

# Session V: Review of Day 1 and Maturity Model

# What was your top takeaway from Day 1?

 Poll in Mentimeter

# Day 1 Recap: In-depth Interviews

▶ CTTI conducted interviews with 36 representatives from 20 different institutions

▶ Narratives described thematically within four categories—

## Drivers

- Organizational culture and commitment from leadership
- Ethical & moral imperative
- Requirements or expectations from sponsors and regulators

## Operationalization

- Hiring, staffing, dedicated effort
- Training – for staff, communities, investigators
- Infrastructure & Resources
- Community & Patient Initiatives

## Return on Investment

- Better science, more generalizable results
- Increase in patient trust of study results
- Improvements in recruitment & retention

## Disincentives

- Staff and infrastructure changes and associated time and cost
- Impact/outcomes not immediately measurable

# Day 1 Recap: Organizational-Level Strategies

- Yale Center for Clinical Investigation (YCCI) shared approach for increasing clinical trial representation through community collaboration and innovation
- Key features include:
  - Commitment and engagement of senior leadership
  - Bi-directional relationship with community leaders and cultural ambassadors to drive the aims and operationalization of strategies
  - Electronic health record (EHR) and a Clinical Trial Management System to continually assess the quantifiable and qualitative results of efforts

# Day 1 Recap: Discussion

- ▶ Concept of cost is misleading
  - Diversity and inclusion should be part of business strategy, making investments in a different way
  - Move away from molecule-specific and study-specific activities only, to ongoing continued investments
  - Having diversity and inclusion infrastructure can be competitive advantage
    - Improved recruitment and retention of participants
    - Trust, faster uptake of results
    - Recruitment and retention of staff
  - There are costs to not enrolling diverse populations

# Day 1 Recap: Discussion

- YCCI example is over a decade of work
- Practices of large research health system have many parallels to other sponsors and stakeholders
- Culture and leadership is very important to drive change and commitments in all organization types
  - Provides an opportunity for better collaboration and alignment across organization and partners
- Important to start somewhere, will see results with sustained commitments
  - Increasing the availability of clinical trials is central to providing the best possible clinical care
  - Recruitment, development, and retention of staff

# Day 1 Recap: Maturity Models

## What are they?

- A subjective, yet structured way to evaluate progress
- A holistic view of the major areas that are important for progress
- A breakdown of major areas into key elements that tend to be more practical and definable
- A set of levels that, while based on an overarching concept of attainment, are specifically defined for each key element.

## Why use them?

- Provide a broad approach to the topic necessary for success
- 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, as well as to identify a desired future state

## Meant to provide broad considerations, not technical details

# Maturity Model

Factors	Level 1 Ad hoc	Level 2 Early	Level 3 Developing	Level 4 Implementing	Level 5 Optimizing
<b>CULTURE &amp; LEADERSHIP</b>					
Leadership Support & Accountability					
Dedicated Personnel					
Investments					
<b>PORTFOLIO STRATEGY</b>					
Scientific Disease Level Strategy*					
Patient Engagement*					
Community Infrastructure*					
Site Feasibility					
Investigator & Site Development and Training					
<b>MEASUREMENT</b>					
Lessons Learned					
Continuous Improvement Metrics					
Measurement of Value and Impact*					

\*Topics of breakout groups



# What other factors of the maturity model should be included in future discussions?

 Poll in Mentimeter

# Takeaways from Breakout Sessions

- ▶ Group 1: Scientific Disease Level Strategy
  - More guidance on:
    - developing for program- or portfolio-level strategy
    - using broad sources of data to inform strategy
    - moving from high-level epidemiological data to more local data focused on the community and patients
  - Types of data to be included: Socioeconomic status, social determinants of health, epidemiological, RWD and publications, census, Ex-U.S. population, patient & caregiver insights, granular community-level data
- ▶ Today: How data related to the social determinants of health should inform both the scientific and operational disease-level strategy

# Takeaways from Breakout Sessions

## Group 2: Community & Patient Engagement

- Community infrastructure and patient engagement should be given their own separate rows
- In terms of infrastructure, include how the patient experience informs researchers and helps them identify stakeholders, generating baselines (complex and variable) within an iterative learning process.
- Currently, sponsor focused — needs to have perspectives for sites, academia, advocacy, etc., so all partners know how and when to add input

## Today: Community infrastructure

# Takeaways from Breakout Sessions

- ▶ Group 3: Dimensions of impact & value of organizational-level patient diversity strategies
  - Clinical
  - Reputation/trust
  - Operational
  - Ability to measure demographic data (baseline + progress)
  
- ▶ Today: Which measures are most relevant to each type of stakeholder?  
Application to maturity model.