May 18, 2023

Increasing Diversity in Clinical Trials Recommendations Launch

WELCOME

- 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

Sally Okun

CTTI Executive Director

Clinical Trials Transformation Initiative

- ***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

MISSION

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

VISION

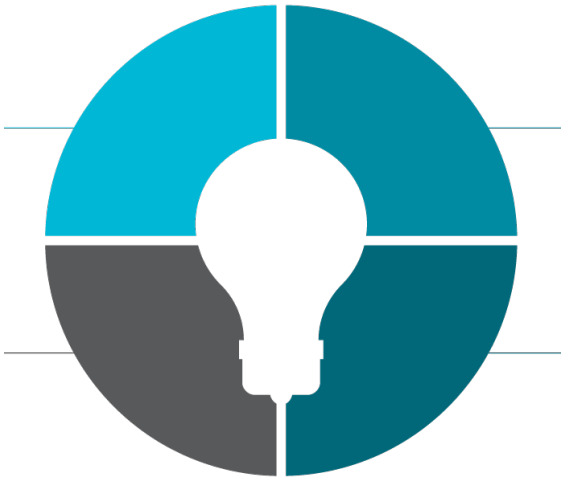
A high-quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based therapeutic prevention and treatment options

CTTI Recommendations

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

Accelerate study start-up times & streamline protocols

Enhance the quality of clinical trials without adding undue burden

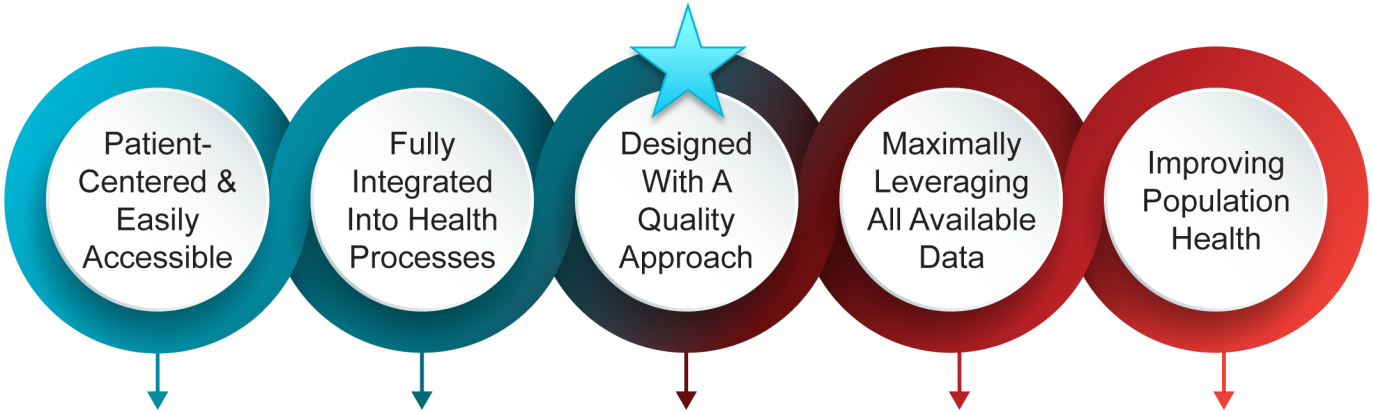


Leverage new technologies to improve efficiency of clinical trials

Identify streamlined strategies to meet regulatory requirements

TRANSFORMING TRIALS 2030

By 2030, clinical trials need to be:



A critical part of the Evidence Generating System

https://ctti-clinicaltrials.org/who_we_are/strategic-vision/

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

Arisha Ali (Amgen)
Beverly Lorell (King & Spalding)
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Cecelia Belmonte* (Amgen)
Christina Brennan (Northwell Health)
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Diana Foster (SCRS)
Glendon Zinser (Susan G. Komen)
Heidi Pereira (Novartis)
Jaime Arango (CITI)
Jamil Rivers (Individual Patient)
Jane Williams (Syneos Health)
Jeff Sherman (Horizon Therapeutics)

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)
Michel Reid (GSK)
Patricia Hurley (ASCO)
Ruma Bhagat (Genentech)
Susan Burriss (GSK)
Suzanne Maahs (Novartis)

*Former project team member **Former affiliation

Agenda

Time (EST)	Content	Presenter
12:00 p.m.	Welcoming Remarks	Sally Okun (CTTI)
12:05 p.m.	Opening Remarks	RDML Richardae Araojo (FDA)
12:10 p.m.	CTTI Diversity Project Recommendations	Luther Clark (Merck)
12:25 p.m.	CTTI Diversity Maturity Model Overview	Dawn Corbett (NIH)
12:35 p.m.	Implementation Perspectives	Moderator: Sara Calvert (CTTI) Panelists: Ruma Bhagat (Genentech-Roche) Tesheia Johnson (Yale) Jane Williams (Syneos Health) Glendon Zinser (Susan G. Komen)
12:55 p.m.	Final Comments and Adjourn	Sara Calvert (CTTI)

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

CTTI Diversity Project Scope

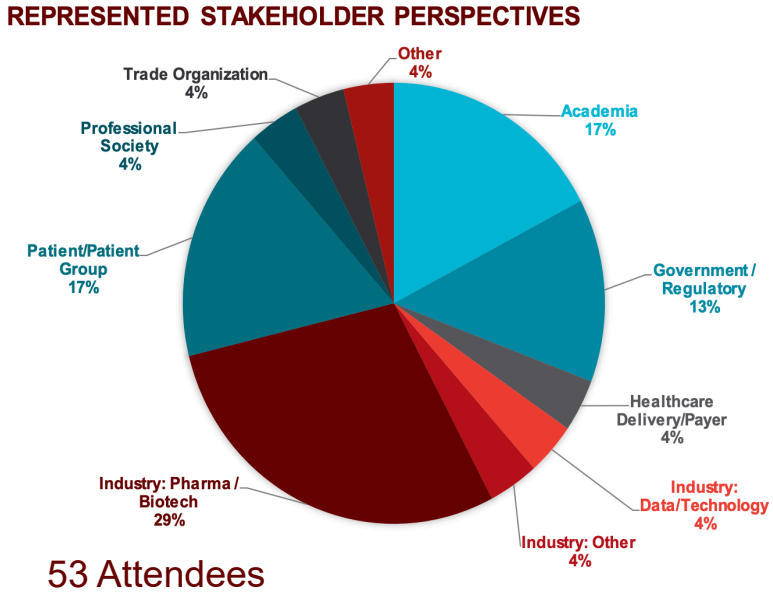
- Inclusion of women and people from racial and ethnic groups who have been historically underrepresented in clinical trials in the United States
  - These groups were selected to enable development of focused recommendations and products
  - Individuals and populations are not monolithic, and it is 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

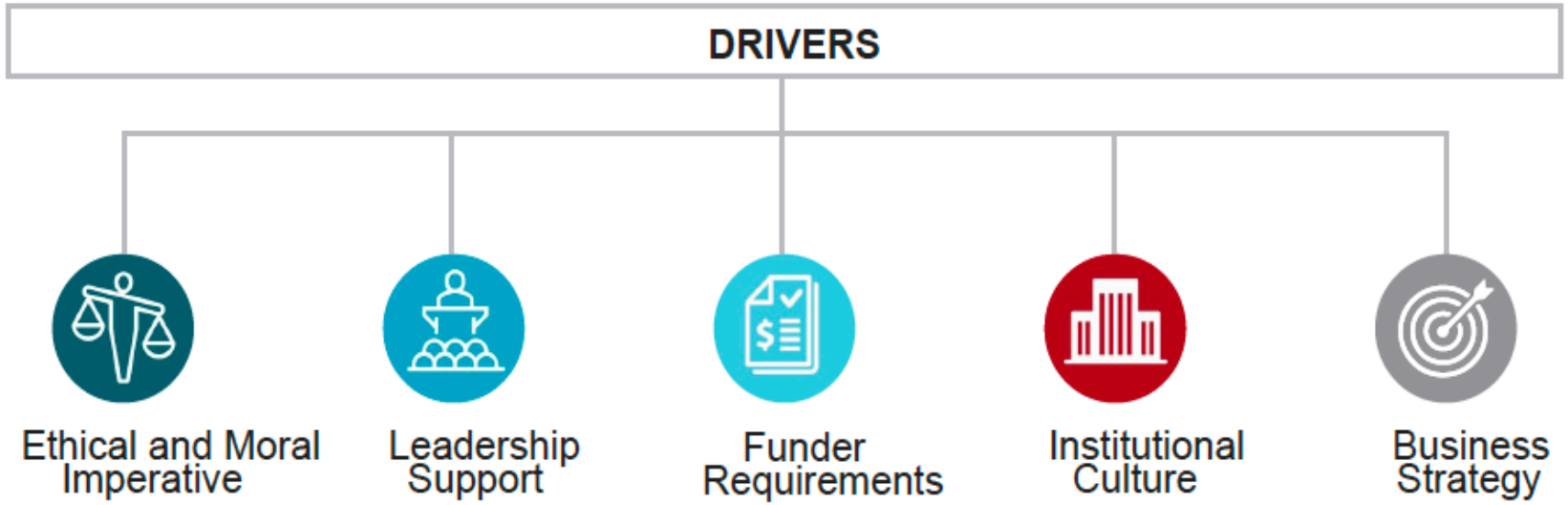
- 8 pharmaceutical and medical device companies (12 representatives)
- 4 patient advocacy organizations (9 representatives)
- 5 academic institutions (9 representatives)
- 3 non-academic medical care centers (6 representatives)

Expert Meeting



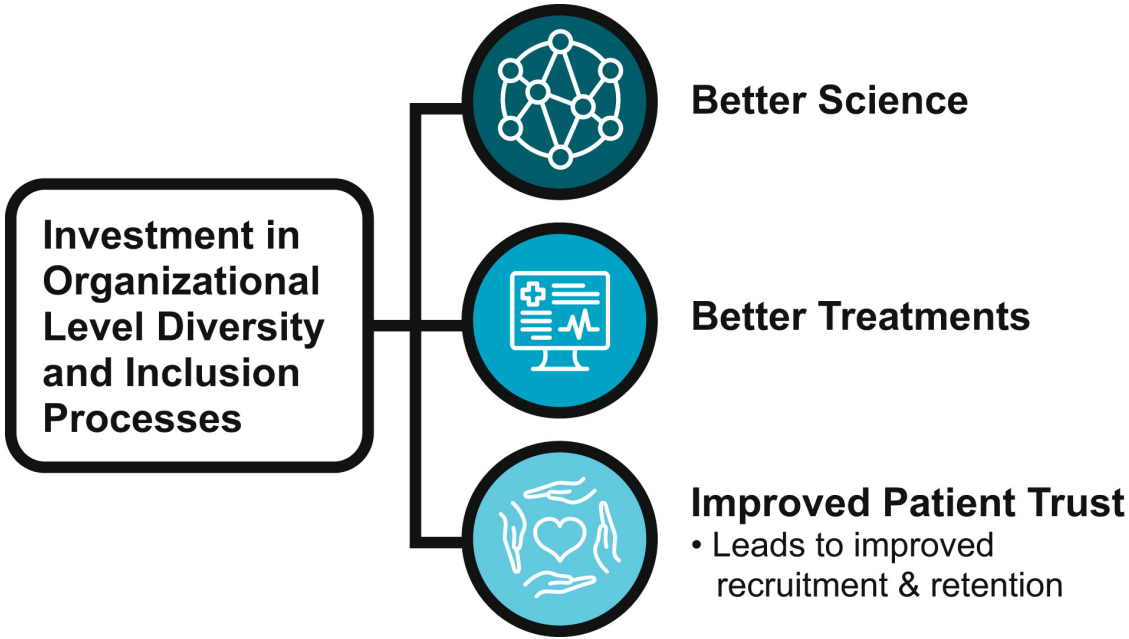
53 Attendees

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



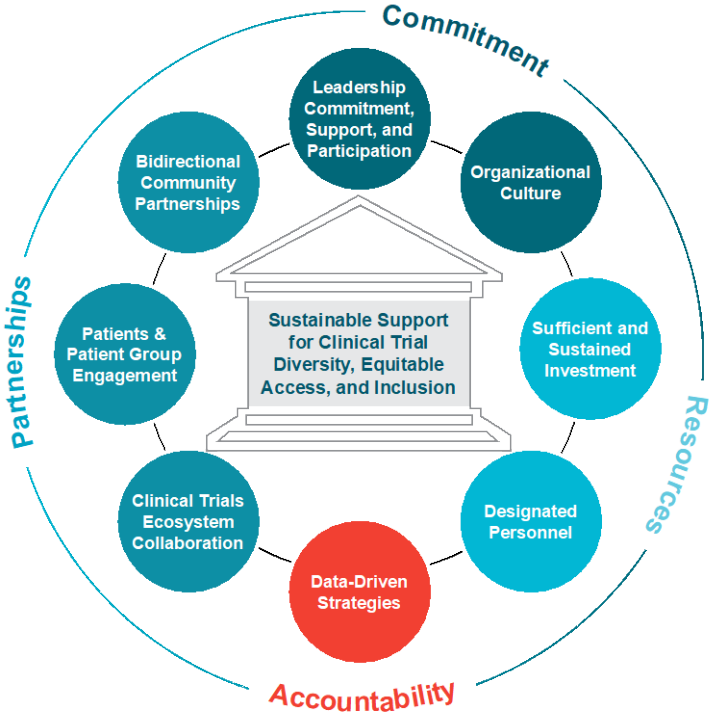
Adapted from - Clin Pharma and Therapeutics, Volume: 113, Issue: 3, Pages: 489-499, First published: 11 January 2023, DOI: 10.1002/cpt.2819

Return on investment – from organizational-level diversity and inclusion processes



Clin Pharma and Therapeutics, Volume: 113, Issue: 3, Pages: 489-499, First published: 11 January 2023, DOI: 10.1002/cpt.2819

Recommendations: Organizational Strategies



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)

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
- Gives 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 – desired levels of development may vary

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

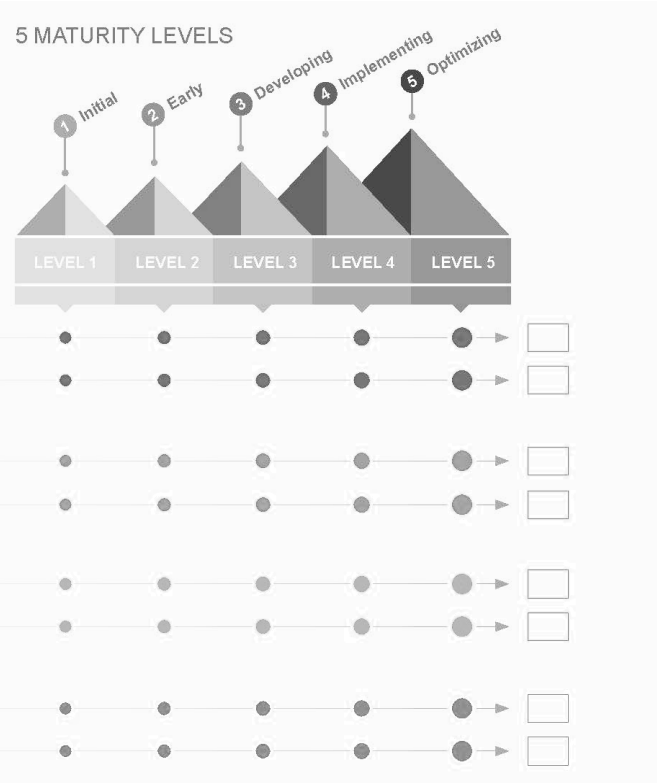
- Bi-directional Community
- Patient and Patient Groups

RESOURCES

- Dedicated Personnel
- Sufficient Investments

ACCOUNTABILITY

- Data Driven Strategies
- Continuous Improvement



Adapted from CTTI's Quality by Design Maturity Model

https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_QbD_Maturity_Model.docx

Each Factor Scored as Level 1-5

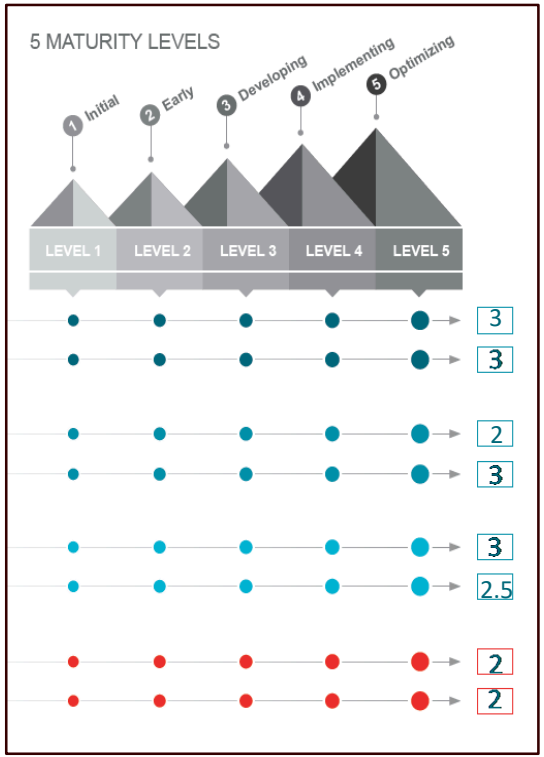
- This maturity model's purpose is to guide research organizations to assess their current infrastructure for improving equitable access to, and diverse participation in, clinical trials and to identify their desired future state.
- Organizations can choose how to use the model; not all rows will apply to every organization and desired levels of development may vary.

COMMITMENT
- Leadership
- Culture

PARTNERSHIPS
- Bi-directional Community
- Patient and Patient Groups

RESOURCES
- Dedicated Personnel
- Sufficient Investments

ACCOUNTABILITY
- Data Driven Strategies
- Continuous Improvement



Each Element can be scored from Level 1 to 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).

Scoring Example: Dedicated Personnel

Factors	**Level 1** Initial	**Level 2** Early	**Level 3** Developing	**Level 4** Implementing	**Level 5** Optimizing
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) f… • Repor… l…nde… & res… • includ… exper… perso… • 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, …ualified, 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

Factors	**Level 1** Initial	**Level 2** Early	**Level 3** Developing	**Level 4** Implementing	**Level 5** Optimizing
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) 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 • En an or an inc to tar • Integrating diversity activities across organization	Team(s) of dedicated, nnel: d across all oups and he sentatives and allies 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

	Level 5 Optimizing
Bidirectional Community Partnerships	Bidirectional community partnerships exist in the operation of clinical trial diversity efforts ***and*** the design and planning of clinical trials. Community and patient groups are embedded within decision-making bodies of the organization and included in research strategy discussions. 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.

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
  - Community-based health fairs and clinics
  - Epic telehealth engagement
  - Radio shows focused on health
  - Social media outreach
  - Integrate community practices

https://globalforum.diaglobal.org/issue/october-2019/advancing-clinical-trial-diversity-through-community-engagement/
https://mrctcenter.org/wp-content/uploads/2020/10/2020-10-14-Diversity-Leaning-In-Webinar-Community.pdf

Implementation Perspectives

Ruma Bhagat

Genentech

Jane Williams

Syneos Health

Tesheia Johnson

Yale University

Glendon Zinser

Susan G. Komen

Moderator: **Sara Bristol Calvert**, CTTI

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

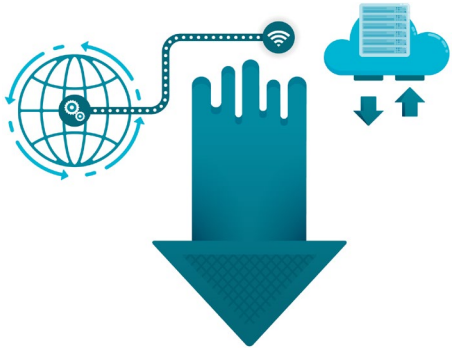
Required under Food and Drug Omnibus Reform Act (FDORA)

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

CTTI CASE STUDY EXCHANGE

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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*Former project team member **Former affiliation

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Survey QR Code

THANK YOU

www.ctti-clinicaltrials.org