of hard metrics
  - Establish goals
  - Gain organizational buy-in
Maturity Model Elements

The Maturity Model focuses on eight elements of organizational-level infrastructure for improving equitable access to, and diverse participation in, clinical trials.

Elements are aligned with CTTI’s Diversity in Clinical Trials Recommendations.

- **COMMITMENT**
  - Leadership
  - Culture

- **PARTNERSHIPS**
  - Bi-directional Community
  - Patient and Patient Groups

- **RESOURCES**
  - Dedicated Personnel
  - Sufficient Investments

- **ACCOUNTABILITY**
  - Data Driven Strategies
  - Continuous Improvement

Adapted from CTTI’s Quality by Design Maturity Model

Each Factor Scored as Level 1-5

In general:
- Level 1 implies little or no coordinated organizational-level strategies.
- Levels 2-4 imply increasingly complete and effective organizational-level strategy implementation.
- Level 5 describes an idealized state of complete implementation, along with continuous improvement efforts.
- Partial scores can be used if some but not all items of a level are met (e.g., 3.5).

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COMMITMENT
- Leadership
- Culture

PARTNERSHIPS
- Bi-directional Community
- Patient and Patient Groups

RESOURCES
- Dedicated Personnel
- Sufficient Investments

ACCOUNTABILITY
- Data Driven Strategies
- Continuous Improvement
### Scoring Example: Dedicated Personnel

<table>
<thead>
<tr>
<th>Factors</th>
<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>
</tr>
</thead>
</table>
| Dedicated Personnel| Some activities to assess or improve diversity in clinical trials may exist at study level. Limited staff responsible for driving practices to ensure representation of diverse populations in clinical trials. | Organization is evaluating staffing needs to establish or support clinical trial diversity strategy and activities.  
- May include small teams, task forces, and/or centers  
- May include internal staff with dedicated time and/or external partners or service providers  
Training for staff is available on an *ad hoc* basis. | Clinical trials diversity team(s)  
- Report to executive leadership  
- Lead development & research  
- Include qualified, experienced personnel  
- Have clear role(s)  
- Lead work to develop, revise, and/or enhance standard procedures, policies, and processes | Team(s) in place  
- Targeted training  
- Integrating diversity activities across organization | Team(s) of dedicated, qualified, personnel: are integrated across all functional groups and processes in the organization Include representatives from diverse communities and allies  
- Implement a strong, comprehensive, and collaborative strategy with internal and external partners |

**Current State: Level 2**

Organization is committed to having dedicated personnel & is evaluating staffing needs.
Identify Future State Example: Dedicated Personnel

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| Dedicated Personnel      | Some activities to assess or improve diversity in clinical trials may exist at study level. | Organization is evaluating staffing needs to establish or support clinical trial diversity strategy and activities.  
- May include small teams, task forces, and/or centers  
- May include internal staff with dedicated time and/or external partners or service providers  
Training for staff is available on an *ad hoc* basis. | Clinical trials diversity team(s) formed who:  
- Report to executive leadership  
- Have dedicated time & resources  
- Include qualified, experienced personnel  
- Have clear role(s)  
- Lead work to develop, revise, and/or enhance standard procedures, policies, and processes | Team(s) in place who:  
- Enact strategy and policies  
- Provide support for other staff and study teams including access to education and targeted training  
- Integrate diversity activities across organization | Team(s) of dedicated, qualified personnel:  
- Are integrated across all functional groups and processes in the organization  
- Include representatives from diverse communities and allies  
- Implement a strong, comprehensive, and collaborative strategy with internal and external partners. |

Desired Future State: Level 3
Organization plans to have dedicated personnel in place in 1 year.
Bidirectional Community Partnerships Example – Level 5

<table>
<thead>
<tr>
<th>Bidirectional Community Partnerships</th>
<th>Yale Center for Clinical Investigation (YCCI)</th>
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<tbody>
<tr>
<td><strong>Level 5 Optimizing</strong></td>
<td><strong>Over a decade of community collaboration &amp; listening</strong></td>
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<tr>
<td>Bidirectional community partnerships exist in the operation of clinical trial diversity efforts and the design and planning of clinical trials.</td>
<td><strong>Community priorities inform YCCI’s priorities – including COVID reprioritization</strong></td>
</tr>
<tr>
<td>Community and patient groups are embedded within decision-making bodies of the organization and included in research strategy discussions.</td>
<td><strong>“Help us discover” clinical research awareness campaign</strong></td>
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</table>
| Ongoing organizational strategy for community partnerships is in place including: standard procedures, plans to identify partners, and ongoing investments, maintenance, and coordination. Iterative learnings from coordinated efforts across the organization are shared. | - Database of volunteers  
- Cultural Ambassadors  
- Advertising and media  
- New clinical research recruitment call center  
- Community-based health fairs and clinics  
- Epic telehealth engagement  
- Radio shows focused on health  
- Social media outreach  
- Integrate community practices |

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Q & A
Please share your initial thoughts

- Please complete brief (<5 min) survey
- Share your initial impressions about the value of the CTTI Diversity in Clinical Trials Recommendations & Maturity Model

https://duke.qualtrics.com/jfe/form/SV_0x3TayDSWQ5pnGS
Next Steps: Dissemination & Implementation

Publication available
Enhancing Diversity and Inclusion in Clinical Trials.
Corneli et al; Clinical Pharmacology & Therapeutics
https://doi.org/10.1002/cpt.2819

Public Workshop to Enhance Clinical Study Diversity
Required under Food and Drug Omnibus Reform Act (FDORA)
Virtual workshop on November 29-30, 2023

Convergence: Achieving Diversity in Clinical Trials
• CTTI, MRCT, FasterCures and NASEM Drug Forum co-convening experts to create alignment across enterprise on shared goals and accountability
Download the Recommendations & Maturity Model

Available now on the CTTI website:
https://ctti-clinicaltrials.org/our-work/quality/diversity/

Learn How Others Implement CTTI Recs

Available now through the CTTI website:
https://connects.ctti-clinicaltrials.org/case_study_exchange
Thank You

Recommendation Advisory Committee

- Kousick Biswas (VA)
- Linda Davidson-Ray (DCRI)
- Kim Fookes (Novartis)
- Emmelyn Kim (Northwell Health)
- Alyssa O’Grady (MJFF)
- Ubong Peters (Genentech)
- Karen Peterson (Karen’s Club)
- Reem Yunis (Medable)

Research Participants – Leadership Interviews

Expert Meeting Attendees*

*https://ctti-clinicaltrials.org/increasing-diversity-in-clinical-trials-expert-meeting/
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