Session V: Review of Day 1 and Maturity Model
What was your top takeaway from Day 1?

Poll in Mentimeter
CTTI conducted interviews with 36 representatives from 20 different institutions

Narratives described thematically within four categories—

<table>
<thead>
<tr>
<th>Drivers</th>
<th>Operationalization</th>
<th>Return on Investment</th>
<th>Disincentives</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Organizational culture and commitment from leadership</td>
<td>• Hiring, staffing, dedicated effort</td>
<td>• Better science, more generalizable results</td>
<td>• Staff and infrastructure changes and associated time and cost</td>
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<tr>
<td>• Ethical &amp; moral imperative</td>
<td>• Training – for staff, communities, investigators</td>
<td>• Increase in patient trust of study results</td>
<td>• Impact/outcomes not immediately measurable</td>
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<tr>
<td>• Requirements or expectations from sponsors and regulators</td>
<td>• Infrastructure &amp; Resources</td>
<td>• Improvements in recruitment &amp; retention</td>
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<td></td>
<td>• Community &amp; Patient Initiatives</td>
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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

From: https://ctti-clinicaltrials.org/accelerating-evidence-generation-resources-for-implementing-a-qbd-approach-to-clinical-trials/
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

<table>
<thead>
<tr>
<th>Factors</th>
<th>Level 1 Ad hoc</th>
<th>Level 2 Early</th>
<th>Level 3 Developing</th>
<th>Level 4 Implementing</th>
<th>Level 5 Optimizing</th>
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<tbody>
<tr>
<td><strong>CULTURE &amp; LEADERSHIP</strong></td>
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<td>Leadership Support &amp; Accountability</td>
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<td>Dedicated Personnel</td>
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<td>Investments</td>
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<td><strong>PORTFOLIO STRATEGY</strong></td>
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<td>Scientific Disease Level Strategy*</td>
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<td>Patient Engagement*</td>
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<tr>
<td>Community Infrastructure*</td>
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<td>Site Feasibility</td>
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<td>Investigator &amp; Site Development and Training</td>
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<tr>
<td><strong>MEASUREMENT</strong></td>
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<td>Lessons Learned</td>
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<td>Continuous Improvement Metrics</td>
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<tr>
<td>Measurement of Value and Impact*</td>
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*Topics of breakout groups
What other factors of the maturity model should be included in future discussions?

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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
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.