CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

October 12, 2021

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.

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

October 12, 2021

CTTI & Diversity Project Overview

Sara Bristol Calvert, CTTI

CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

Multi-stakeholder,

public-private partnership

co-founded by Duke University & FDA

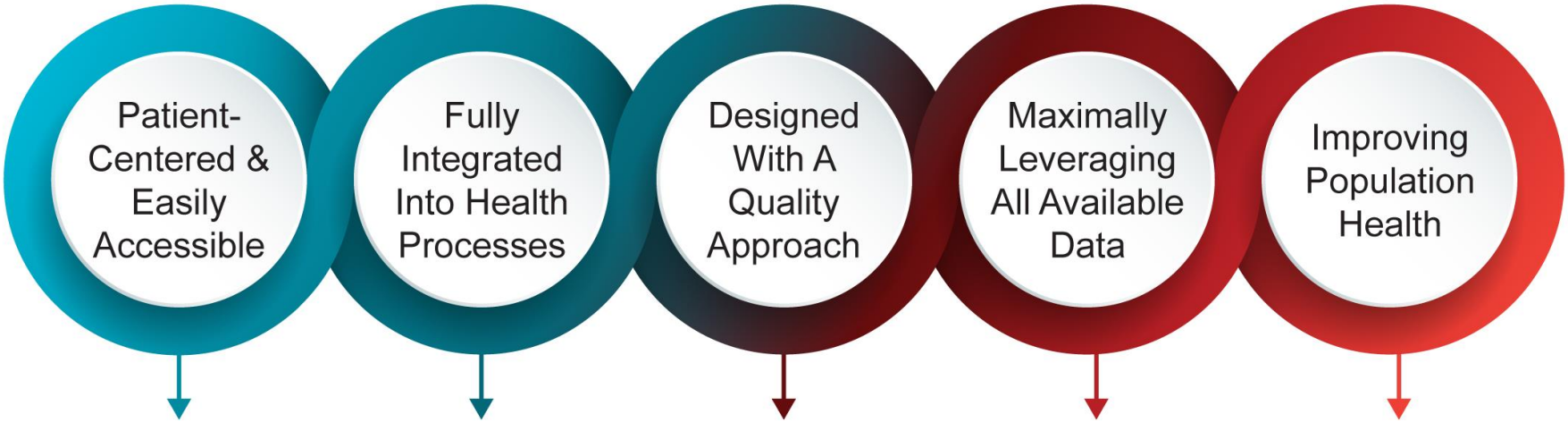
Participation of 500+ more orgs and ± 80 member organizations

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

CTTI

TRANSFORMING TRIALS 2030

By 2030, clinical trials need to be:

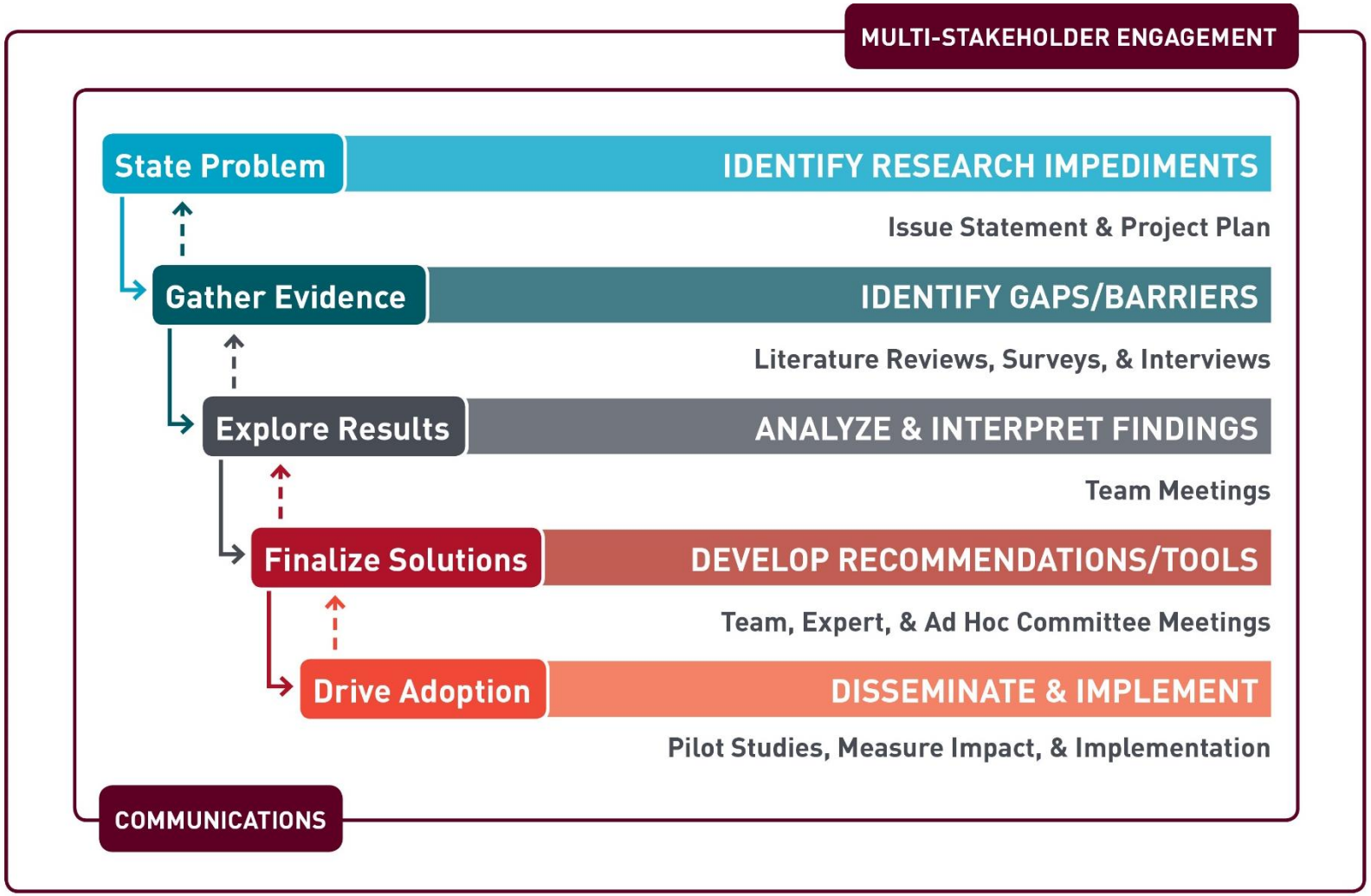


A critical part of the Evidence Generating System

https://www.ctti-clinicaltrials.org/transforming-trials-2030

CTTI

CTTI Methodology



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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/

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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.

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

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Agenda for October 12, 2021 (Day 1)

Time (EDT)	Topic
1:00 p.m.	**Welcoming Remarks & Project Overview**
1:05 p.m.	**Session I: Evidence Generation Results – In-depth Interviews**
1:55 p.m.	*5-Minute Break*
2:00 p.m.	**Session II: Organizational Strategies to Increase Diversity in Clinical Trials – Yale Center for Clinical Investigation**
2:55 p.m.	*10-Minute Break*
3:05 p.m.	**Session III: Diversity Maturity Model Breakout Discussions**
3:55 p.m.	*Wrap-Up & Adjourn Day 1*

Agenda for October 21 (Day 2)

1:00 p.m.	Welcome: Review Day 1 & Look Ahead to Day 2
1:05 p.m.	Session IV: Representation in U.S. Clinical Trials
1:35 p.m.	Session V: Review of Maturity Model
2:05 p.m.	Session VI: Breakout Discussions
3:35 p.m.	Closing Comments & Adjourn