Increasing Diversity in Clinical Trials
Expert Meeting
Housekeeping

Please make sure we can recognize you in Zoom.

- Selecting “computer audio” is best
- Or if joining by phone, make sure to enter your Participant ID (check Zoom audio controls, dial #participant ID# at any time)

This meeting is being recorded for note taking purposes only.

Cameras are encouraged during discussions and breakout sessions.

Please Use Chat: All questions, comments, and ideas will be saved and considered as we develop project recommendations and tools.

Questions & General Discussion Period: You can also use the raise your hand function in Zoom during discussions. We’ll get through as many questions as we can.
CTTI & Diversity Project
Overview

Sara Bristol Calvert, CTTI
Multi-stakeholder, public-private partnership co-founded by Duke University & FDA

Participation of 500+ more orgs and + 80 member organizations

MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials.
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://www.ctti-clinicaltrials.org/transforming-trials-2030
CTTI Methodology

**State Problem**
- Gather Evidence
- Explore Results
- Finalize Solutions
- Drive Adoption

**Communications**

**Identify Research Impediments**
- Issue Statement & Project Plan

**Identify Gaps/Barsriers**
- Literature Reviews, Surveys, & Interviews

**Analyze & Interpret Findings**
- Team Meetings

**Develop Recommendations/Tools**
- Team, Expert, & Ad Hoc Committee Meetings

**Disseminate & Implement**
- Pilot Studies, Measure Impact, & Implementation

**Multi-Stakeholder Engagement**
CTTI
Increasing Diversity in Clinical Trials Project
Diversity Pre-Project Work

**Issue**

- Underrepresentation of racial minorities, ethnic minorities, and women in U.S. clinical trials:
  - Limits knowledge of investigational medical products’ safety and efficacy.
  - Reduces the availability of evidence-based treatment guidelines for underrepresented populations.
  - Serious human subject projection issue and broader public health threat.

**What was missing from the landscape at the start of this project?**

- Consideration of the whole protocol (design & operational considerations)
- Coordinated action across key system-level actors
- Efforts to scale and replicate throughout & across institutions
- Sufficient resource allocation

Pre-work Executive Summary: https://ctti-clinicaltrials.org/topics/quality/diversity/advancing-the-landscape-increasing-diversity-in-clinical-trials/
Progress Across Clinical Trials Enterprise

- Increased awareness and calls for systemic change for clinical trials to meet the needs of diverse populations

- Great work is being done through diversity, equity and inclusion programs and initiatives

- Continued need for sharing of information to ensure sufficient resource allocation:
  - Successful organizational-level strategies
  - Clinical, scientific, and economic impact
Project Overview

**Purpose:** Demonstrate the clinical, scientific, and economic value of:

1. Increasing diversity in clinical trials, and
2. Adopting organizational-level practices that increase inclusion of diverse patient populations throughout the development lifecycle of medical products.

**Scope:** Inclusion of women & racial/ethnic minorities in clinical trials.

**Anticipated Impact:** Greater inclusion of diverse patient populations in clinical trials.

https://www.ctti-clinicaltrials.org/projects/diversity
Meeting Objectives

1. Present findings from project evidence generation: in-depth interviews with key decision-makers

2. Refine a maturity model for organizational-level strategies to increase diversity in clinical trials

3. Identify specific multi-stakeholder, portfolio-level strategies to increase the participation of underrepresented racial and ethnic minorities and women in clinical trials
CTTI’s Approach to Expert Meetings

Multi-Stakeholder Collaboration
Registered attendees represent experts, leaders, and contributors from:

- Academia, Heathcare System, Sites (10)
- CROs and Operational Partners (7)
- Government / Regulatory (8)
- Industry Sponsors – Drugs, Biologics, and Medical Devices (15)
- Technology or Operational Partner (3)
- Patient/Caregiver and Patient Group (10)
- Professional Society, Trade Org (6)
- Other: IRB, Consulting, Training (4)

Principles

- Everyone participates, no one dominates
- Disagree without being disagreeable
- Stay open to new ideas
- Articulate hidden assumptions
- Listen for the future to emerge
## Agenda for October 12, 2021 (Day 1)

<table>
<thead>
<tr>
<th>Time (EDT)</th>
<th>Topic</th>
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<tbody>
<tr>
<td>1:00 p.m.</td>
<td>Welcoming Remarks &amp; Project Overview</td>
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<tr>
<td>1:05 p.m.</td>
<td>Session I: Evidence Generation Results – In-depth Interviews</td>
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<tr>
<td>1:55 p.m.</td>
<td>5-Minute Break</td>
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<tr>
<td>2:00 p.m.</td>
<td>Session II: Organizational Strategies to Increase Diversity in Clinical Trials – Yale Center for Clinical Investigation</td>
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<tr>
<td>2:55 p.m.</td>
<td>10-Minute Break</td>
</tr>
<tr>
<td>3:05 p.m.</td>
<td>Session III: Diversity Maturity Model Breakout Discussions</td>
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<tr>
<td>3:55 p.m.</td>
<td>Wrap-Up &amp; Adjourn Day 1</td>
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## Agenda for October 21 (Day 2)

<table>
<thead>
<tr>
<th>Time (EDT)</th>
<th>Topic</th>
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<tbody>
<tr>
<td>1:00 p.m.</td>
<td>Welcome: Review Day 1 &amp; Look Ahead to Day 2</td>
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<tr>
<td>1:05 p.m.</td>
<td>Session IV: Representation in U.S. Clinical Trials</td>
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<tr>
<td>1:35 p.m.</td>
<td>Session V: Review of Maturity Model</td>
</tr>
<tr>
<td>2:05 p.m.</td>
<td>Session VI: Breakout Discussions</td>
</tr>
<tr>
<td>3:35 p.m.</td>
<td>Closing Comments &amp; Adjourn</td>
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